Competition Law and Indian Pharmaceutical Industry

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EXECUTIVE SUMMARY

(Non-technical Summary)

Competition law and policy is central to managing healthcare markets in many nations. This report addresses, from the perspective of competition law and policy, issues concerning anticompetitive practices prevailing in the pharmaceutical industry in India and its competitiveness as a provider of safe and affordable drugs. The pharmaceutical sector is among the highly regulated sectors across the globe. Yet, it is often noted that the required degree of competition is often missing from these markets. The pharmaceutical sector is increasingly under mounting amount of scrutiny in developed country jurisdictions --viz., Europe and United States-- as there are indications that competition in pharmaceuticals markets may not be working well. For instance, though, fewer new medicines are being brought to market, and the entry of generic medicines is at times restricted through anticompetitive practices. India being one of the biggest emerging markets of the pharmaceutical sector, there has not been any comprehensive study on the pharmaceutical industry from the perspective of competition law and policy. Moreover there are apprehensions that some of the anti-competitive practices go unscrutinised in India due variety of reasons. Hence there are good reasons to look into current state of competition prevailing in the pharmaceutical sector in India.

In 1978, the Declaration of Alma Ata emphasized upon the need for urgent action by all governments, all health and development workers and the world community to protect and promote health of all the people in the world. Many WHO Resolutions have timely emphasized the need for universal access to healthcare. In India, although the fundamental right to health is not explicit, it is recognized as a derived fundamental right under Article 21 of the Constitution of India- which is life and blood of any Democracy. In *N D Jayal* v. *Union of India* [2004 (9) SCC 362] this right came to be specifically recognized as part of right to life under the Constitution of India. Right to access to quality and affordable medicines is an important component of right to health. At times, the right to access to medicines gets violated in the midst of many anti-competitive practices.

This study is an attempt to examine various issues pertaining to the pharmaceutical sector in India from the perspective of competition law and policy. This study has applied Competition Assessment Framework for analysing pertinent issues of competition in developing countries. At the outset it is important to understand that the study does not focus on all aspects of health care industry. Competition issues in pharmaceuticals largely pertain to the area of prescription medicines are discussed in this study. It must be noted that there is an inherent development dimension in the application of competition law and policy to economic activity and its application to the pharmaceutical industry is more so important.

The pharmaceutical industry is an important source of health care for billions of population globally and in India. Hence it is a highly regulated sector. The pharmaceutical industry is influenced by a host of practices which may primarily relate to price regulations, insurance and reimbursements, drug procurement by government agencies, patent laws, innovation polices, biotechnology and safety policies, drug regulation, data protection, trademarks and use of international non-proprietary names, drug promotion regulation, drug advertising regulation etc... Hence competition law has to work in tandem with all such diverse set of laws, polices and regulation governing the pharmaceutical sector.

At another level, information asymmetry does lead to erratic working of competitive forces in the pharmaceutical markets. In prescription drug industry (also referred to as the ethical drug industry), the physician selects the drug and the patient-consumer only pays. Drug promotion and direct to consumer marketing also add to the passive exploitative situation created by information asymmetries. Hence the idea of a rational consumer making rational choices based on prices and availability of substitutes in not akin to the working of the prescription drug market. Thus the very notion of consumer choice leading to price competition, fails in the prescription drug market. It may be noted that even in the presence of effective substitutes, the most expensive brand is also the top selling brand. Besides this, consumer drug information availability and acceptability is inherently very low in case of pharmaceutical products. The root cause lies in the nature of the product consumed- where consumers have least information about the drugs being prescribed and the therapeutic efficacy of one drug over another. Further, perverse incentive linkages in the pharmaceutical supply chain are a cause of greater concern. While not many studies have flagged the multiplicity of relationships among different actors – viz., the manufacturer, wholesaler (stockiest), retailers (pharmacists) and physicians- the very structure of profitability and profit distribution, coupled with a lax regulatory structure allowing unethical drug promotion contribute to skewed nature of consumption pattern and hence impacts effective competition in pharmaceutical markets.

The study has examined issues concerning working of pharmaceutical sector both from a horizontal and vertical point of view. It should not be lost sight of the fact that the pharmaceutical sector in India has grown out of policy patronage adopted since 1970s. The most important policy decisions were to limit the grant of patent only to process and not to products and the drug policy of 1970. Subsequent to this pharmaceutical prices came to be regulated through the Drug Price Control Orders (DPCOs) which have been amended from time to time. According to the Department of Pharmaceuticals, India is the 3rd largest manufacturer of pharmaceutical products (in terms of volume) and it ranks 14th in terms of value. Data also shows that Indian generic export have shown a steady increase since 1990's and is a major supplier of generic drugs to both developed and developing countries. The generic price competition offered by Indian companies has been globally recognised. The pharmaceutical industry is currently divided into three tier structure. Large MNCs operate as originator drug companies and generic companies along with large Indian generic companies. Medium and small scale industries are also engaged in production of branded generics and contract manufacturing related activities. Much of the small scale is engaged in production of generic-generic medicines. Though, there are public sector undertakings in the pharmaceutical sector, their presence has become marginal.

Knowledge about market share and sales are important in understanding the dynamics of competition. Therefore, the study has examined market shares of top companies based on sales. It is noted that sales are largely driven by nature, operation and brand of the firm. While there is *prima facie* no evidence for such market shares having been gained through direct exercise of market power, it is evident that in the pharmaceutical industry passive market power and information asymmetries can lead to higher market shares.

Foreign direct investment (FDI) is another issue that has been discussed briefly in the report. The pharmaceutical industry witnessed higher levels of FDI in the recent past, but it does not share a larger percentage of the total FDI inflows. However, Indian companies have made a host of strategic acquisitions abroad. But this general trend can be no more witnessed at least for the last couple of years. Interestingly, there is a reversal of trend in acquisitions. The past two years have witnessed a lot of consolidation activities within the Indian pharmaceutical industry. Most of these acquisitions are strategic, largely to capture the growing Indian market. Many generic firms have been acquired in the process. Many joint collaborative ventures have also taken off; largely for marketing purposes. However, such acquisitions have also been a host of potential concern due to its long term effect on generic competition. It is expected that the current trend in acquisitions to stay for long. The concern is due to possible change in strategies of generic companies to engage in price competition in domestic market. Such consolidation is also witnessed due to drastic change in patent norms- now allowing for product patents since 2005. Polices of open FDI are also acting as an incentive for increasing consolidation and market concentration.

On the innovation front, the R&D based pharmaceutical industry globally is running through productivity crises. Very few new chemical entities have come out in the recent past. Moreover, some of the blockbuster drugs are under the threat of patent expiration. In this context of drying up R&D pipeline, major players in the pharmaceutical industry are actively engaged in incremental innovation and other forms of derivatives so that. It is a well known fact that the pharmaceutical industry heavily relies on the patent system and hence the patent system is increasingly under stress due to flux of applications. In India, most patent applications filed on products are foreign owned. The introduction of the product patent regime in 2005 has paved the way for increase in foreign filings. However, the relation between patents and innovation structure still remains a challenged paradigm. It is noted that India's performance in generating new inventions has been low even considering patents filed by Indians at the USPTO. However, this must not be attributed as competitive weakness in the pharmaceutical sector. The Indian industry is slowly witnessing a catch-up in high end drug discovery and innovation.

The pharmaceutical markets in India are growing at an exponential rate. However, price competition among retailers can be hardly witnessed. The Indian pharmaceutical market has three types of substitutable drugs being sold. The first category includes originator drugs (patented or newly innovated) - they have a brand name. The second category includes brand name generic or branded generic drugs. The third category is generic-generic drugs- which are sold without a brand name. As per ORG IMS research provisional estimates, India's pharmaceutical market may grow 12-13 percent in 2009; ORG IMS had earlier forecast a 14-15 percent growth but has revised it down, given the current global economic turmoil. However, the pharmaceutical supply chain is beset with problems. Many problems may occur whenever consumers find it difficult to evaluate the qualities of the products. In the case of medicines, due to the power relation that exists between patient and doctor, the patients are neither in a position to choose nor evaluate the quality of the products they consume. This skewed doctor-patient relationship leaves a lot of scope for information asymmetry. The problem is that the information asymmetries may prevent effective branded generics from competing with innovator products, generic-generics competing with brand name generics and innovator drugs etc… In the pharmaceutical sector, it is known that the innovator drug is the standard of quality; the issue is not whether the innovator is effective, the issue is whether the generic is as effective as the innovator. There is a real danger, therefore, that consumers/ physicians who find it difficult/ costly to evaluate the qualities of generics

might develop a strong preference for innovator medication or have a brand preference among the generics. This is true especially for the physician who has had a bad experience of prescribing one generic medication in the past and decided to shun all generic medications.

It is a well documented fact that Pharmaceutical companies spend vast sums of money on drug promotion. They use various tools and methods such as sales representatives, samples, advertisements in broadcast and print media and sponsorships for promoting drugs. It is also known fact that drug promotion closely linked to unfair trade practices. An analysis of the drug promotion matrix in India reveals that there are various unfair trade practices prevailing in the industry. Considerable amount is spent in such activities. In fact, authoritative studies, including those by the EU Competition Commission have noted that pharmaceutical companies spend more on promotion and advertising and less on research and development. Such practices are also recorded through existing reports and experiences in the pharmaceutical sector. Studies have reported that there is some anecdotal evidence, and there have been news reports in popular media, including medical and other journals highlighting the nexus between different actors in the supply chain emphasizes the need for a further comprehensive study examining various issues. In this study, certain evidence pertaining to materials used in drug promotion and advertising is also analysed. This is to suggest that consumer preference for branded and generic prescription medication is related to relative prices, reputation and budget constraints. There is evidence of inefficient allocation of resources in the distribution of pharmaceutical products as studies available indicate that the profitability margins of different actors is quite high and keep huge mark-ups for non-DPCO drugs and non-scheduled drugs in the pharmaceutical industry in India. This has implications on competition in the sector and unfair enrichment through wealth transfers. Besides this, the study has made an attempt to capture the attitudes and opinions of major stakeholders about the substitutability of prescription medicines. The study has brought out some interesting facts about how various actors in the supply chain influence preference for a particular drug.

Another issue that is dealt in this study is of drug procurement. In India, drug procurement is done largely by the government. Data shows that the money that is spent for drug procurement is not more that 10% of the overall expenditure on health. Hence it constitutes a small but significant figure in consumption of pharmaceuticals in India. Drug procurement on behalf of the government is undertaken by various ministries, primarily the health ministry. There are special programmes undertaken by the government. They are also actively involved in procurement. Prior to 1990's, drug procurement in most states was decentralized. However, problems in shortage and wastage have led to centralization of drug procurement in most states. The study has examined the most popular drug procurement model of the Tamil Nadu Medical Services Corporation (TNMSC), popularly called as the "Tamil-Nadu model". Established in 1995, the model has proved to be one of the most efficient ones in drug procurement. The success of the model is attributed to the larger involvement of multi-stakeholders in selection and finalization of the drugs meant for procurement. The tendering process is based on the TN Transparency in Tenders Act, 1998 and rules of 2000. After due advertisement, tenders are sought in two covers- one for the technical bid and other for the price bid. There are clear guidelines and forms for submission of both the bids. Once the bids are received, as series of finalization and evaluation process is undertaken. It is interesting to note that the TN model allows for a flexibility margin of 15% as earnest bid required from the small scale industry. The study notes that there is considerable price difference between prices retail prices and TNMC prices. While there is general downward trend in prices, studies show that the year 2007-2008 saw an increase in prices of more than 50% of drugs procured. It is noted that competition is low in case of high-priced specialty drugs.

Issues concerning regulation are at the heart of competition. The study starts with the current structure of Intellectual property law and the issues they pose to e*x ante Competition*. Patents are a major source of market power in the absence of effective product market competition. It must be noted that patent system is at the core of price competition related issued among branded and generics. Generic entry after the expiry of the patent is a major reason for drastic fall in prices. The Patent Act, 1970 since its inception did not provide for product patents. This was in the light of experience prior to 1970 when product patents led to aggressive monopolies by pharmaceutical MNCs. It was noted that the prices were one of the highest in the world. Hence two expert studies conducted by the government resolved in favour of withdrawal of product patent regime for pharmaceuticals. The TRIPS Agreement (1995) as a cornerstone Agreement in setting common binding standards has mandated that both products and process patents in all fields of technology shall be available. Hence the 2005 Amendment to the Patents Act, 1970 reintroduced product patents for pharmaceuticals.

The study discusses the content of patent law in relation to pharmaceuticals. It notes that section 3(d) of the patents Act is a major public health safeguard. It is noted by experts that out of 68 cases so far where a pharmaceutical patent application was opposed by generic companies and/or public health groups, the patent office rejected the patent in 46 cases (i.e. approximately 68% of the time). In these 46 rejections, around 60% (28) were based on failure to comply with section 3(d). This briefly illustrates the importance of section 3(d) in preventing "evergreening" of pharmaceutical inventions. However, the section is best with legal complexities and has been a subject matter of dispute since its inception. The Novartis case is

now appealed to the Supreme Court. The working of the pre-grant and post-grant opposition mechanism has also proved to be beneficial. An appeals court decision has made it mandatory to hear the request for a pre-grant opposition even while it was discretionary on the part of the patent office. It is noted that pre-grant opposition is a right and a right granted under a statute cannot be enforced without the remedy of hearing. While pre-grant opposition acts as a screening to weed out questionable patents, it may not act as a full proof mechanism. Other limitations and exceptions are also important- mainly, scope of research exemptions, government use, Bolar provisions and parallel imports. Although there are no judicial decisions calling to question the scope of such exceptions, the study has argued for a broader interpretation advocating the fill use of flexibilities under TRIPS Agreement. Recent landmark judgments reviewed during the course of this study reveal increasing restraint on the part of the judiciary in granting temporary injunction when the validity of the patent is called into question.

The patents Act, 1970 also allows for compulsory licensing (CL) in certain cases. It must be noted that compulsory license is based on a payment of a certain agreed royalty rate to the patent holder. Unlike other exceptions, the use of compulsory license cannot be without patent to the patent holder. The compulsory licensing provisions available under the Indian Patent Act could be broadly classified into (a) general compulsory licensing provisions, (b) a provision relating to pharmaceutical patents in case of emergency, and (c) a license to export pharmaceuticals to countries with insufficient manufacturing capabilities. The grounds on which a general compulsory license can be requested by an interested person after the expiry of three years of granting of patent are: (a) the reasonable requirements of the public have not been satisfied; (b) the patented invention is not available to the public at a reasonably affordable price and (c) the invention is not worked in the territory of India. The section also explains the circumstances that result in not satisfying the reasonable requirement of the public. Protection of the existing trade and industry, development of new industrial activities, promotion of export, availability of the product at affordable price, prevention of unreasonable terms–such as grant-back requirements, packaging, prevention of challenges–in voluntary licences, exploitation of the market based only on import etc. are the circumstances covered in this provision.

While the three year rule is only because of an international commitment under Paris Convention, which states that in case of non-working of the patent a compulsory license shall be issued only after the expiry of three years. However, the Patents Act, 1970 makes such a rule applicable in all cases, except in cases of emergency. It is evident that current CL provisions does not allow for grant of CL prior to three years even in case of anticompetitive practices provided for that Act. Next, the effectiveness of CL can be questioned since the mechanism is not time bound. Further, the emergency provisions can do away with rigid procedural formalities by a mere notification by the government. It is expected that compulsory licensing provisions may act as a deterrent to the ability of patent holders to set high prices.

The introduction of the Protection and Utilization of Public Funded Intellectual Property Rights Bill, 2008 in the Rajya Sabha in December 2008 has triggered debates among public interest organizations, science policy makers, academia, and other stake holders including some sections of the industry on issues of Intellectual Property (IP) protection of public funded research as envisaged in the Bill. The PUPFIP Bill proposes the mandatory creation of intellectual property on all public funded research. It further provides that the ownership of such intellectual property rights shall lie with the university/institution which has got government funding which can then license the IPR to private parties. These private parties can then commercialize the research and bring it to the market. These proposals have led to concerns that there are few safeguards in the Bill to ensure that the public interest is paramount in setting research priorities or that products of such public funded R&D are available and affordable. Experiences in comparative jurisdictions show that the Bayh Dole (US law) law has not lived up to the virtues of providing general stimulus to all research based institutions. The results are highly skewed. Further there were also problems relating to licenses and price related considerations. Experts from the US have sounded an alarm for developing countries against the Bill and have recommended developing countries not to imitate the Bayh Dole as it was not a complete success. Apart from this, the long term implication of this law on publicly funded R&D is not clearly examined. Hence the Bill may prove to be a primarily reason for higher prices of patented products generated out of publicly funded research.

Many countries regulate drug price directly or indirectly. It is understood that some form of price regulation is necessary to maintain price competition in pharmaceutical markets. Some countries also effectively regulate prices of patented drugs through different means, including price negotiations and other methods of price control. On issues concerning price controls it is noted that prior to 1962 there was no price control, price of medicines were high, domination of MNC. First Price regulation in Medicines was introduced in 1962. Drug Prices Control Order issued under the Essential Commodities Act, 1955 has been in place since 1970s. Subsequently DPCO was revised in 1979, 1987 and 1995. Currently there are 74 drugs under price controls. The Hon'ble Supreme Court in the *K.S. Gopinath case* (2003), directed the government to ensure that "… essential and life-saving drugs do not fall out of price control". However, the dwindling numbers from the list of scheduled drugs under price control conveys a different story. Prices are controlled both for bulk drugs and formulations

which are scheduled drugs. They are taken from the national essential drug list. There are formulas and procedures which the NPPA takes into consideration. The NPPA is also mandated to monitor prices for non-scheduled drugs including patented drugs and control prices thereof.

There have been recent attempt to bring out a formula for price negotiations of patented drugs. While there is committee constituted under the department of pharmaceuticals, no relevant background papers are available in the public domain. As per interviews and informal sources, the price negotiations of patented drugs will be based on lowest market price available. There are three categories envisaged for this purpose. First category: Patented drugs where drugs are of significant therapeutic efficacy and substitutes are not available. Second Category: Patented drugs where drugs are of significant therapeutic efficacy but substitutes are available. Third category: Patented drugs without significant therapeutic efficacy. Under price negotiations for patented drugs, only the first category will be considered. If the prices marked by companies is lowest in the world (market price as reference price), than further negotiations will not ensue. However, if not, then negotiations will be made to bring it down to lowest world market price. Further, 40-70% reduction is envisaged for prescriptions generating out of public facilities. From the experiences of other countries, it is argued that price negotiations as opposed to price control may not bring down the costs so as to make it accessible to the public at large. It may also undermine the use and willingness to utilize safeguards available viz., compulsory licensing under the Patents Act, 1970. Without effective price control, it is noted that the skewed nature of pharmaceutical markets would allow firms to fix prices without the acting of market forces. Hence price controls which duly acknowledge costs and certain amount of profits are a prerequisite in the pharmaceutical industry.

Drug regulation can play a significant role in enhancing or reducing ex ante competition in the pharmaceutical market, including the early entry of generic drugs. The Drugs and Cosmetics Act, 1940 is one of the major regulatory norms based framework which actively decides on entry of pharmaceutical products into the market. The purpose of the Drugs and Cosmetics Act is to regulate the sale, manufacture, distribution and sale of drugs in the country. The main objective is to prevent substandard drugs for maintaining high standards of medical treatment and to eradicate the dilution of the necessary concomitants of medical or surgical treatment The Act clearly mentions that its provisions have to be implemented in addition to other laws existing in relation to drugs. There have been concerns about the certain definitions in the Act which have defined the term "spurious". It is apprehended that this will be used as a potent weapon to enforce intellectual property rights which are private in nature. While it is true that drug safety issues are a core concern, the misuse of certain recent amendments is also apprehended. All this has come in the light of some studies claiming that 35% of fake drugs in the world were from India. However, no systematic study has been undertaken to generate any credible data. The Indian Government's own estimates for the extent of spurious drugs vary between 0.24 to 0.47 per cent and for substandard drugs from 8.19 to 10.64 per cent (A report of the Expert Committee on "*A Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs",* Ministry of Health, Government of India, November 2003).

Quality standards play an important role in the sale of pharmaceuticals. In fact there are various types of standards prescribed by various agencies. For example, Good Manufacturing Practices (GMP) prescribed in the form of drug safety standards are laid down by the WHO. Schedule M of Drugs and Cosmetics Act prescribes good manufacturing practices for pharmaceuticals. Schedule M basically deals with requirements for plant, equipment and premises for pharmaceutical products. The Parliamentary Standing Committee on Health and Welfare in their 12th report on Drugs and Cosmetics (Amendment) Bill, 2005 had recommended stringent measures against manufacturing spurious and sub standard medicines and drugs. Following such practices, it felt, was necessary for sustaining export of drugs. This called for an amendment of Schedule M. Amendment of Schedule M was done at the Bureaucratic Level, as only the Drugs Act Amendments need Parliament approval. But its implications are immense. The pretext of amendment was improvement of quality but SSIs claim that there are unreasonable clauses of the Amendment which are not acceptable to the SSIs as they may eliminate SSI. There arose a huge debate with respect to these amendments and the Najma Heptullah Committee was constituted to study the impact of implementation of the revised schedule M on the small scale pharma units in the country. The Committee put forth certain questions to the Ministry of Health with regard to new amendments and it impact on SSIs. The Ministry was of the opinion that the amendments would not be detrimental to small scale units as most of them after due consultation with large industry organizations.

The issue of data exclusivity has created a lot of controversy in the recent past. There have been attempts to mix up the issues of data exclusivity and data protection. Clinical test data generated by the innovator companies have come to be of special significance when read with Article 39.3 of the TRIPS agreement. However, the terms in Article 39.3 provide flexibility to countries, allowing them to interpret the provision in the manner that would suit them best. According to the proponents of 'data exclusivity', the regulatory authority cannot rely on data submitted by the originator companies for approving the second and subsequent applications for the same product. Data exclusivity would also affect the generic pharmaceutical industries in the country and also lead to an increase in prices in the country. Satwant Reddy committee,

constituted by the Government of India to study the issue of regulatory data protection and Article 39.3 of TRIPS reported that Article 39.3 does not require "data exclusivity" and that, at the present moment, it may not be in India's national interest to grant "data exclusivity" to pharmaceutical drug data. A Parliamentary report has confirmed the same position that India need not provide for data exclusivity at this juncture as a matter of policy choice. The issue has been at the heart of debate since the MNCs are strongly lobbying for the same.

As in the case of data exclusivity, there have been attempts from the MNC pharmaceutical companies to import the idea of patent linkages to drug regulatory sphere in India. 'Patent linkage' refers to the process of linking drug approval to patent status. Recently, pharma major Bayer sought to restrain generic competitors from getting their patent infringing version from marketing approval. This was an attempt to bring in patent linkage within the Indian drug regulatory framework. However, a HC decision has settled the position that a drug regulatory body cannot be used to police patents and hence the concept of linkage cannot be read within the Drugs and Cosmetics Act or in the Patents Act, 1970. Patent linkage can have tremendous implications for generic entry since test data may then not be relied under the expiry of the patent.

The supply chain and interactions among various actors in the supply chains reveals a web of unfair practices. Examining various regulations in place it is noted that there is no practical legal distinction made between prescription and non-prescription medicines in many cases. The direct to consumer advertising of OTC pharmaceuticals allowed. Certain advertisements may run afoul of the law. There is no adequate regulation on prohibiting promotion of drugs inconsistent with approved information. There is no adequate regulation on prohibiting promotion in disguise. There is no statutory framework, except the code of ethics of the Medical council of India to suggest that no gifts/financial benefits/benefits in kind should be offered to health care professionals as inducements to prescribe particular medicines. Drugs and Magic Remedies Act does not have a full proof mechanism to require that promotional materials are submitted for pre-approval. Except for the Advertising standards council of India code, no other statutory provision can be pointed out that sets out specific standards in relation to information available on the internet i.e. to prevent consumers from gaining inappropriate access to information. Further, the pharmacy Act does not allow for generic drug substitution. Many studies have noted that countries which have allowed for drug substitution have seen low consumer spending on drugs. All such loopholes in the regulatory framework can have both long and short term implications on prices and pharmaceutical consumption.

In examining the competition law, the study has undertaken an overview of the conceptual, policy and practical foundations for the application of competition law in the pharmaceutical industry and markets. The study reviews the positions in comparative jurisdictions (primarily United States of America (US) and European Union (EU). Positions in comparative jurisdictions are examined by referring to respective legislative provisions and through the developments in case law jurisprudence. The starting point with reference to the EC treaty and application of Articles 81, 82 along with council regulation 139/2004 (the Merger Regulation) and block exemptions are looked in to. Similarly the Antitrust law in the US governed by the *Sherman Act, 1980, Clayton Act, 1914 and the FTC Act, (1914), Title 15 U.S.C. §§ 41-51and the Robinson-Patman Act of 1936* (as amended up-to date) are among the legal texts considered.

Defining relevant market is *sine qua non* in assessing the market power/share of the violator in question. Thus the key question would be to define the relevant market in question and identification of the market power in the particular market. Defining the concept and practice of 'relevant market' is essentially an economic one. However, competition law and case law developments in comparative jurisdictions do provide the necessary framework essential for legal certainty and for defining the thresholds. However, they are only persuasive in nature. Experience in comparative jurisdictions suggests that in non-merger cases, the FTC/ Commission and private plaintiffs generally argue for narrow markets, limited to a single drug and its generic equivalent in some cases and to generic drugs excluding the bioequivalent 'brand-name' (all drugs under valid patents are called brand name drugs in the US) drug in other cases. In its merger challenges, on the other hand, the FTC has alleged markets ranging from those based upon a particular chemical compound, to broader markets based upon various drugs' manner of interaction or dosage form, to still broader markets of all drugs used to treat a disease or condition. In numerous pharmaceutical merger challenges, the competition authorities have included in the market not only currently marketed drugs but also other drugs under development, by considering "innovation market". As market definition issues are extremely factual and often resolved in appeals, there are only few pertinent court decisions providing guidance about how to define markets in the pharmaceutical industry.

Certain relevant product markets identified in the US context involving combinations have included: 1) drugs for the treatment of a particular disease or condition; 2) drugs; that have the same mechanism of action, and 3) specific compounds. Various commentators have emphasized that the FTC-DOJ (the Department of Justice) decisions on defining pharmaceutical markets lack consistency. It has been noted in many cases that the Small but Significant and Non-transitory Increase in Price (SSNIP) test, which is used to define the relevant market, could apply only with major variations. A brief summary of review of FTC cases would suggest that there can be a variety of factors that the FTC-DOJ may consider for

defining relevant product markets in pharmaceuticals, including but not limited to, for example, whether drugs have the same dosage and delivery forms such as injectable, liquid, capsule, tablets, or topical; whether drugs have the same frequency of dosage, such as once -a- day or extended release; whether drugs have the same strength of dosage, distinguishing, for example, 15mg and 50 mg tablets; whether drugs are branded or generic; whether drugs require a prescription or are sold over-the counter; whether drugs are currently marketed or are in development; whether drugs treat the same disease, condition, or indication; whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same "mechanism of action"); whether drugs have the same specific chemical compounds. It is pertinent to note that patented product may in itself form a relevant product market provided other factors are fulfilled. The above tests adopted have at times considered some or few of these above mentioned considerations in defining relevant product markets. It points to the flexible nature of tests that have emerged in comparative jurisdictions. Thus fundamentally, the tests to determine relevant product market in case of pharmaceuticals are not static. Relevant policy consideration may go into determining the exact nature and scope of the definition.

On the other side of the Atlantic, few other cases have tried to define what should constitute relevant product markets within the context of EU Competition Law. In one of the high profile merger cases, although allowing the merger, the Commission in its opinion relying on past cases and practices the commission applied the Anatomical Therapeutic Chemical (ATC) Classification System devised by The European Pharmaceutical Market Research Association (EphMRA) and has stated that the *third level of the ATC classification* allows medicines to be grouped in terms of their therapeutic indications and can therefore be used as an operational starting point for market definition. However, in certain cases it may be necessary to analyze pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC 3 classes on the basis of demand-related criteria. The Commission also defined separate markets for OTC (as opposed to prescription) pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories. A review of case laws defining relevant product markets in pharmaceuticals essentially suggests that pharmaceutical markets are fundamentally different from other markets. Who is the customer- since doctor chooses and the patient pays? Does price matter at all- since costliest drug is the top selling? Should a single drug define the market in-itself? Should generic drugs be in the same market as pioneer drugs or a distinct product market? Further there is little guidance from comparative jurisdictions whether the "*Cellophane* trap" (a type of incorrect reasoning used in market regulation methods) applies in case of pharmaceutical product. Defining pharmaceutical product markets requires a thorough understanding of the role of government regulation, technological innovation, and competition in the industry.

It is vital to the assessment of relevant market to know the geographical boundaries where the market power is alleged to have been exercised in an anticompetitive manner. The definition of relevant geographic markets has had impact on the outcome of many cases. There may be legal, technical or practical reasons as to how one market may differ from the other. Market power is commonly defined as the ability to profitably charge prices above the competitive level for a significant period of time. Evaluation of the presence or absence of market power is a key element of most antitrust and competition analysis and many Competition commissions have issued guidelines on the evaluation of market power in the merger context and other areas. These guidelines typically follow the framework of market definition followed by calculation of market shares along with a summary measure of market concentration—typically the Herfindahl- Hirschman Index (HHI), which sums the squared market shares of firms in the relevant market. In performing market power analysis, other structural features of the market are also considered.

Agreements between firms are of great significance to the study of competition. Business undertakings get into routine agreements for carrying on economic activities. While not all agreements can be termed as anticompetitive, certain agreements between competing firms or among firms in the supply chain may constitute a violation of competition law. Agreements can either be horizontal or vertical. Mergers are a form of horizontal agreement but they raise distinctive competitive concerns. The concept of restriction on competition is an economic one. Thus generally economic analysis is needed to determine whether an agreement could have an anticompetitive effect. A small class of agreements may be considered to have as their object restriction of competition.

There is a worldwide consensus against hard core cartels. Horizontal agreements between undertakings to fix prices, divide markets, to restrict output and to fix the outcome of competitive bidding are the most contentious among the variety of targets of competition authorities in comparative jurisdictions. It is clear from the decisions of the commission that price fixing in any form is caught, including the obvious blatant price fixing. Thus there is a body of decisions that have condemned agreements which might directly or indirectly facilitate level price fixing. The *Vitamins case* (2003) is one of the most severe cartels that occupied considerable attention of competition authorities' world over. The EC Competition Commission fined eight undertakings totalling to Euro 855.23 million (reduced to Euro 790.50 million later) for running the vitamins cartel. MNCs like Roche, BASF, Aventis were found to be involved in cartels. However, Aventis paid substantially less as it turned out to be the whistle blower. It must be noted that price fixing in any form is caught. Article 81 (1) and its

application in any cases have led to the emergence of a set of jurisprudence that it is not just blatant price fixing that is caught, but also any agreement that might directly or indirectly suppress price competition. Cases also suggest that it is not a defence that a participant in a cartel sometimes does not respect the agreed price increases. However, the most important aspect of the cartel is that the leniency programme helped a great deal in ascertaining the cartel. The prosecution in the vitamins case is the cornerstone of treatment of complexity presented by cartels. This study has comprehensively discussed the Vitamins case. Quota restrictions may also take form of cartels. If output is limited or reduced, price will rise- and hence output restrictions have the same effect as price cartels.

Collusive tendering agreements also form part of horizontal agreements that pose significant anticompetitive effects on the market. However, it is not necessary that such collusive tendering agreements do affect the markets in reality. Such agreements are condemned *per se*. A review of collusive bidding cases in the EU does not show action taken against pharmaceutical companies. There may be many forms of collusive bidding. The firms may agree to quote identical prices, or parties may rotate the bid, form complementary bidding, subcontracting etc... Information exchanges may at times result in action under Article 81 of the EC treaty. It is important to note that this issue has been given thoughtful consideration over many years. There are relevant test the European Court of Justice jurisprudence lays down in identifying what type of information sharing should be exempted from the application of Article 81 (1). Thus in case of information agreements a full market analysis may be warranted since such an agreement is not condemned by object but by effects on the market.

Since competition law cannot prohibit all horizontal agreements outright because of efficiency gains that may follow from cooperation that are sufficient to outweigh any restriction on competition that might ensue, the Commission adopted *Guidelines on Horizontal Cooperation Agreements* in the year 2000. The guidelines state that horizontal cooperation agreements may lead to substantive economic benefits, in particular given the dynamic nature of markets, globalization and the speed of technological progress. In particular, of much importance to pharmaceutical sector is the treatment of R&D agreements under the Commission's guidelines. Such agreements are evaluated on the basis of their effects, rather than objects, since the object of such agreements are not among the hard core restrictions on competition. The Commission shall evaluate agreements based on their nature. The starting point in the Commission's approach to evaluating R&D agreements is to see whether an agreement could have the effect of restricting competition by analyzing the position of parties in the market. This would essentially require the evaluation of relevant markets as evolved by the Commission through its guidelines and practices.

The Commission considers that R&D agreements would normally fall outside the scope of Article 81(1). But those R&D agreements which have in them elements that can effect or restrict competition may well fall within the scope of Article 81(1). Thus Regulation 2659/2000 provides for a block exemption on R&D agreements. Horizontal agreements between unrelated rivals not to business with another firm/s are also considered *per se* illegal boycotts under EU and US antitrust law. While there are no case laws from comparative jurisdictions on group boycotts in pharmaceuticals, some guidance can be deduced from cases in other products.

Producers of goods will distribute their products into the market either directly to consumers or through a supply chain in the market. At the same time there can be consumers who purchase goods for their own use or for further selling. Contracts are the basis for such transactions and the legal tradition has been responsive for valuing such contracts. Thus there may be concerns that vertical agreements can have appreciable adverse effect on competition. Not all vertical agreements can be categorized as restraints, but certain agreements surely will. Since such contractual agreements cannot be avoided as a matter of practice, they need to be evaluated based on their impact in the market. However, there can be *per se* invalidation of certain type of vertical agreements. In fact, until very recently, the US followed an approach to condemn resale price maintenance on *per se* basis until it was overruled by decision in 2007. Thus it would be pertinent to evaluate each of such possible agreements from a comparative jurisdictional point of view.

The oft cited pro-competitive benefits of vertical agreements in promoting a healthier distribution system are well known. In one of the seminal decisions of the US Supreme Court where the validity of resale price maintenance was questioned, RPM were held to be unlawful per se. In this case retail druggists were fixing prices and using manufacturers as their "enforcer". Here the US Supreme Court implicitly noted in the decision that the enforcement of prices through examination of the record led to facilitating cartels, which was the main function of imposing RPMs. However, the decision did not address situations where RPM may not have been used to facilitate collusion or where economic understanding of the effects of RPMs was that they produced pro-competitive benefits.

In the EU, the Block exemptions provided by regulation 2790/99 OJ [1999] L 336/21 provides useful guidance on the type of practices exempted under the category of vertical restraints. These exemptions typically provide 'safe havens' for considering the scope of application of Article 81(1). Further, the *Guidelines on Vertical Restraints* are to be read in conjunction with the block exemptions. There are both pro-competitive and anticompetitive forms of agreements. The

combined effect of the *de minimus* doctrine and the block exemption is that most vertical agreements where the market share of each of the parties is below 15% will fall outside the scope of article 81 (1). Further, most vertical agreement that might violate Article 81(1) will be block exempted under the above mentioned regulation provided that the supplier's market share is less than 30% and that the said agreement does not contain any hardcore back listed provisions mentioned in the block exemption. The block exemptions also provide that the exemption shall apply to vertical agreements "containing provisions which relate to the assignment to the buyer or use by the buyer of IPRs, provided that those provisions do not constitute the primary object of such agreements and are directly related to the use. Sale or resale of goods or services by the buyer or its customers". However, the application of such a rule is fraught with difficulties. The most common form of vertical restraints are single branding agreements, exclusive distribution agreements, exclusive customer allocation agreements, selective distribution agreements, franchising agreements, exclusive supply agreements, tying agreements, recommended and maximum resale price agreements. The four factor test is applicable in evaluating whether such agreements have pro-competitive effects on the market.

Abuse of dominance basically concerns itself to the unilateral acts of dominant firms as it might infringe competition laws. Article 82 of the EC Treaty prohibits abuses of a dominant position. As per the case-law developments, it is not in itself illegal for an undertaking to be in a dominant position and such a dominant undertaking is entitled to "compete" on the merits. However, the undertaking concerned has a special responsibility not to allow its conduct to "impair genuine undistorted competition" on the common market. In the US, section 2 of the Sherman Act makes it unlawful for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations . . . ." The first step in the application of Article 82 requires the assessment of whether an undertaking is in a dominant position and of the degree of market power it holds. Developments in case-law emphasize that holding a dominant position confers a special responsibility on the firm concerned, the scope of which must be considered in the light of the specific circumstances of each case. Dominance has been defined under EC law as a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on a relevant market, by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers. The Commission may consider a combination of several factors to ascertain the dominant position derives from a combination of several factors which, taken separately, are not necessarily determinative. It may also consider that effective competitive constraints are absent even if some actual or potential competition remains.

In case of price base exclusionary conduct leading to anticompetitive foreclosure, the approach of the EU Commission is to intervene only where the conduct concerned has already been or is capable of hampering competition from competitors which are considered to be as efficient as the dominant undertaking. Thus to determine whether even a hypothetical competitor as efficient as the dominant undertaking would likely be foreclosed by the conduct in question, the EU Commission will examine economic data relating to cost and sales prices, and in particular whether the dominant undertaking is engaging in below-cost pricing, on the condition that sufficiently reliable data are available. The cost benchmarks that the Commission is likely to use are average avoidable cost (AAC) and long-run average incremental cost (LRAIC). If the data suggest that the price charged by the dominant undertaking has the potential to foreclose as efficient competitors, then the Commission will integrate this in the general assessment of anticompetitive foreclosure also by taking into account other relevant quantitative and/or qualitative evidence. Further, the EU Commission in the enforcement of Article 82, considers efficiency claims put forth by dominant firms will form part of the examination.

There are certain specific forms of abuse that need special consideration. A lot of jurisprudence has evolved since the implementation of the EC treaty and interpretation given by the Commission, CFI and the ECJ. Such practices are in the nature of: Price related abuse of dominance and non-price related abuse of dominance. In price related abuse of dominance exploitative pricing practices, predatory pricing, rebates that have similar effects to single branding agreements , margin squeezing, price discrimination are the major forms of conduct that form part of abuse of dominance under Article 82. In non-price related practices, tying and bundling, exclusive dealing, refusal to supply are considered as the type of conduct demanding the application of Article 82.

Again, excessive prices can be detrimental to more than a single market when the owner of an essential facility charges an excessively higher price for granting access to such facility and this could be regarded as constructive refusal to supply consequently leading to the abuse of dominant position. The best example for this is the Commission's finding that Microsoft had charged unreasonably for accessing interoperability information. While it is difficult to assess costs, it is not totally impossible as explained by some reports of the UK OFT also confirmed by a decision in the UK. However, Competition commission's in comparative are averse to price regulation. The South African Competition Commission has showed that there can be abuse of dominance through excessive pricing of patented pharmaceutical products. It was under pressure from South African Competition Commission that GSK, which was the world's largest producer of AIDS medicine

holding a 50 percent stake of the $5 billion market, was forced to issue licenses on two major antiretroviral (ARV) drugs- known as AZT and Lamivudine- to four generic producers. In another similar case, Boehringer-Ingelheim (BI) was forced to license nevarapine – a major ARV to prevent mother to child transmission of HIV infection- to three producers. This led to forced but voluntary licenses being issued by drug companies to other producers at a low royalty rate of 5%. This case has turned out to be a trend-setter for developing country jurisdictions to follow a nuanced policy on addressing unfair and exploitative pricing policies adopted by drug companies in case of patented drugs.

The EU Commission will generally in cases of predatory pricing intervene where there is evidence showing that a dominant undertaking engages in predatory conduct by deliberately incurring losses or foregoing profits in the short term, generally termed as "sacrifice", so as to foreclose or be likely to foreclose one or more of its actual or potential competitors with a view to strengthening or maintaining its market power, thereby causing consumer harm. Thus the commission views conduct entailing a sacrifice if the dominant undertaking, by charging a lower price for all or a particular part of its output over the relevant time period, or by expanding its output over the relevant time period, incurred or is incurring losses that could have been avoided. The Commission will take AAC as the appropriate starting point for assessing whether the dominant firm incurs or incurred avoidable losses. Furthermore, the commission will also apply that test of harm to consumers, if sufficient reliable data are available. The efficiency argument will generally not hold well in predatory pricing cases. However, provided that the conditions mentioned above are fulfilled, the Commission will consider claims by dominant undertakings that the low pricing enables it to achieve economies of scale or efficiencies related to expanding the market.

A dominant undertaking may try to foreclose its competitors by tying or bundling. “Tying” refers to situations where customers that purchase one product (the tying product) are required also to purchase another product from the dominant undertaking (the tied product). Tying can take place on a technical or contractual basis. Tying occurs when the tying product is designed in such a way that it only works properly with the tied product (and not with the alternatives offered by competitors). Contractual tying occurs when the customer who purchases the tying product undertakes also to purchase the tied product (and not the alternatives offered by competitors). “Bundling” usually refers to the way products are offered and priced by the dominant undertaking. In the case of pure bundling the products are only sold jointly in fixed proportions. In case of mixed bundling, often referred to as a multi-product rebate, the products are also made available separately, but the sum of the prices when sold separately is higher than the bundled price. The EU Commission will take action under Article 82 where an undertaking is dominant in the tying market and where, in addition, the following conditions are met: (i) the tying and tied products are distinct products, and (ii) the tying practice is likely to lead to anticompetitive foreclosure. Exclusive dealing refers to the strategy of a dominant undertaking which may try to foreclose its competitors by hindering them from selling to customers through use of exclusive purchasing obligations or rebates. It also includes exclusive supply obligations or incentives with the same effect, whereby the dominant undertaking tries to foreclose its competitors by hindering them from purchasing from suppliers. The EU Commission considers that such input foreclosure is in principle liable to result in anticompetitive foreclosure if the exclusive supply obligation or incentive ties most of the efficient input suppliers and customers competing with the dominant firm are unable to find alternative efficient sources of input supply.

There is no standard definition for the term ‘essential facilities doctrine’. Generally, it may be understood as a company which has a dominant position in the provision of facilities which are essential for the supply of goods or services on another market abuses its dominant position where, without objective justification, it refuses access to those facilities. Thus in certain cases a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed. The existence of an essential facilities doctrine has been acknowledged both in the European Union and the United States. Though there are differences in the way the doctrine is applied on either side of the Atlantic, the basic premise is the same: that where access to a facility is essential in order for a person to operate on a certain market, the owner of the facility may, in certain circumstances, be obliged to grant access to that person. Refusal to supply is seen as an important facet of the same. It is important to note in this context that the courts have never expressly used the term ‘essential facilities doctrine’ rather it appears that most such issues were dealt with under the broad rubric of ‘refusal to supply’ cases. Opinions of the United States courts also suggest that antitrust liability under the essential facilities doctrine is particularly appropriate only when denial of access is motivated by an anticompetitive animus usually demonstrated by a change in existing business practices with the apparent intent of harming rivals. In general, the US Supreme Court has shown reluctance to apply the EFD doctrine. However, the EU position might be considered as more flexible after its decision in Microsoft. While the EFD can be especially helpful in accessing patented knowledge, especially in biotechnologies.

Competition law concerns itself with the possibilities of mergers and combinations (acquisitions and conglomerates) will lead to market being less competitive in future than it is currently. However, there are hardly few decisions rendered by the Apex courts on mergers and combination. Most of the principles are set the competition commissions and settled through

consent orders. In cases involving mergers and acquisitions, the competition authorities across the world have followed an approach to define the markets are broadly as possible. The basic premise behind merger control is that it may lead to market concentration. Hence it is essentially based on the effect such combination will create on competition within a particular jurisdiction. The pharmaceutical industry, as noted above, survives in an oligopolistic structure. Hence merger control and regulation of combinations have special importance in this sector. While the commonly applied test has been has been to look at whether a merger or acquisition is likely to result in "substantial lessening of competition", this tests has no more restricted in to the product range. In the European context, the Commission is taking a further step for an innovation approach in the Merger Control, studying not only competition *in the market* but also *for the market*. The competition *in the market* approach, on one hand, takes into account the existing products and considers the R&D efforts only like a part of the product market. The competition *for the market* assessment, on the other hand, considers the R&D efforts, like a separate market from the existing products. This approach is called "*Innovation Market",* and supposes that the projects for the development of new products/services are analysed as a different market. It has its origin in the American approaches. However, this tests has come under heavy criticism because innovation is non-predictable and may not be desirable at all times; Innovation is speculative and includes unidentifiable market participants; the relationship between R&D and innovation is unclear; the market structure most conducive to innovation is unclear.

However, despite severe criticisms the innovation market test in merger control has survived. Many cases examined in the US and EU context allude to this important fact. After having examined both the frameworks, it can be concluded that "*Innovation Market*" assessment has a very limited role in the European Merger Control where the R&D pipelines are focussed to new products and the rate of success is absolutely uncertain. The American approach is broader, and it is not limited to the European restrictions. The FTC is takes into account pipelines in early stages of the development process to define the *relevant "Future Market".* Thus, while in the American approach, the "*Innovation Market*" is intended to predict the future product market effects, the European approach, tries to establish the post-merger incentives to reduce R&D projects. The "*Innovation Market"* analysis is one instrument more in the hands of the Agencies to control the concentration operations. This extra-power is useful to avoid negative post-merger situations, which escape the traditional merger examination.

The issue of lawful exercise of Intellectual property is also under constant scanner. While both the jurisdictions treat IPR monopoly as not in fundamental conflict with competition law- as the object of both is to promote innovation and competition, it is not fully resolved if competition better facilities innovation or IPR does more so. However, the IP Licensing Guidelines issued by the US FTC-DOJ (1995) and the EU Technology Transfer Block Exemption provide a framework where IPRs are treated as not different from other forms of property. However, there are complex set of tests underlying the analysis of the relationship of IP vis-à-vis competition law.

Although intellectual property law and antitrust law are complementary, there are divergent decisions possible. Case law jurisprudence in comparative jurisdictions assert that unilateral right to refuse to grant a patent license is a core part of the patent grant and that antitrust liability for mere unilateral, unconditional refusals to license patents will not play a meaningful part in the interface between patent rights and antitrust protections. It is noted that competition law liability for refusals to license competitors would compel firms to reach out and affirmatively assist their rivals, a result that is "in some tension with the underlying purpose of antitrust law." It is believed that such liability would restrict the patent holder's ability to exercise a core part of the patent—the right to exclude. Conditional refusals to license that cause competitive harm are subject to antitrust liability. In the EU, the *Magill and IMS* cases established the possibility of a claim to a license under Article 82 in exceptional circumstances, in particular where such licensee intended to produce a new product for which there is a potential consumer demand. It test was severely applied in the recent case of *EU* v. *Microsoft* (2007), where the CFI held that Microsoft was dominant in two markets and had abused its dominant position by refusing to supply interoperability information.

In some cases decided by US courts, there has been a host of consent orders in pharmaceutical cases largely pertaining to drug settlements in the US also called as pay for delays. The US has a very unique system to patent term extension and parallel providing entry of generics. The Hatch Waxman Act requires that 180 exclusivity shall be given to the company first challenging the originators patent. As a consequence many generic companies and originator companies collude to give up the exclusivity or not to challenges patents. There have been conflicting decisions by the Federal circuits mostly emphasizing that such agreements may not be anticompetitive since it provides the originator companies an opportunity to exercise it lawful monopoly during the term of the patent- thus promoting innovation. However, commentators have argued that there can be a case of presumptive illegality in case of drug-patent settlements. Currently, the US-FTC has petitioned the US Supreme Court to declare them as illegal.

The nature of inherent conflict between grant and exploitation of IPRs vis-à-vis the resolve to keep the markets competitive has been traditional. Many economists of the Chicago and Post-Chicago school of thought remark that IPRs may not be in inherently conflicting with competition law. It is emphasized that the object of both the laws is to promote innovation by creating dynamic efficiencies. And yet, there is tension in the means in which rights conferred under IPRs may conflict with principles of competition law. The relationship amongst patents working as property and the structure of innovation is based on the *premise* that patents promote innovation, and not that it actually does so. Be it as may be, at least in case of pharmaceuticals, as noted in chapters above, it is an argument that without patent protection new medicines would not be invented. However, this view is at best, controversial. But one important aspect would be to consider what the possible situations if one were to depart from a static view of markets. It is clear that the EU and U.S authorities do not presume market power in case of patents and other intellectual property rights. It is presumed that they work like real properties. However, there is sufficient difference between real properties and intellectual properties, which the guidelines in US and EU fail to note. This distinction has been traditional. One reason behind treating IPRs and real properties distinctly is also because of the very nature of IP, which fails to set clear boundaries of innovation. Patent laws especially, doesn't provide sufficient note of the proper scope of rights. In case of IP, subsequent innovation is built upon the earlier ones.

On the issues of licensing restrictions, the guidelines note that "Field-of-use, territorial and other limitations on intellectual property licenses may serve procompetitive ends by allowing the licensor to exploit its property as efficiently and effectively as possible. These various forms of exclusivity can be used to give a licensee an incentive to invest in the commercialization and distribution of products embodying the licensed intellectual property and to develop additional applications for the licensed property. The restrictions may do so, for example, by protecting the licensee against free-riding on the licensee's investments by other licensees or by the licensor. They may also increase the licensor's incentive to license, for example, by protecting the licensor from competition in the licensor's own technology in a market niche that it prefers to keep to itself. These benefits of licensing restrictions apply to patent, copyright, and trade secret licenses, and to know-how agreements". Thus the US approach warrants that most forms of licensing restrictions are always pro-competitive. It approaches the issue of licensing arrangements by assuming that they promote integration because as they facilitate the combination of the licensor's intellectual property with complementary factors of production owned by the licensee. As per the A restraint in a licensing arrangement may further such integration by, for example, aligning the incentives of the licensor and the licensees to promote the development and marketing of the licensed technology, or by substantially reducing transactions costs. If there is no efficiency-enhancing integration of economic activity and if the type of restraint is one that has been accorded per se treatment, the Agencies will challenge the restraint under the per se rule. Otherwise, the Agencies will apply a rule of reason analysis. Regulation 772/2004 on Technology Transfer agreements confers block exemption on technology transfer agreements pursuant to article 81(3) of the EC treaty. The underlying dictum in regulation 772/2004 is that technology transfer agreements usually improve economic efficiency and are pro-competitive (recital 5). However, it also notes that it also depends on the degree of market power and also on the degree of competition that will be faced by undertaking with substitute technologies or products. Unfortunately, there isn't much guidance through cases on the interpretation of allowable restrictions under the block exemption.

In India, the Monopolies and Restrictive Trade Practices Act (MRTP) was enacted in 1969 as per the recommendations of the Monopolies Inquiry Committee. The MRTP Act aimed to provide structural remedies in its attempt to curb monopolistic behaviour as such structural nature of the law, by which it was understood that beyond a particular threshold such anticompetitive behaviour affected competition adversely. However, it was restricted to the private sector. Later, in the year 1984, Sachar committee looked into changes requires in MRTP to make it more effective. The reforms of 1991 changed many perceptions about the MRTP, as it was thought that many provisions in the law were not favourable for create an environment for private investments. Certain provisions were off the Act. However, a further need to change the structural approach of the MRTP was felt by the Government and hence Raghavan Committee was appointed to look in to Competition Law and policy. Set up in 1999, the Raghavan Committee reviewed the existing MRTP and found that there was no provision within MRTP to deal with anticompetitive practices, and thus declared that MRTP could not be amended without substantial changes. It suggested a new competition law for India. The Committee found fewer reasons to adopt a structural approach and suggested *per se* illegality rule only in few instances. In many other conducts, it as prescribed a *rule of reason approach.*

In the thick of all these changes the pharmaceutical industry in India grew. The industry saw that many of its practices being challenge and susceptible to the practices falling under MRTP. Some interesting cases have come up before the courts and tribunals during the MRTP regime. Although not all cases led to rationale outcomes, sometime the courts juggling with the application of certain provisions, it essentially remains the fact that economic analysis was not always an important ingredient in arriving at conclusions. Even though it relied on factual assertions, the case laws tend to adopt a structural approach. However, the courts when it came to interpretation of the Act went for the purposive interpretation. The cases

mentioned here bears the testimony. In some interesting cases the followed as an outcome of MRTP on price regulation, the courts have held that the restriction so imposed on the drugs and pharmaceutical products, fail to qualify the term so used as 'reasonably necessary'**.** It also opined that the new system of obtaining NOC/LOC will prove to be a detriment to the consumers as it will deny them the use of new pharmaceuticals and drugs and thus will be hit by the provisions of section 33(1)(b). Also the Tribunal failed to see, how the system as claimed will be affecting in the rise in unemployment in the sector. In another case the tribunal noted that higher price was coupled with falling sales leading to the maintenance of the price at an unreasonable level and high ratio of the profits to the share capital. In this connection, the Court was of the opinion that while the sale is dependent on the demand of the product in the market, the production of the product in turn depends on various factors. It was found that the price prevalent at the relevant period of time was stated to conform to the prices fixed by DPCO. Thus the charge of monopolistic trade practices was not maintainable.

On the issue of free sample distribution which raises anticompetitive concerns, the court held that since the drug so concerned has to be prescribed by the registered practitioner, the court believed that samples of drugs are to be tested first and then medicated. It was also agreed by the Tribunal that, *since marketing is one of the essential concomitant of sale, considerable cost is also incurred in the same.* In many ways, this decision has tacitly justified the issuing of free samples by drug companies to physicians, one of the methods in drug promotion. On the issue of price fixing among retailer and wholesaler, the Tribunal looked into the provision so encapsulated in the MRTP act, section 33(1) (d) and said that it deals with an agreement between the sellers or an agreement between the buyers. The impact of this decision is on those types of vertical agreements like resale price maintenance where fixing margins on recommended prices could lead to price escalation thereby reducing competition.

Another case on restrictive price maintenance, the Tribunal was of the opinion that since the prices are mentioned as maximum retail prices, it is obvious that the retailers are authorized to sell the drug less than what has been prescribed in the list. On the issue of boycott of the life saving drugs brought about by the active connivance and encouragement of the errant parties is a restrictive trade practice as it causes to consumers and general public considerable suffering because of non-availability of the medicines, commission rejected the argument of the charged parties that the boycott was only a non-co-operation movement. The boycott was held to be a clear restrictive trade practice. In a case related to irregularities in issuance of tender, the court was of the opinion that the terms of the invitation of the tender are not subject to judicial scrutiny. The government always has a free hand in setting the terms of the tender. In a case that revealed the jurisdictional conflict between NPPA as a price regulator and MRTP as a Commission deciding on reasonability of prices and its impact on competition, the court asserted by the respondents in that case issues of pricing are considered by the NPPA that commission should look into pricing only when it has implications for competition. While the case was dismissed on grounds of the accused company having negligible market share, the issue of jurisdiction was not set any ratio. In a case related to excessive pricing, it was held that excessive pricing or pricing pattern having no relationship with the cost of the input is not anti-competitive if such a trade practice does not have the effect of preventing, distorting or restricting competition in the market.

The reforms of 1991 brought in the necessity of a new law dealing with issues concerning competition. The Raghavan committee report noted that most countries had modern legislations for preserving competition. It also noted that the existing MRTP was grossly ineffective to deal with new situations. The Indian competition Act, 2002 is clear to the extent that it is the effect of the monopoly that is the target of regulation and prohibition. The Act prohibits or regulates three type of activities:

- *Anticompetitive agreement (section 3)*
- *Abuse of Dominant Position (Section 4)*
- *Regulation of Combination (section 5 and 6)*

Since the Act was to a large extent a response to economic reforms and globalisation process and hence to maintain a standard law dealing with type of practices regarded as raising competition concerns is also responsible for the new law. After a long wait, on 15 May, 2009, the Ministry of Corporate Affairs notified certain sections of the Competition Act, 2002 by powers vested in it under section 1(2). Sections 3 and 4 are operational from the 20th day of May, 2009.

It is pertinent to note that the CCI may inquire into any alleged contravention of the provisions contained in subsection (1) of section 3 or sub-section (1) of section 4 either on its own motion or on receipt of any information, in such manner and] accompanied by such fee as may be determined by regulations, from any person, consumer or their association or trade association; or a reference made to it by the Central Government or a State Government or a statutory authority.

The study has examined various issues in the Competition Act and its application to the pharmaceutical industry in India. In case of pharmaceuticals, the following questions may be pertinent in defining relevant market under the definition given in the Act. The physical characteristics test would require the commission to consider the drugs have the same dosage and delivery forms such as injectable, liquid, capsule, tablets, or topical; the end use test suggests and inquiry if drugs have the same frequency of dosage, such as once -a- day or extended release; whether drugs have the same strength of dosage, distinguishing, for example, 10mg and 30mg tablets;

Consideration of the price of goods or services would require an inquiry if the drugs are branded or generic; price constraints through price controls and negotiations may be considered as a constraint on supra normal pricing. However, price negotiations can add to the deceptive element since it does not fully constrain the alleged monopolist from pricing. Currently, since most drugs (except 74 drugs) from the National Essential Drug List are not under price controls, it would mean that price control may also not be an essential consideration.

The distinction between prescription drugs and OTC drugs may have substantial difference in assessing relevant markets. In case of prescription drugs, since information asymmetries are greater, it would require that such an important constraint on consumer choice be taken into consideration. Further, whether drugs are currently marketed or are in development; whether drugs treat the same disease, condition, or indication; whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same "mechanism of action"); whether drugs have the same specific chemical compounds. The commission may thus inquire into a variety of factors. Generally, in case of pharmaceuticals, ATC classification is considered as standard for understanding the class of therapeutics. As seen above, ATC is classified into five levels. ATC 3-4 level classification is considered to be the most relevant in defining the relevant product market in case of pharmaceuticals.

It may be noted that the SSNIP test may not be of much help in defining relevant markets. It is so because cross elasticity in demand in very low in case of prescription drugs. Hence this test must be used with caution in the pharmaceutical context. Further, the question is if *cellophane fallacy* applies in case of pharmaceuticals. It is interesting to note the consequences of the application of *Cellophane Fallacy* in determining the scope of relevant product market in case of pharmaceuticals. *Cellophane fallacy* is inapplicable when there are excellent substitutes. In most cases, it is difficult to envision a situation where doctors would prescribe alternate medicines to cure a disease. Interchangeability is highly impossible given that patient needs can be addressed only through particular drugs. In a prescription market situation, it is evident that there does not exist a high cross-elasticity of demand. At a high enough price, interchangeability with poor substitutes may not look good to doctors who prescribe the medicine. Thus the *Cellophane fallacy* does not apply in case of pharmaceuticals. Pharmaceutical companies also compete in marketing drugs. Several different market participants are involved today in purchasing pharmaceuticals, which may complicate market definition analyses.

Generally, in pharmaceutical case, *sans* intervention by state governments, geographic markets are national markets. In the Indian context, it is unlikely that drug procurement can sufficiently alter conditions in the relevant market. However drug procurement by state authorities may constrain the demand for pharmaceutical products. But this is more often than not the case with government procurement in India. Supply side constraints imposed by transportation costs and local requirement relating to manufacturing and sale. In terms of consumer preferences, not much of a difference may be found in terms of Thus in the context of pharmaceuticals the relevant geographic market would mean national markets unless there is huge variation in prices due to local procurement schemes by the government.

Section 3(1) prohibits anticompetitive agreements. It is pertinent to note that the Commission must follow factors specified under section 19(3) are compulsory. However, it creates a confusing situation if all agreements under section 3 must undergo this scrutiny. It is so because certain horizontal hardcore cartel agreements are per se void. In such situations it is evident that factors under section 19(3) need not be taken into consideration. More importantly, terms used in the factors specified in section 19(3) require an economic analysis, where only further regulations can clear the haze.

In its application to the pharmaceutical sector section 3(3) can prove helpful in dealing with hardcore agreements more specifically in the supply chain. Mass boycott of products, medicos agreeing to prescribe or not to prescribe a particular brand etc… are within the purview of section 3(3) prohibitions. Some agreements under section 3(3) are *per se* void if they are in the nature of hardcore cartels and do not require any factors to be considered under section 19(3). It is pertinent to note that section 3(3) can be used in effectively deterring collusive practices in drug procurement. While there is no direct evidence of bid rigging practices in Indian drug procurement, it must be noted that there is less effective competition prevailing in bidding of speciality drugs. They can be in the nature of market allocating agreements. Section 3(3) however, does not prohibit combinations which are in the nature of acquisitions, merger or conglomerates. They are governed by sections 5 and 6 of the Act. It is pertinent to note that joint ventures are kept out of the application of section 3 provided such joint venture agreements increases efficiency in production, supply, distribution, storage, acquisition or control of

goods or provision of services. It is pertinent to note that many market / R&D agreements in the nature of joint ventures are routinely entered in pharmaceutical will be kept out of the purview if such agreements if such agreement increases efficiency. However, there is no clear definitional understanding of what accounts to efficiency and hence one may retort to section 19(3) for guidance.

Vertical restraints can be challenges under section 3(4) of the Act. As noted in this study the pharmaceutical supply chain is beset with practices that can be regarded as vertical restraints. Certain tie practices, especially combinational therapies can be validly challenged. However, this must not be confused with fixed dose combination (FDCs) which are directed to single patient required different doses of different medicines. However, tie-in practices which require a retailer or consumer to purchase some other good along with the one demanded falls within the mischief of this section. Price discounts and other forms of exclusive arrangements are also caught within section 3(4). However, much is yet to be desired from the guidelines that the CCI will come forth with.

It is pertinent to note that section 3(5) partially excludes the operation of agreements concerning intellectual property rights as antithesis to competition. Again, much is yet to be desired from the guidelines as to what practices are prohibited. It must be specifically noted that certain anti competitive practices which lead to the prohibition of protection of the existing trade and industry, development of new industrial activities, promotion of export, availability of the product at affordable price, can be successfully challenged under the Patents Act, 1970. A compulsory license may be issued for after such allegations are satisfactorily proved before the patent controller. The patents act also allows issuance of compulsory license where prevention of unreasonable terms–such as grant-back requirements, packaging, prevention of challenges–in voluntary licenses, exploitation of the market based only on import etc. led to anticompetitive fallouts. However, there is no necessity of the rule of reason analysis to be applied in case of the patent law. Suffice it would be to prove that such provisions do exist in the agreements. It must also be noted that for a successful application under the patents act, there is no consideration for an inquiry in to the relevant market. This illustrates that compulsory licensing provision under patent laws are in the nature of public interest provisions and not based on stricter competition law analysis. As stated above, the regulation from the CCI will have to clarify the caps and thresholds that would be kept for regarding agreements to fall within the mischief of this section. The EU block exemptions on technology transfer may only provide an illustrative guide. However, the competition commission is bestowed with full powers to reasonably fix the thresholds. However, it is evident that section 19(3) factors will have to be considered. Exception to exclusion under section 3 category also pertains to entering into anticompetitive agreements for the purpose of export market. Section 3(5) also allows for the right of any person to export goods from India to the extent to which the agreement relates exclusively to the production, supply, distribution or control of goods or provision of services for such export.

Dominance, per se is not illegal but its abuse is. The vexed question which is to be answered is “determination of dominant position’. Cases analyzed in the context of US and EU jurisdictions amply assert that willingness of the courts to understand that law does not make mere size of a corporation, however impressive, or the existence of unfettered power on its part, an offence, when accompanied by unlawful conduct in the exercise of its power. It may be noted that the competition laws of all jurisdictions do not contain a general prohibition on the abuse of dominance or on the misuse of market power. Some laws only prohibit specified conducts by undertakings in a dominant position or having a substantial degree of market power.

Section 4 (1) of the Indian Competition Act states, “No Enterprise shall abuse its dominant position”. There are however certain differences in these basic provisions. While the Indian law prohibits abuse of dominant position by enterprises in general, the certain countries may have provisions in the law that prohibits the “abusive exploitation of a dominant position”. Needless to say dominance has been traditionally defined in terms of market share of the enterprise or group of enterprises concerned. However, a number of other factors play a role in determining the influence of an enterprise or a group of enterprises in the market. These include, besides market share, the size and resources of the enterprise; size and importance of competitors; economic power of the enterprise; vertical integration; dependence of consumers on the enterprise; extent of entry and exit barriers in the market; countervailing buying power; market structure and size of the market; source of dominant position viz. whether obtained due to statute etc.; social costs and obligations and contribution of enterprise enjoying dominant position to economic development. The Commission is also authorized to take into account any other factor which it may consider relevant for the determination of dominance.

There are primarily three stages in determining whether an enterprise has abused its dominant position. The first stage is defining the relevant market. As noted above, the analysis in case of pharmaceutical products in complex. The second is determining whether the concerned undertaking/enterprise/firm is in a dominant position/ has a substantial degree of market power/ has monopoly power in that relevant market. The third stage is the determination of whether the undertaking in a dominant position/ having substantial market power/monopoly power has engaged in conducts specifically prohibited by the statute or amounting to abuse of dominant position/monopoly or attempt to monopolize under the applicable law.

Explanation to section 4 define dominance as "a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to— (i) operate independently of competitive forces prevailing in the relevant market; or (ii) affect its competitors or consumers or the relevant market in its favour". It is pertinent to note that the act does not distinguish between passive or active market power. An effect based test would allow the application of this section if the enterprise has become dominant due to existence of passive market power. The Act clearly states that there shall be an abuse of dominant position if an enterprise or a group directly or indirectly, imposes unfair or discriminatory condition in purchase or sale of goods or service; or price in purchase or sale (including predatory price) of goods or service. Predatory pricing is also included. It is pertinent to note that the Commission take note of unfair prices in case of pharmaceuticals also. Nothing in Act mandates the Commission not to intervene in price regulation only because of the existence if NPPA or issue compulsory license because of the existence of provisions for compulsory license under patents act, 1970. In cases of unfair pricing the recourse taken by the South African commission may be considered.

Pharmaceuticals suffer from the problem of excessive pricing and predatory pricing cases are very rare except where patents are about to expire and brand manufacturer wanting to preserve his long held monopoly. In case of application of the essential facilities doctrine, the Act deals with EFD under section 4 and Section' however the treatment is different. Our Supreme Court has imposed ceratin obligations which are similar to EFD. The court held that writ can't be issued in the matter of contractual obligation. Moreover no writs can be issued if the rights are of a private character. The court recently held in ABL Industries that writ can be passed in contract matters if one the parties is Govt. and it's *essential* for the govt. to work fairly. Furthermore, Indian law has institutionalized the entire concept of Essential Facilities through certain Acts. As applied to the pharmaceutical sector, the EFD can prove helpful in accessing patented knowledge. The remedy is generally in the nature of compulsory licensing.

It is pertinent to noted that section 4 analysis requires under section 19(4) the Commission shall, while inquiring whether an enterprise enjoys a dominant position or not under section 4, have due regard to all or any of the factors mentioned therein.

Three important factors can be understood to have positive implication for section 4 analysis. What are social costs is not defined. Again, section 4 may warrant development dimension to the understanding of dominant position. However, most importantly the commission may consider any factor that is relevant for an abuse of dominant inquiry within the scope of section 19(4).

Section 5 prescribes the thresholds under which combinations shall be examined. While the threshold prescribed have a potential to include many medium and big size acquisitions in the Indian pharmaceutical market, it is important to note that section 5 and 6 provisions have not been notified. Section 6 states that "No person or enterprise shall enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void". Section 6 mandates a pre combination review notice to be given to the commission within 30 days of the decision of the companies to enter into a combination. Section 20(4) requires that for the purposes of determining whether a combination would have the effect of or is likely to have an appreciable adverse effect on competition in the relevant market, the Commission shall have due regard to all or any of the factors mentioned there in.

Without provisions relating to combinations being notified, it would be difficult to put on hold acquisitions that might have adverse effect on competition in India. It is important to note that the tests developed in comparative jurisdictions can only provide a guide in the absence of specific regulations issued by the CCI. What is import for review of combinations is also an assessment of impact of combination on innovation markets. It is pertinent to note that acquisitions which involve takeover of generic companies may lead to change in priorities of generic companies. Overall effective competition in generic markets may thus be reduced.

Section 49(3) Chapter VII dealing with Competition Advocacy bestows powers to the CCI to conduct advocacy on competition issues. However, this in itself does not explain the need for role of advocacy in the pharmaceutical sector. There is a need for advocacy because the competition Act in India is itself new and its possible application is a complex analysis; not all government functionaries consider elements in formulating policies relating to pharmaceuticals. The classic example in this case is the Draft National Pharmaceutical Policy of 2006 issued by the Department of pharmaceuticals which does not mention the use of competition law as an instrument to abate excessive pricing by pharmaceutical companies**;** Pharmaceutical sector, as it stands, is a highly regulated sector and various regulatory authorities govern different aspects of the industry**;** The pharmaceutical industry heavily relies on the patent system where possibilities of abuse of patents stand a higher chance. This is specifically because legal monopolies through patents are market interventions to cure market failures in innovation. Abuse adding to it may aggravate concerns for competition; there is high amount of scrutiny in the pharmaceutical sector globally. Incidences of pharmaceutical companies abusing patents and dominant position prevail widely. This is also confirmed by the recently concluded EU Pharmaceutical sector Inquiry (July 2009)**.**

Hence there is a need for a muliti-pronged strategy for creating awareness about competition issues on ex ante basis. Since there are different actors in the Pharmaceutical industry and healthcare markets, strategies can be specifically with reference to various actors have been suggested.

In conclusion, it is recommended that the CCI will have to keep a strict vigil around various issues identified in the report. They pertain to patent abuse, practices in the pharmaceutical supply chain, price monitoring in drug procurement and possible anticompetitive practices, other practices affecting the supply chain, sensitizing various stakeholders in the pharmaceutical supply chain and issues concerning vertical restraints, encouraging physicians to prescribe generic substitutes, send opinions on innovation policies, use of compulsory licenses in case of high prices for patented drugs, issuance of guidelines clarifying the relationship between competition law and intellectual property rights, interventions in case of excessive pricing and coordinating with the NPPA for price monitoring and providing recommendations where appropriate, and suggesting the combinations provisions to be notified to prevent anticompetitive mergers/acquisitions.

CHAPTER I

INTRODUCTION: THE IDEA OF COMPETITION REGULATION IN THE PHARMACEUTICAL SECTOR

1.1 Introduction to the study

1.1.1 ***Objectives of the study*:** The current study focuses on issues governing competition in the pharmaceutical sector in India, with special emphasis on practices regulated or prohibited by the Indian Competition Act, 2002 (as Amended by the 2007 Act). The overarching objective of the study is to "understand the nature of the pharmaceutical industry and market and explore its implications for industrial capacity, consumer access and public health, with reference to the Competition Act, 2002." The other underlying objectives are:

➢ To present an overview of Indian Pharmaceutical Industry and markets and to strategize means to identify anti-competitive activities prevalent in the pharmaceutical market. Examine the industry from horizontal as well as vertical agreements point of view.
➢ Tabulate experiences of jurisdictions with established competition law regimes with reference to the context of the study.
➢ Explore the relationship between pharmaceutical industry and health service providers and the anti-competitive practices prevalent in the market.
➢ Correlate industry dynamics and behaviour with the practices regulated by the Competition Act of 2002 by the CCI.
➢ Propose areas of advocacy and identifies possible strategies.

1.1.2 The study has made an attempt to cover all important aspects pertaining to the terms of reference and has made an in-depth analysis of some issues that are of crucial importance for enforcement of competition law in the pharmaceutical sector in India. The study follows the Competition Assessment Framework (CAF) methodology prescribed by the UK Department for Industrial Development (DFID), as agreed to in the terms of reference of the study.

1.1.3 ***Chapterisation**:* The study is structured into seven chapters. To ensure easy readability of the report even while addressing technical issues and to maintain a flow in the study, the chapters are divided in a problem-solution mode. This introductory chapter (Chapter I) is titled *"The Idea of Competition Regulation in the Pharmaceutical Sector"*. It is divided into two parts. The first part provides a brief introduction to the report, with stated objectives, structure and chapterisation and methodology. Here details concerning the use of CAF framework and its limitations are discussed, the same includes structure of interviews (structured and unstructured). This section also provides the scope of the study along with its limitations. The second part briefly introduces the reader to the development dimension of competition law and policy, and relevance to the pharmaceutical industry. It also visits some basic economic analysis, concepts, functions and emphasizes on the welfare effects of competition law for consumers and its usefulness for maintaining a competitive industry framework in the pharmaceutical sector. It briefly introduces the reader to issues concerning the pharmaceutical sector in India that are addressed in this paper. Here a brief conceptual backdrop is provided highlighting the tension points that this report has attempted to address. The third part provides details about the methodology used for the study.

1.1.4 Chapter II titled *"The Pharmaceutical Industry and Markets in India: Overview of the Changing Dynamics"*. This chapter primarily elaborates upon the industry and the market structure and has made an attempt to identify possible anticompetitive practices in the pharmaceutical industry and markets in India. Here both desktop and field research has been included. It includes a brief history of the pharmaceutical industry; current

structure of the pharmaceutical industry; exports-imports and balance of trade; market shares and net-worth of leading firms; inward and outward foreign direct investments; mergers, acquisitions and alliances; emerging trends and patterns in the pharmaceutical industry in India; innovation, R&D and patents; introduction to pharmaceutical market in India and the structure of pharmaceutical distribution network; drug promotion and advertising; flagging the relationship between various actors in the pharmaceutical supply chain- with emphasis on hospital pharmacy practices; pricing practices in the pharmaceutical industry in India; drug pricing, availability and affordability and its interaction with health care concerns- with emphasis on geriatric medicines; drug procurement systems and concerns for competition; The chapter briefly concludes with conclusions and recapitulation.

1.1.5 Chapter III is titled as *"The Regulatory Web of the Pharmaceutical Sector in India: Its Implications for Ex-ante Competition."* The chapter primarily focuses on the complex regulatory structure governing the pharmaceutical industry in India- with a focus on laws, policies and statutory framework governing various authorities. It discusses issues pertaining to patent law and ex *ante competition*; Trademark law and the use of international non-proprietary names; Public funded R&D Bill and its possible impact on innovation and diffusion of pharmaceutical technologies; drug price regulation in India; NPPA, price controls and *ex ante price competition;* drug regulation and competition; brief survey of web of laws governing actors in the supply chain and health care markets; consumer drug information and other miscellaneous factors that implicate *ex ante* competition. The chapter ends with conclusions and recapitulation.

1.1.6 Chapter IV is titled as "*The Application of Competition Law in the Pharmaceutical Sector: A view From Comparative Jurisdictions".* This chapter primarily aims at conceptualizing and contextualizing the law, policy and application of competition/antitrust law to the pharmaceutical sector by placing reliance on comparative jurisdictions. The EU and US framework is primarily relied upon, with timely reference to positions in the UK and South Africa whenever demanded. The chapter starts with identification of "relevant markets" and assessment of "market power" in the pharmaceutical sector ; classification of therapeutics; treatment of anticompetitive practices; treatment of abuse of dominance; regulation of combinations (merger control); interaction between intellectual property rights and competition law; other miscellaneous issues. The chapter ends with a brief summary of conclusions and recapitulation**.**

1.1.7 Chapter V is titled as *"Competition Law and Its Interaction with the Pharmaceutical Industry: Position in India".* It primarily deals with the application of Indian competition Act, 2002 (as amended by the 2007 Act) to the practices identified above. However, the chapter also provides the brief application of the erstwhile MRTP law in terms of its provisions and their effectiveness; the MRTP experience in the pharmaceutical sector: some cases and analysis; the Competition Act, 2002 and its application; treatment of anticompetitive agreements; treatment of abuse of dominance and regulation of combinations; treatment of interaction between intellectual property rights and competition law; other miscellaneous issues. The chapter ends with conclusions and recapitulation.

1.1.8 Chapter VI is titled as *"Competition Advocacy in the Pharmaceutical Sector".* This chapter aims to provide practical suggestions in implementation of the Act and identifies strategies for advocacy around issues identified as possible anticompetitive practices/ effects in the course of the study. Here a need for multi-pronged strategy to deal with various actors is also suggested by keeping in mind horizontal and vertical industry dynamics and market perspective. Issues concerning advocacy with regulatory institutions in also discussed. The chapter ends with brief conclusions and recapitulation.

1.1.9 Chapter VII ends with "*Conclusions and Recommendations".* This chapter also identifies some of the potential areas for future research and gaps that remained unaddressed in this study.

1.1.10 ***Methodology of the study:*** The study is based on the operational framework provided by DFID's *"Competition Assessment framework (CAF): An Operational Guide for Identifying Barriers to Competition in Developing Countries",* published in 2008. The CAF provides a flexible diagnostic tool that poses sets of questions that are grouped by theme. The nature of questions will depend on the particular sector taken up for assessment. It then follows with steps to analyse the state of competition in the selected sector. It includes:

identifying the markets and competitors, examining the market structure, looking for barriers to entry, looking for anticompetitive conduct, considering vested interests and the principal beneficiaries, and identifying government policies or institutions that limit competition. The reason for adopting the CAF is mainly because economic conditions, laws and institutions can vary greatly between countries and hence it would be important to contextualize the study in a developing country context. Hence the CAF was a natural choice for the study when compared to other guidance reports available, for example the "Market Studies-Guidance on the OFT Approach" (OFT, 2002).[1] While positions in comparative jurisdictions have been relied upon, they may not be coherent enough to provide operational guidance with specific focus on issues and concerns in developing country markets.

1.1.11 The CAF is used as a step-by-step framework as the chapters proceed. Chapter II basically emphasises on identifying market structure and possible anticompetitive practices. While existing literature was carefully scrutinised an analysis of the anti-competitive practices is also done. For most part the CAF has been practically applied to chapter II of this study. In many ways, all chapters of the CAF (except certain parts in some chapters) have provided ample guidance to demarking the scope of this study, considering the terms of reference. The methodology is specifically mentioned in chapter II, III (partly), IV, V, VI, VII, VIII of the CAF providing guidance on various issues addressed in chapter II of this study. Hence various factors mentioned therein are duly considered. Chapter II of this study also takes guidance from chapter IV of the CAF which deals with "examination of market structure". Partial guidance is also taken from chapter III of the CAF that provides for means to "identify the relevant markets and competitors" for the purpose of chapter II of this study. Guidance is also taken from chapter VII of the CAF dealing with "consider (ation) of vested interests" of various stakeholders. It has been primarily useful in identifying vested interests in the supply chain network, primarily to flag the dynamics of relationship between such actors. However, in this study relevant markets are not identified at this stage. Relevant markets are identified both, conceptually and contextually in chapter IV and chapter V of the study. Chapter III of this study proceeds to identify regulatory barriers. This is in line with chapter V of the CAF which deals with entry barriers. The pharmaceutical industry is one of the highly regulated sectors world-wide. Hence pertinent guidance is obtained from the CAF in this section. Chapter III of this study also relies on guidance provided in chapter VI of the CAF dealing with "ascertain(ing) if government policies or institutions limit competition". Here, policy and legal issues primarily concerning trade and industrial policy barriers are identified, including issues very unique to the regulated sector- for example drug regulation and competition issues in the pharmaceutical sector. Chapter VI of this study deals with contextualizing the identified practices in accordance with practices identified in chapter II. Here chapter VIII of the CAF that deals with signs of anti-competitive conduct by firm and stakeholders is analyzed. The CAF provides special guidance in drawing conclusions. Again, the concluding chapter heavily relies on the CAF in drawing conclusions for this study.

1.1.12 While the CAF has been generally, to the most part, been useful in conducting this market study, there are also some limitations identified in the CAF guidance as specifically pertaining to this study. First, while CAF is comprehensive enough to deal with market studies in any sector; it does not invoke or address means to address competition concerns that are specific to the pharmaceutical sector. Annex C of the CAF does not deal with issues in the pharmaceutical sector and this has been the major impediment. Second, and perhaps owing to the special nature of the terms of reference, this study is expected to primarily focus on legal issues and contextualize them to market practices. The CAF guidance is not of particular help in addressing anticompetitive conduct and contextualizing them to laws in specific countries. Even while legal frameworks in different developing countries may be considerably different, the CAF could provide an overview of ways and means to contextualize legal frameworks with the practices and conduct of actors identified in particular markets. Third, the CAF does is not designed to identify advocacy strategies. Again, owing to specific nature of the terms of reference, this advocacy part of the study did not particularly benefit from the CAF guide. Fourth, The CAF does not specifically indentify common consultations as part of the market study. This would be of practical help in taking expert views and stakeholders before finalizing the study. However, barring the limitations identified above, the CAF has been usefully applied in the study.

[1] 'Market Studies- Guidance on OFT Approach (2002)' can be obtained from [Online]: http://www.oft.gov.uk/shared_oft/business_leaflets/enterprise_act/oft519.pdf

1.1.13 ***Data collection and research inputs***: The study uses data on the pharmaceutical industry from various sources such as CMIE- Prowess, existing studies and reports. The legal and policy framework is studied by collecting texts and materials from Westlaw, Hein Online for study in comparative jurisdictions. Online web resources, websites of comparative competition authorities. The report has used structure and non-structured interviews to flag the relationship between pharmaceutical industry and health service providers and the anti-competitive practices prevalent in the pharmaceutical market. In order to understand the views and opinion of the various stakeholders, different media sources are used. As part of field study, interviews with key stakeholders are also conducted. However, the study does not present any quantitative analysis.

1.1.14 ***Scoping the Study and Limitations:*** The study examines all possible issues that underline the objectives framed above. However, this study is scoped in at least four levels. First, the objective of the study is limited to pharmaceutical industry/ sector and not to the healthcare industry/sector in general. Hence issues of competition in relation to hospitals and other service based segments of the pharmaceutical industry are not part of this study. Second, the pharmaceutical industry comprises allopathic medicines and other forms of traditional and alternative medicines like Ayurveda, Unani, Homeopathy, Siddha, Naturopathy and Yoga. This study is specifically concerned with the use of allopathic treatment (both organic and inorganic chemistry) where concerns of competition and its interaction with health care are paramount. This is also because of wider acceptability and standardization of allopathic treatment as being universal to modern health care. Third, pharmaceutical products/processes can be divided in to therapeutics (drugs), diagnostics, vaccines and prophylactics (preventive technologies- products/methods). Since the scope of examining all such product/process categories is prohibitively outsized, the study has examined only therapeutics. This is also because the medicines are directly consumed by people and the large amount of consumer and competition law and policy concerns emerge in this product range, primarily in relation how drugs are innovated and patented, generic availability and pricing practices and nature of interactions in the pharmaceutical distribution markets. However, it is not to suggest that the markets for vaccines, diagnostics and prophylactics do not carry any competition concerns- which can definitely be a distinct stand alone study. Fourth, the therapeutics markets can be divided into over the counter drugs (OTC) and prescription drugs. OTC drugs are directly sold to consumers and hence consumers have a choice for making brand preferences. Hence to some extent it can be said that demand and supply factors work in a competitive market environment. There is an increasing tendency to get more drugs out of the prescription ambit. There are both advantages and disadvantages to this issue. It is not to suggest that OTC drug market present no competition concerns in an increasingly drug advertising driven market where information asymmetries and lack of effective consumer drug information forms the perverse genesis of this market. Even while the study refers to OTC drugs in pharmaceutical market overview, the major focus of this study is in relation to prescription drugs or what is generally called as “ethical drugs”. It is a known fact that prescription drugs are chosen by the doctors- who are generally price insensitive due to a variety of reasons, including perverse incentives– but purchased by patients (consumers). Hence consumer and competition concerns are more in ethical drug market, which the study rightly focuses in its entirety.

1.1.15 While the study examines the pharmaceutical sector and market positions of companies their strategies and practices, it does not specifically point to practices of one particular company or firm or any particular. However, general practices have been identified. Even with reference to pricing, while pricing practices of companies have been highlighted, it is not to suggest that any one company/enterprise is *prima-facie* in violation of any law. As mentioned earlier, this study does not warrant a quantitative analysis of anticompetitive practices prevailing in the market. However, the study has provided good amount of updated data on various aspects of the pharmaceutical sector. But some data on certain fronts has been lacking due to unavailability. This is especially in the area of mergers and acquisitions. Hence the study extensively relies on empirical evidence already provided in different studies.

1.1.16 On the legal side and policy of this study (mainly chapters III, IV and V), comparative analysis is carried out extensively in case of competition law approaches. However, where positions in comparative (foreign) jurisdictions converge, concomitant positions in all jurisdictions are not being analyzed. This is clearly to prevent any repetition of legal approaches and positions. Where domestic law is sufficiently developed, no

recourse is taken to positions in foreign jurisdictions. In the chapter relating to advocacy strategies (chapter VI), the focus of this study has been to identify issues for advocacy rather than informing the CCI on possible approach in ensuring advocacy. The concluding chapter (chapter VII) does make some recommendations, but where issues concern suitable amendment in the law, no particular wording for any amendment has been suggested. It would be beyond the scope of this study to engage in any such exercise.

1.2 The Development Dimension of Competition Policy and its relevance to the Pharmaceutical Sector

1.2.1 Competition law and policy are closely linked to development and industrial policy of any nation. Many international and intergovernmental organizations working in the area of competition policy have sufficiently advocated the need for maintaining an effective competition law (UNCTAD, 2008; World Bank 2001).[2] The UNCTAD study notes that appropriate application of competition law and policy can facilitate growth and development by poverty reduction and maximizing consumer welfare (UNCTAD, 2008).[3] New and emerging economies, including India, have a 'state-of-art' competition law in place.[4] As with many other competition law frameworks in developed countries, the Indian Competition Act, 2002, also prohibits or regulates three set of practices viz., anticompetitive agreements, abuse of dominance, and regulation of combinations.[5] However, considering that the legal regime for competition law in place is of recent origin, there are considerable challenges in its implementation and enforcement. More specifically, challenges that are presented by reduction in policy space in the application of competition laws in developing countries (Singh, 2002).[6] Phenomenal changes in the economic and political thinking towards market oriented economics in recent years and its increasing prominence/influence over new and emerging economies has provoked a great deal of interest in the conceptualization, rule making, application and implementation of competition law for the benefit of the maximizing societal welfare (Pitofsky, 2008). Since competition law is dominated by a set of policy choices, there are considerable difference that one may find in the application of competition/antitrust law in the US and the EU (the two most prominent jurisdictions).

1.2.2 It should be noted that the early evolution of competition law and policy in different countries did not lay emphasis on the role of economics or conceptualization and evaluation of economic effects involved (Whish, 2008).[7] The evolution and adoption of competition law and policy as during the yesteryears was overly

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[2] The World Bank study shows that, in 1997, developing countries imported US$81.1 billion worth of goods from industries where companies were involved in price-fixing arrangements in the 1990s. These goods represented 6.7 per cent of imports and 1.2 per cent of GDP in developing countries. These figures reveal the significance of the economic impact of the damages of anti-competitive practices on developing economies.

[3] The UNCTAD Study notes that: "One of the policy options available to governments to prevent or eliminate anti-competitive practices is the introduction and enforcement of competition law. The interrelationships between competition law and other government policies, such as consumer protection, macroeconomic policies and poverty alleviation, are an important catalyst to economic development and better livelihoods. Among these policies the synergies accruing between competition and consumer protection law enforcement to protect consumer interest and welfare are worth noting" (UNCTAD, 2008).

[4] The Competition Act, 2002 (No. 12 of 2003) [As Amended by the Competition (Amendment) Act, 2007) [Hereinafter the Act]

[5] Sections 3, 4, 5 and 6 of the Act.

[6] Singh (2002) specifically examined the role of competition policy in emerging markets from a developmental and international perspective. He concludes that contrary to conventional wisdom, evidence suggests that the intensity of competition in leading emerging markets is certainly no less than that observed in advanced countries. The paper analysed and adduced evidence which indicates that maximum competition is not necessarily optimal, in terms of dynamic efficiency. The paper also recommended that developing countries need a competition policy today, because of (a) privatisation and deregulation, and (b) the huge international merger movement. The author also concluded that there is little evidence to indicate that the current international merger wave will enhance global economic efficiency. Very specifically, the paper castigated that approaches of current competition policies in the US and the European Union are unsuitable for developing countries. Countries at different levels of development and governance capacities require different types of competition policies for ensuring a development-oriented international competition authority to control anti-competitive conduct and growth by mergers of large multi-nationals.

[7] It should be noted that competition law and policy has often traded ascendancy with the political zeitgeist- to suggest that application and enforcement of competition law and evaluation of economic concepts is ever-changing, at best fluid. This can be explained by recent rethinking done by many Chicago and post-Chicago legal scholars and economists about the role that competition law can play in ensuring the health of the economy and for maximizing consumer welfare (Pitofsky, 2008). The argument put forth by such scholars is that some practices under the United States antitrust law (competition law) - to which many jurisdiction look up to for understanding economic concepts, albeit by not placing excessive reliance- has often fondled with the foundational requirement of antitrust law and

structural. But Competition law and policy evaluation has come a long way since the 1970. The evaluation of economic concepts that influence the policy space of competition law has largely emerged out of Chicago and post-Chicago scholarly analysis in the United States and other developed countries. However, competition law and policy has been unable to conclusively answer very fundamental questions that pertain to its interaction with theories of industrial organization. Since '*Pareto efficiency*' is illusionary in market economies, competition policy has not answered how much of competition is actually good for growth oriented markets. Consequently, how much of oligopoly, how much of dynamic efficiency v. static efficiency and its role in developing country markets remains challenged.

1.2.3 Post-Chicago theorists have attempted to rebuild the lost ground and have argued for a nuanced application of competition law and policy to maximize consumer welfare (Pitofsky, 2008). Some commentators have even argued that certain efficiency arguments presented by Chicago School has come a long-way in influencing the courts and policy makers towards conservative economics without placing reliance on material facts and empirics in competition law and policy analysis (Fox, 2008). Furthermore, since the economic and financial crises gripping the whole world, many jurisdictions have begun to rethink how to reorganize their antitrust law framework so that it is free from the biases of mechanical application of the law by resorting to an overly crude interventionist approach, but at the same time does not carry the orthodoxy of conservative economics propounded by the Chicago school of thought.[8]

1.2.4 Competition law is primarily territorial, which means that each country has a sovereign right to have a unique policy and legal framework of competition law, unless they are constrained to do so by any internationally binding obligations. While the geographical coverage of competition law has expanded over the time, what has also expanded is the scope of activities to which competition law applies. Competition law can be treated as a distinct branch of administrative law that focuses on regulating markets and promoting competition where routine economic activities take place. It also has its genesis in the principles and ethos of Constitutional Law of some major countries. This is primarily because the application or non-application of competition law as a distinct type of economic regulation can have major impacts on the degree of welfare maximization, which is not just economic, but social and political as well.

1.2.5 Competition is necessary at all times for full and effective functioning of the markets. Hence competition can both be seen as a process as well as an outcome. The primary concern of competition law is that the market power acquired by a firm, undertaking or association of persons and various other actors during the course of routine economic activities can unduly harm the consumers if such actors are able to exert their market power by engaging in a host of conduct that can be regarded as anticompetitive under the province of competition law. The assessment of market power for the purposes of competition law unquestionably involves an evaluation and understanding of economic concepts.

1.2.6 Generally, comparative jurisdictions that have in place some form of competition law are concerned with the three types of practices that can have adverse effect on competition (Whish, 2008). They are anticompetitive practices; abuse of dominance and regulation of combinations (merger control).[9] There can also be public

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policy and has thus overshot the mark (Pitofsky, 2008). This suggests that there can be drastic changes in how competition law and policy will revive itself in developed jurisdictions, and how it may influence the legal, economic and policy thinking in emerging economies like India.

[8] As noted in a briefing by the US FTC Commissioner in June 2009, notes: "While the orthodox Chicago School of economics has long been at the forefront of antitrust analysis, there are several other economic theories percolating under the surface that I believe supply a better understanding of how market participants – more specifically sellers and buyers – actually behave. But the fundamental issue for those of us responsible for enforcing the antitrust laws remains the same – when should the conduct of those firms be viewed as anticompetitive?" *see,* Federal Trade Commission, *Antitrust Law Enforcement: What To Do About The Current Economics Cacophony?,* Remarks of J. Thomas Rosch Commissioner, Federal Trade Commission before the Bates White Antitrust Conference Washington, D.C. June 1, 2009

[9] **Regulation of combinations:** Combinations broadly refer to mergers, acquisitions and amalgamations where acquisition of control by a person over an enterprise is carried out by such entities engaged in similar business. Generally, combinations are reviewed on *ex ante* basis by competition authorities as they may deprive consumer choice available in the market and hence may have to pay higher prices.

restrictions on competition[10] and extra-territorial application of competition law when effects of particular conduct in one jurisdiction are felt in another jurisdiction.

Anticompetitive agreements: Agreements that have as their object or effects the restriction of competition are unlawful within the preserve of competition law. They can either be in the nature of horizontal or vertical agreements. Horizontal agreements among competitors- which are generally viewed with great scepticism and are severely punished- may pertain to price fixation, market division, restrictions on output/supplies. Vertical agreement between firms at different levels of the market- though considered to cause less competitive harm- could nevertheless be harmful to competition in some cases. Practices like resale price maintenance along the supply chain form part of vertical agreements.

Mergers and Acquisitions (M&As): 'Merger' happens when two or more companies combine together to form a single entity through a purchase acquisition or a pooling of interests.

'Acquisition', also known as 'takeover' or 'buyout', is the buying of one company (the 'target') by another

Abusive of Dominance: A monopolist or a dominant firm that has substantial market power which enables it to behave with a position of strength independently of competitive forces or to affect its competitors or consumers in the market in its favour may engage in abusive behaviour. Practices like reducing prices below cost to drive out competitors from the market, or deter entry by competitors so as to subsequently charge higher prices can form part of abusive behaviour.

1.2.7 There are well evidenced arguments that very few industries are as overwhelmingly influenced by regulation as the pharmaceutical industry.[11] It is so because of the nature of demand for drugs (demand side economics), the identity of drugs brought to market and the nature of competition in the drug market over time is all shaped by effective regulation (or lack thereof). The pharmaceutical industry is also affected on the supply side especially due to problems in R&D outputs, including impediments in generic entry of drugs after the expiry of a patent. The main objectives of regulation in pharmaceuticals are primarily in relation to:

- securing a reward to R&D to assure a continuous flow of innovative new medications;
- ensuring the safety of drugs; and

[10] **Public restrictions on competition:** Other authorities of the State may also be responsible for restrictions and distortions of competition in the general economic policy environment or in some specific regulated sector. Such impact on competition may accrue due to legislative measures, regulations, licensing rules or provision of subsidies, government procurement etc… Competition authorities in various jurisdictions are bestowed with an authoritative role to scrutinize such public restrictions of competition and to pursue competition advocacy role by commenting on, and at times, may also recommend the removal of such restrictions.

[11] OECD (2000), Competition and Regulation Issues in the Pharmaceutical industry, DAFFE/CLP(2000)29, p. 21

- controlling the quantity and enhancing the quality of drug expenditures.[12]

1.2.8 The pharmaceutical sector, globally, since its inception is characterized by the process of "creative destruction"[13]. The early half of 20th century marked the origin of the modern pharmaceutical industry and the therapeutic revolution. Remarkable success of sulpha drugs and penicillin in improving healthcare combined with the rapid increase in demand during the Second World War gave impetus to the modern pharmaceutical industry based on private investments. Many players sought to enter the pharmaceutical business during that period and thereafter. Investments in production and distribution were a consequence of the global opportunity and led to the sector becoming more organized. However, even while there are large numbers of small players in the global pharmaceutical Industry, only top 10-20 Multi-National Corporations (MNC's) dominate the market, in terms of sales value and market shares. New inventions determine the growth prospects for the industry (for originators and for generic firms that rely on originators drug) and availability of such medicines to the public at large. The industry has a two-tier structure. The largest firms account for the majority of the R&D investment in the industry and hold the majority of patents. A large number of smaller firms manufacture off-patent products or under license to a patent-holder. While there is significant heterogeneity in terms of firms' strategic orientations, innovative and production capabilities, competition in the top segment of the industry has always centered on new product introductions, often undertaken by the oligopolistic core of the industry. However, such an oligopolistic structure is in a very limited way constrained by generic price competition after expiry of the patent term and by incremental inventions that may, at times, act as substitutes. Pharmaceutical firms are engaged in manufacturing of bulk drugs and formulations.

1.2.9 It may be noted that there is an emerging tendency in the pharmaceutical industry structure where small and medium size bio-pharma enterprises are also contributing to "creative destruction" paradigm in biotechnology.[14] However, their contribution to the working of competitive forces in the industry remains uncertain. As of 2008, top 10 global R&D based companies held a consolidated global market share of 46.4 per cent and the share of top 20 was 63.7per cent Pfizer, top global pharmaceutical major alone had a 7.6% of global market share. (See Table 1.1). Drug that are launched by firms involved in bringing out newly patented products in the market are called as 'originator drugs' or branded medicines (USA). Firms that are involved in bringing out copies of the originators drug in the market are called as generics. Generics may be sub-classified into branded generics and generic-generics (non-branded). There is sufficient evidence to corroborate that prices charged by originator (patented firms) have always been monopolistic in the absence of effective generic price competition.[15] Since prices fall steeply after introduction of generic drugs into the market, it can be verily concluded that patent holders are not only entitled to charged monopolistic prices, but they do charge monopolistically. More often originator companies are able to effectively engage in pushing their drugs into the market though high end drug promotion activity due to supra-normal profits attached to their products. It is not to suggest that generic pricing is all healthy. However, in case of generic drugs there are effective substitutes possible in the market. Even generic pricing and acceptability of the drug in the market is highly influenced by promotion.

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[12] *Ibid.*

[13] A Schumpeterian concept which describes the process of transformation that accompanies radical innovation. According to this the market revitalize itself from within by scrapping old and failing businesses and reallocating resources to newer, more productive ones.

[14] Mariana Mazzucato and Giovanni Dosi (*Etd.*), "Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech" Cambridge University Press (2006)

[15] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) (hereinafter, FTC, *Generic Drug Study*), *at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

Table 1.1 – Sales and market share of Top 20 global pharmaceutical companies

Company	Country	Sales US$ (Millions)	Market share (%)
Pfizer	USA	45983	7.6
Glaxo Smith Kline	UK	36702	6.1
Novartis	Switzerland	31366	5.2
Sanofi-Aventis	France	30877	5.1
Johnson & Johnson	USA	27112	4.5
Astra Zeneca	UK	26566	4.4
Merck & CO	USA	24854	4.1
Roche	Switzerland	23300	3.9
Abbott	USA	17552	2.9
Amgen	USA	16054	2.7
Top 10		**280181**	**46.4%**
Wyeth	USA	14888	2.5
Lilly	USA	14623	2.4
Bayer	Germany	12404	2.1
Bristol-Myers Squibb	USA	12240	2.0
Boehringer Ingelhelm	Germany	11157	1.9
Takeda	Japan	9962	1.7
Teva	Israel	9282	1.5
Schering – Plough	USA	8641	1.4
Daiichi Sankhyo	Japan	5617	0.9
Novo Nordisk	Denmark	5589	0.9
Top 20		**372355**	**63.7**

Source: IMS International (Smith et.al. 2009).

1.2.10 It is true that the pharmaceutical sector is a high-technology and knowledge-intensive industry. However, there is an ongoing productivity crisis in the pharmaceutical industry. Many reports assert that fewer new chemical entities turn out in to consumable products, higher spending on R&D combined with intellectual property and regulatory barriers are responsible for the declining productivity in the pharmaceutical Innovation.[16] Many chemical entities do not pass the regulatory approval hence draining out the scarce R&D investments. While the healthcare markets have witnessed new products, they are characterized by incrementally modified drugs (IMDs) improvements in terms of new drug delivery systems, improvements in life style drugs, second uses and indications. Hence there is also a market pressure on generics to provide for low cost drugs across the world. There is also a 10/90 gap in global R&D in neglected diseases affecting developing country population (also called as Type III) diseases.[17] This is typically the case of "missing markets" and a classic case of market failure in innovation. Hence there are global attempts to revive the public R&D paradigm to reverse this trend.

'10/90 Gap in Global R&D'

The '10/90 gap' is the disequilibrium within health research whereby only 10% of global health research is devoted to conditions that account for 90% of the global disease burden. First acknowledged by the Commission on Health Research for Development in 1990, it has become one of the most contentious issues in the international research community.

[16] See EU Competition Commission Pharmaceutical Sector Inquiry Report (2009). Also see, Report to Congressional Requesters NEW DRUG DEVELOPMENT: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts, (2006), Washington DC.

[17] WHO, "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property", (2008).

1.2.11 Empirical studies have shown that the distinction between R&D based large and manufacturing based small players is clear, but for an increasing trend in medium and small size biotechnology firms worldwide (Cockburn, 2004). Commentators point to the rising research and development costs of pharmaceuticals as a reason for the changing structure of the pharmaceutical industry. (Cockburn, 2004). However, even while the world is witnessing increasing internationalization of pharmaceutical markets, almost all pharmaceutical majors are located in developed countries and yet operate world-wide (Chaudhuri, 2005). At the root of the global pharmaceutical industry lies the patent system and marketing power that has allowed structural oligopoly in the industry. In other words, R&D based companies enjoy dominant status in the industry. The only competition that such firms can actively face is from the generic industry, which enters the market after expiry of the patent. It has been noted widely that the pharmaceutical industry is highly patent driven and without such protection R&D based companies would not have any incentive to make private investments in innovative research (Taylor and Silberston: 1973). Thus allowing adequate generic competition and price competition are the perennial problems grappling the pharmaceutical industry worldwide.

1.2.12 Most economies regulate the pharmaceutical industry in multiple ways and at multiple levels. In fact, very few aspects of the industry are unaffected by regulatory controls. The demand for pharmaceuticals is fundamentally influenced by the presence of health insurance (whether public or private).[18] However, it depends on whether or not general health insurance schemes pay for all or part of the costs of some pharmaceuticals (particularly "prescription" pharmaceuticals). Since the insured consumer does bear full cost, it can have impact on demand behavior. Thus insurance companies may adopt a variety of mechanisms to control the quantity and quality of drug expenditures, including placing limitations on formularies, drugs prescribed, on physicians and pharmacists. In case of hospital pharmacies the demand of for a particular drug is highly influenced by spatial monopoly. Where consumers are seeing a particular hospital, there are higher chances that they would shop from the hospital pharmacy only. Due to spatial monopoly and necessity of getting the drug in time, they have no incentive to shop for the cheapest pharmacy and competition between pharmacies cannot be relied upon in case of hospital pharmacies to ensure efficient and effective delivery of pharmacy services. In these cases it is necessary to regulate the margins of hospital pharmacies based upon their procurement costs- which are at times low due to skewed buying power.

1.2.13 Another point is that there can be substantial differences in policies regarding price controls leading to differences in the wholesale prices and retail prices of pharmaceuticals across different countries. It is noted by expert reports that although competition law applies in full to the pharmaceutical industry (with possible derogation for "regulated conduct"). Most European countries have some form of price reimbursement system and also some form of direct price control mechanisms.[19] Many countries regulate drug price directly or indirectly. It is understood that some form of price regulation is necessary to maintain price competition in pharmaceutical markets. Some countries also effectively regulate prices of patented drugs through different means, including price negotiations and other methods of price control. Health insurance and re-imbursement schemes may also play a predominant role abating such anti-consumer effects of pharmaceutical prices. National healthcare and procurement policies play a predominant role. In cases of drug procurement, it is quite notable that monopoly can only be challenged through monopsony. Even national policies on standardisation can implicate entry and exit of players in the market. Although there are pro-competitive benefits of standardisation, it *per se* tends to exclude small competitors in the industry. How standards evolved and applied can have long term effects on the competitive structure of the market.

1.2.14 It is a well evidenced and argued fact that the pharmaceutical sector is highly regulated. Since the innovation structure of the pharmaceutical industry is linear, it heavily relies on a patents based framework. Patents provide exclusivity for a limited period of time and hence exclude competition in new products entering the markets. This creates immense problems for effective functioning of competition in the pharmaceutical sector since patents act as a strong market intervention that provides for legal monopolies. *Prima-facie*, substitutes are hard to come in a patent controlled innovation environment. It certainly has implications for knowledge

[18] OECD (2000), Competition and Regulation Issues in the Pharmaceutical industry, DAFFE/CLP(2000), 29.

[19] European Commission, Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States, OBIG- DG Competition (2006)

accumulation, diffusion and price competition in the pharmaceutical markets. The most immediate consequence of such interventionist distortion in competition is in terms of consumer welfare losses. While consumers are benefited by entry of new products into the market, they are also impacted by higher prices for a limited period of time due to the existence of patent protection. Generally, pharmaceutical patents are issued for four different categories of inventions. They are in the nature of drug substance, method of use, formulation, and process. Licensing, patent acquisition and enforcement strategies involving abuse of dominant position can effectively drive out competition in the pharmaceutical sector. It is important in this general context to understand that the rate of innovation in the global pharmaceutical industry has come down considerably. The pharmaceutical sector has remarkable reputation in debates about IPR policy, more specifically patent policy, and has served as the harbinger of major national and international controversies about the relationship between IPRs, R&D incentives, pricing and access to medicines. However, notwithstanding the intensity of debate, on some crucial questions there is relatively little empirical evidence to support informed policy-making about what level of IP protection is good for developing economies in the light of impact of IP on consumer welfare and self sufficiency of medicines.[20]

1.2.15 At another level, information asymmetry does lead to erratic working of competitive forces in the pharmaceutical markets. In prescription drug industry (also referred to as the ethical drug industry), the physician selects the drug and the patient-consumer only pays. Thus pharmaceutical companies are able to exercise passive market power. Harriott (2005) demonstrates the importance of simultaneously modelling information acquisition and information dissemination, in terms of furthering our understanding of the nature of markets with asymmetric information. He concludes "whenever there is asymmetric information in a market, there will always be an incentive for the uninformed to acquire information and consequently incentives for the informed to disseminate information. To understand these markets, one must explicitly take account of the information acquisition and dissemination mechanisms, as failing to do so might eliminate important interaction effects between the two mechanisms on the market" (Harriot 2005).[21] However, Harriot (2006) is of the opinion that adverting can have pro-competitive effects in such cases as it essentially subsidizes the costs of information to consumers. He also argues that many a times it is the ignorance of the consumers which is firms' source of (passive) market power.

1.2.16 Drug promotion and direct to consumer marketing also adds to the passive exploitative situation created by information asymmetries. Hence, the idea of a rational consumer making rational choices based on prices and availability of substitutes in not akin to the working of the prescription drug market. Thus the very notion of consumer choice leading to price competition, fails in the prescription drug market. It may be noted that even in the presence of effective substitutes, the most expensive brand is also the top selling brand. Consumer drug information availability and acceptability is inherently very low in case of pharmaceutical products. The root cause lies in the nature of the product consumed- where consumers have least information about the drugs being prescribed and the therapeutic efficacy of one drug over another. Further, linkages in the pharmaceutical supply chain are a cause of greater concern. While not many studies have flagged the multiplicity of relationships among different actors – viz., the manufacturer, wholesaler (stockiest), retailers (pharmacists) and physicians- the very structure of profitability and profit distribution, coupled with a lax regulatory structure allowing unethical drug promotion does lead to a skewed nature of consumption patterns due to passive market power and hence impacts effective competition in pharmaceutical markets.

1.2.17 Empirical studies and public policy concerns expressed by policy makers, technocrats, academia and the popular media alike show that the without effective generic competition, pharmaceutical majors enjoy automatic dominance in charging monopolistic prices. This essentially brings into question the issue of access and affordability of medicines in a developing country context. Since the Agreement on Trade Related Aspects of Intellectual Property Rights (1995) [TRIPS Agreement] mandates all WTO member countries (except LDCs currently under transition period) to provide for effective patent protection, for products and process without discrimination as to the field of technology, generic price competition in pharmaceuticals has turned out to be

[20] Cockburn, WIPO Study, p. 150.

[21] As quoted by The Fair Trading Commission (FTC), 2007, P.8, from Harriott, Kevin K. (2005), "Advertising and Consumer Search in Differentiated Markets," PhD Dissertation, Texas A&M University.

a major issue.[22] The AIDS crises in African countries put at the forefront the issue of public-health and its interaction with the international framework on patents in pharmaceuticals. The Doha Declaration on Public Health in 2001 is an outcome of consensus among WTO member countries where countries resolved that the TRIPS agreement does not and should not be interpreted in manner detrimental to the public health concerns of member countries.[23] However, the issue is not laid to rest. To frame the issue: should developing countries (middle and low income countries) contribute to pharmaceutical R&D in developed countries for diseases substantially affecting developing countries? Would it lead to differential pricing or generic competition and hence avoid consumer welfare losses? The argument is that pharmaceutical majors substantially recoup their investments in developed country markets and hence revenues sourced from developing countries amounts to additional profits, but at the cost of affordable access to medicines. However, considering that the existing international patent system being a reality, and not wanting to underscore its importance for pharmaceutical research, competition law authorities have geared up world over to enhance generic price competition in respective markets.

1.2.18 Trends from 1985 to 1999 indicate that the value of medicine production has grown four times more rapidly than the world's income.[24] However, medicine production is highly concentrated in the industrialized countries, where just five countries – the USA, Japan, Germany, France and the UK – account for two-thirds of the value of all medicines produced. Among developing countries, large volume markets of lower-price medicines exist in the highly competitive domestic markets of China and India. The 10 best-selling drugs account for 12% of the value of all medicine production (WHO, 2004).[25]

1.2.19 It is true that India has certainly made remarkable strides in increasing the life expectancy of its citizens. During the beginning of the 1930s, the average life expectancy of an Indian adult was only 32 years. As of 2000, the average life expectancy stands at 64 years. This can be largely attributed to the self sufficiency policy in medicines and other regulatory instruments adopted in 1970.[26] However, not all is healthy about the health situation in India. The last two decades saw life expectancy at birth in India has increased by approximately double the increase in life expectancy in middle income and high-income countries. However, the average Indian life expectancy is 15 years less than that of a citizen of a high-income country. There are different reasons, mostly of political economy, public funds for health services in India have been focused largely on medical services, and public health services have been neglected. This is reflected in a virtual absence of modern public health regulations, and of systematic planning and delivery of public health services.[27]

1.2.20 Public health expenditures are among the lowest. Hence a large part of the population relies on private health care systems. Consequently, there are bound to be economic constraints on access to medicines. The ratio of India's purchasing power parity-adjusted per capita income to that of middle-income countries is 52 per cent and that of high income countries is 10.6 per cent. The ratio of India's purchasing power parity-adjusted health expenditure per capita is 35 per cent of middle-income countries and 3.6 per cent of rich countries. Drugs and medicines account for a vital and substantial share of healthcare in India. Household out-of-pocket (OOP) expenditure in India constitutes a sizeable 69 percent of overall healthcare expenditure.[28] Of this, three-quarters of the total OOP health expenditure is spent on drugs. Estimates derived from National Sample Survey (NSS) data for 2004-05 suggest that over 12 percent of household non-food consumption expenditure

[22] It is noted that "TRIPS Agreement standards amounted to a veritable revolution in international intellectual property law from which research based pharmaceutical industry emerged as one of the biggest winners. Faced with take it or leave it decision, all developing country members of the WTO including those with growing pharmaceutical production capabilities, such as India, Brazil, and eventually China, agreed to respect relatively stringent world-wide norms of patent protection no later than 2005". See, (Reichman, 2009).

[23] See, WTO *Declaration on TRIPS Agreement and Public Health,* November 20, 2001, WT/MIN(01)/DEC/2.

[24] WHO, World Medicines Situation Report (2004).

[25] *Ibid*

[26] Both the Drug policy of 1978 and the Patents Act 1970 favored domestic industries to a great extent as there were many provisions which ensured immunity for domestic players from foreign players.

[27] Monica Das Gupta, Public Health in India: An Overview, World Bank Policy Research Working Paper 3787, December 2005

[28] S. Selvaraj, Centad Policy brief series: No. 1: 2008, July Draft Pharmaceutical Policy, 2006: Tilting balance from Public Health to Corporate Interest.

was directed into paying for healthcare. Further evidence shows that, while 70 percent of the households' OOP health expenditure in urban India goes into buying drugs, in rural India the share is as high as 77 percent.[29] It is intriguing to note that usage of public health services by the bottom 20 per cent of the Indian population (classified by income) which is only marginally higher than the top 20 per cent of the population.

1.2.21 In this situation, it becomes extremely important to follow a drug policy which ensures maximum generic price competition. Since the advent of the product patent regime in 2005, there are questions about affordable access to medicines. Currently, drugs prices in India are among the lowest in the world. Prices of drugs in India were once considered to be one of the highest in the world when the product patent regime was in force prior to 1970. Subsequent polices reversed this trend. But considering that the current policy framework is towards excessive deregulation, it remains to be seen if a policy of active intervention from a competition law and policy perspective would find favour.

[29] *Ibid.*

The Pharmaceutical Industry and Markets in India: An Overview of Changing Dynamics

2.1 Introduction:

2.1.1 This chapter examines the pharmaceutical industry in India from a horizontal and vertical point of view by analyzing the market structure and competitors, along with issues concerning competitiveness of the pharmaceutical industry in India. It also examines the pharmaceutical market from a horizontal and vertical point of view and has attempted to flag the dynamics of relationship between various actors in the pharmaceutical markets. Here an attempt is also made to identify and highlight possible anticompetitive practices that are prevalent different levels in the pharmaceutical industry and markets.

2.1.2 It is widely recognised that the Indian pharmaceutical industry, known for its technical prowess in generic production, has grown out of favourable policy choices adopted since 1970's (later discussed in detail). Health concerns were central to the policies articulated and adopted during this period. However, there are critical challenges presented by the reversal of many of such policies on the Indian generic industry and for the access to medicines situations in India. The recent years have witnessed a host of reports, studies and analysis conducted by the academia, industry, technocrats and policy makers on issues concerning the pharmaceutical industry in India. Some reports have highlighted the pertinent threat presented by introduction of product patent regime and consequent change in the market structure, while others have dealt with opportunities presented in the post-2005 regime. While some authors are skeptical about the future of the generic industry, many others would argue that increasing consolidation in the industry would lead to emerging survival strategies and help the industry to grow. We would briefly visit some studies here under.

2.1.3 Many studies have noted that the strength of the Indian industry lies in offering price based competition to the global pharmaceutical industry by producing generic version of patented drugs (Gelh Sampath, 2006; Chaudhuri, 2005). They also point out that another interesting facet- the current maturing of the industry in to an innovation based one, which could possibly repeat the success of the global majors located in the developed countries. (Gelh Sampath, 2006).[30]

2.1.4 Even considering that the industry is maturing and moving up the value chain, some studies have pointed out to several inherent limitations of Indian firms to mature in to global firms due to low R&D intensity (Pradhan, 2006). However, they suggest that a host of competitive strategies like greenfield direct investment, overseas acquisitions, strategic alliances and contract manufacturing have emerged as favourites to Indian pharmaceutical firms recently and these many be an opportunity to mature from mere survival techniques. (Pradhan, 2006)

2.1.5 Others have provided for mixed reactions, and some have even gone to the extent of emphasizing that the future of the generic pharmaceutical industry looks bleak. A SWOT analysis of the Indian Pharmaceutical Industry in new WTO regime conducted in the year 2002 reveals that the "much acclaimed expertise in process development skills" of the Indian pharmaceutical were made possible by the amendments made to the Indian Patents Act 1970 (Narayanan, 2002). Another study highlighting the historical development of the Indian pharmaceutical industry and envisaging trends in the light of post-2005 regime also concludes that the current expertise in reverse-engineering and process skills were possible only due to the conscious and strategic industrial policy with reference to patent laws and regulation of foreign participation. (Chaudhuri, 2005); (Pradhan, 2006).

2.1.6 Some commentators argue that such strength should be utilized maximum to benefit from opportunities that arise from vertical disintegration of research, clinical trials and manufacturing by the multinationals entering post 2005. (Narayanan, 2002). Studies also point out to weaknesses that such opportunities will be limited to a few firms in this sector. IPI faces threats in the form of competition from other Asian giants particularly China which has similar expertise in process development and reverse engineering Narayanan, 2002). They further argue that considering

[30] The study concludes that firms in the Indian pharmaceutical sector vary considerably in their innovative capabilities and operations. The Study has categorized them into three groups which are called the innovators, the niche operators/ collaborators and the manufacturers. The study also shows that there is considerable variation in terms of clearly different configurations of a large number of innovation-related factors, such as export potential, skilled manpower, annual sales and R&D investments, intellectual property rights as well as structural properties (Gehl Sampath, 2006). Thus it appears *prima-facie* that some part of the industry, a small percentage though, is moving up the value chain and the rest of the industry is working and trying to build on a different framework.

new patent regime being a reality, various strategies like producing off patented products, new patented products by acquiring compulsory licensing or cross licensing, collaboration with multinationals not only in R&D and manufacturing but also in marketing new patented products and improving the standards of production to widen the export market (Narayanan, 2002). However, they also warn that unless efforts are geared towards improving the domestic R&D and increasing the FDI in R&D, optimal benefits may not accrue. Even on the issue of processing quality FDI, they remark such investments do not result in increasing the FDI per se but contributes to improving technology (Narayanan, 2002).

2.1.7 On the export front, frequent data cited by the academia and policy reports have shown that there has been a consistent surge in the exports. However, a recent study has pointed out that various data sources on drugs and pharmaceuticals trade have not adopted a uniform definition of the term "drugs and pharmaceuticals", and this has resulted in diverging conclusions on the performance of the industry on the trade-front (Joseph, 2009). By using various data sources, the study points out that there has been a decline in the growth rate of exports of intermediates and bulk drugs and formulations, which account for 90.8 per cent of the export of drugs and pharmaceuticals from India in 2006-07. However, bulk drugs and other drugs and pharmaceutical products, as per the study have exhibited substantial export growth (Joseph, 2009).

2.1.8 Some studies looking at the emerging Indian biopharmaceutical industry have concluded that though the number of biopharmaceutical companies constitutes less than 3 per cent of the total pharmaceutical industry in India, it has still gained a strong foothold in the field of vaccines (Narayanan, 2008). Vaccines were primarily the domain of the public research institutions and they played a prominent role in transferring know-how. Such companies also have a lot of emphasis on the export (Narayanan, 2008).

2.1.9 The consequence of the post-2005 product patent regime on the Indian pharmaceutical industry, has been rather controversial. Studies have pointed out that the existing successful forays of the Indian pharmaceutical firms would have to be assessed in the context of its role in accessing medicines at affordable prices (Dhar and Gopakumar, 2006). The study argued that the industry's focus and emphasis for patenting, involving the incrementally modified drugs, does reflect the bleak side of the industry (Dhar and Gopakumar, 2006). The study states about possible foreign collaborations and benefits accruing from it for moving up the value chain in R&D. However, this, they point out is at the peril of lack of prioritizing R&D for neglected diseases. They lay emphasis on the fact that the TRIPS consistent Indian regime may have to keep its option open for future amendments to stay attuned once sufficient experience is gained during the post-2005 TRIPS regime (Dhar and Gopakumar, 2006).

2.1.10 From a competitiveness perspective, a review of evidence shows that the Indian pharmaceutical industry is at a crucial crossroad. Certain practices within the industry which were hitherto regarded as within the routine activities of working of the pharmaceutical industry may need a comprehensive re-look. Practices within the industry and distribution networks can substantially undermine effective competition and thus reduce consumer welfare. Further, since the advent of the product patent system in developing countries, coupled by poor health infrastructure and lack of social security, it can push significant population in to poverty. This presents immense challenge in maintaining an essential competitive framework for growth of R&D based industry with adequate generic competition within the pharmaceutical industry in India.

2.2 Brief history of the pharmaceutical industry in India

2.2.1 Indigenous medicines were in use even prior to the British rule in India. Western medicine- scientifically termed as allopathic- came to known only during the British Era. The pioneering efforts of some few indigenous people led to the steady establishment of the modern pharmaceutical industry, even though the then British Government did set up some medical schools for education in modern pharmaceutical research (Chaudhuri, 2005). The Bengal Chemical and Pharmaceutical Works (BCPW) established in 1892 is example in this regard. Subsequent efforts by others have also been duly recorded (Chaudhuri, 2005). Drug production meeting around 13% of Indian requirement was produced by several other indigenous firms during and after the Second World War. By 1930's efforts were also made in the direction of producing synthetic bulk drugs.

2.2.2 Before the therapeutic revolution, there wasn't much difference between the activities of indigenous and foreign firms in India since they were essentially manufacturers and not inventors. But whatever inventive activities prior to the therapeutic revolution were conducted by individuals, including Indians. Indigenous sector dominated the pharmaceutical industry in India until 1950. The therapeutic revolution led to the change in equations between

Indian pharmaceutical industry and global multinationals. 1940's and 1950's saw new medicines being marketed by MNC's in India. But indigenous industry remained unaffected by the change in dynamics. The focus was exclusively on manufacturing and not on research. This in a way strengthened the skills in developing new manufacturing technologies (Chaudhuri, 2005). A collaborative effort between CSIR and private manufacturing industry led to development, application and advancement of substantial skills in the pharmaceutical industry in India.

2.2.3 However, post 1950 MNC's gained the ground with new medicines being introduced in the Indian markets. A strong product patent system then prevailing under the British Patents and Designs Act, 1911 (prevailing in India even after independence) led to increasing influence of MNCs in the Indian pharmaceutical markets. The Government seemed not to be initially concerned to create national champions during that period. A faulty system of industrial licensing exuberated the problem, as it leaned in favour of easy entry for MNCs prior to 1970s- even at the peril of indigenous industry. This was also because MNCs carried certain special type of processing of formulations, which was not carried out by Indian companies during that period. India was one of the unique countries which provided for special and national treatment to MNCs. (Chaudhuri, 2005).

2.2.4 Thus by 1970s, the share of indigenous companies was reduced from 62% (1950) to 32% in 1970. The share of MNCs stood at 68% in 1970s, which increased from 32% held in 1952 (Chaudhuri, 2005). However, it must be noted that during this period, the government established the IDPL and HAL with both indigenous and foreign technology collaboration.[31] This provided the necessary impetus to the private industry players and instilled some confidence during the later stages of pharmaceutical industry development. The contribution of the CSIR laboratories is also well recognised for the private sector having developed substantial reverse engineering skills post 1970.

2.2.5 During late 1960s and in 1970s, there was a conscious attempt to give preference to national industry. This was in consequence to foreign monopoly dominating in the Indian health care sector. The socialist policy advocated by the government of the day and comprehensive review of legislations and policies having a potential to impede domestic participation paved the way for growth of the domestic generic industry in India. After a thorough review of the Patents and Deigns Act, 1911, the Ayyangar report examining the legislation came to a conclusion that foreign patent holders dominated the industry through large number of filing and grants. It viewed that the then prevailing patents law failed to work in "national interest". Thus came in to being the Patents Act, 1970 – which limited patents only to process in case of pharmaceuticals and agricultural chemicals. Further the term of patents was also reduced to 7 years. Apart from this, the Foreign Exchange Regulation Act, 1973 and the National Drug Policy, 1978 provided essential impetus to the growth of the Indian generic industry (Chaudhuri, 2005). Thus post 1970 reversed foreign domination of the pharmaceutical industry in India. Large scale bulk drug production was possible and this led to the change in industry landscape. A decade later, in late 1980 and early 1990, the Indian generic industry steadily increased the exports and came to be recognised as an important player in global generic industry. Substantial price controls initiated in 1979 through the Drug Price Control Orders, based on National Drug Policy, 1978 were pioneering efforts in the direction of ensuring equitable access to health. This led to entry of large number of firms thus contributing to the fundamentals of the present top generic companies in India.

2.2.6 The technical skills augmented by the generic industry in reverse engineering pharmaceutical products developed elsewhere are also remarkable. Reverse-engineering though leading to the same product as that of the originators, involves the investment of substantial time, skill and capital investment. However, as noted above, the Indian generic industry with the help of public sector research institutions could rework on processes and bring new product with a fraction of cost of originator drugs and with decreasing lagging time as explained in table 2.1.

[31] Curently, the following are the five public sector drug companies operating in India: Indian Drugs & Pharmaceuticals Limited(IDPL) Hindustan Antibiotics Limited(HAL) Rajasthan Drugs & Pharmaceuticals Limited(RDPL) Karnataka Antibiotics & Pharmaceuticals Limited(KAPL) Bengal Chemicals and Pharmaceuticals Ltd.(BCPL). Though some of them have been declared sick by the BIFR (Bureau f Industrial Financing and Restructuring) a few years back, presently, revival packages are being implemented by the department of Pharmaceuticals. Some of them have also started supplying generic medicines to Jan Aushadhi, Government's new venture to provide generic drugs at affordable cost.

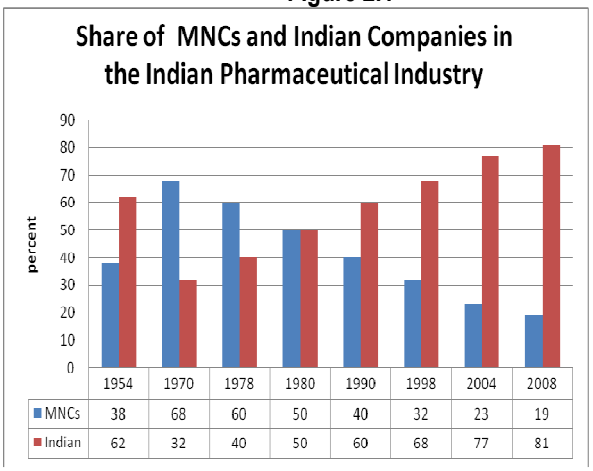
Table 2.1 Introduction of New On-Patented drugs and the Time- lag

Drug Name	Year of Global Introduction	Year of Indian Marketing Approval or Introduction in India	Introduction Lag (Years)	Year of European Patent Expiry
Cefuroxime sodium	1978	1988	10	1994
Cefaclor	1979	1991	12	1994
Netimicin	1980	1988	8	1994
Aciclovir	1981	1988	7	1995
Ranitidine	1981	1985	4	1997
Captopril	1980	1985	5	1997
Norfloxacin	1984	1988	4	1998
Ketoconazole	1981	1988	7	1998
Famotidine	1984	1989	5	1999
Ceflazidime	1983	1988	5	2000
Ciprofloxacin	1986	1989	3	2001
Ofloxacin		1990		2001
Roxithromycin		1992		2001

Source: Lanjouw, 1998.

2.2.7 After 1990s, export led growth and increase in domestic consumption led to a dominating share of Indian firms in the market. In 1998, the domestic companies held 68% of the market share which grew to 77% in 2003. As of 2008, the share of domestic and foreign companies stood at Rs. 50183.33 crores and Rs. 11441.08 crores respectively. Hence the current market share held by foreign companies is 19% while Indian companies hold 81% of the markets. Figure2.1 provides details of the shares held by Indian and foreign companies over a period of time. Since then the industry has also started investing abroad though acquisitions, mergers and collaborations. Even in the new economic context of liberalization, privatization and globalisation, the foreign companies faced substantial barrier in penetrating into the Indian markets. However, post 2005, the Industry has been witnessing new trends and the landscape is fast changing. The large and the medium industry are attempting to strategize themselves in the changing landscape. The generic industry is having a different bargain contributed by increasing technical collaborations and a recent spate of mergers and acquisitions. This changing landscape poses intricate questions about the sustained growth and future of domestic generic industry- quintessential to ensure self-reliance in matters of health care and to ensure price competition.

Figure 2.1



Source: compiled from Chaudhuri, 2005 and CMIE prowess database

2.3 The Current Structure of the Pharmaceutical Industry in India

2.3.1 The pharmaceutical industry in India stands 4th in terms of volume and 13th in value terms across the world (Report of the Taskforce, 2008). A more authentic account from the Department of pharmaceuticals, Ministry of chemicals and fertilizers states that the Indian pharmaceutical industry ranks 3rd in terms of volume- i.e. 10% of global shares

(Department of Pharmaceuticals, 2009).[32] The Indian Pharmaceutical Industry is also among top five producers of bulk drugs. Firms can be either in production of bulk drugs or formulations or may manufacture both. Firms in to formulations may be further classified into innovating firms and non-innovating firms. However, R&D is insignificant when compared to global R&D by MNEs (as discussed latter). India accounted for 8 percent of global production and 2 percent of world markets in pharmaceuticals. Major part of the domestic pharmaceutical drug requirements are met by the domestic industry. In the segment of Active Pharmaceutical Ingredients (APIs) India ranks third in the world producing about 500 different APIs (Report of the Taskforce, 2008). After USA which has 169 ANDA approval (needed for marketing generic drugs in the US), India had the highest number of 132 approvals US in the year 2007. Table 2.2 presents a self-explanatory table highlighting the key trends of the pharmaceutical industry in India.

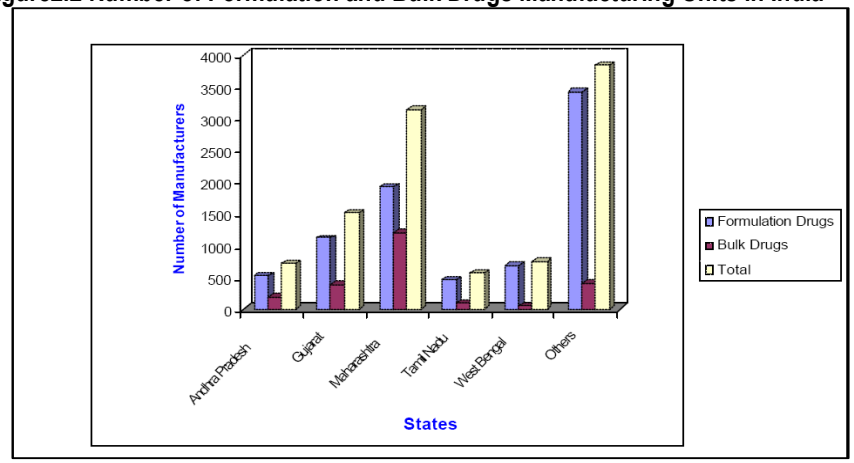
Table 2.2 key trends of the pharmaceutical industry in India

Year	1965-66	1980-81	1994-95	1997-98	2001-02	2002-03	2005-06
Capital Investment	140	500	1200	1840	2150	2500	3200
Production Formulation	150	1200	7935	12068	13878	15960	18750
Bulk Drugs	18	240	1518	2623	3148	3777	5113
Import	8	113		2868	3128	3441	4267
Export	3	46	2184	5353	5959	6631	7980
R&D Expenditure	3	15	140	220	260	320	560

Source: CMIE compilation; Moutushi Hati 2007

2.3.2 There are about 8174 bulk drug manufacturing units and 2389 formulations units spread across India. Total: 10563 units. Large numbers of firms are concentrated in the states of Maharashtra and Gujarat. Figure 2.2 and table 2.3 depict the geographical distribution of both bulk drugs and formulation units in the Indian pharmaceutical industry and the percent concentration of pharmaceutical industry on state wide basis.

Figure2.2 Number of Formulation and Bulk Drugs Manufacturing Units in India



Source: NPPA, 2007

[32] However, the Indian Drug Manufacturers Association provides different data. IDMA in its 47th Annual publication of 2009 states that India ranks 2nd in terms of volume (IDMA, 2009). India accounts for around 8% of world's production by volume and 1.5% by value (IDMA, 2009)

Table 2.3 State-wise number of manufacturers of pharmaceutical units in India

S.N	State	Number of Manufacturing Units			% Share	Cumulative % Share
		Formulation	Bulk Drugs	Total		
1	Maharashtra	1928	1211	3139	29.7	29.7
2	Gujarat	1129	397	1526	14.4	44.2
3	West Bengal	694	62	756	7.2	51.3
4	Andhra Pradesh	528	199	727	6.9	58.2
5	Tamil Nadu	472	98	570	5.4	63.6
6	Others	3423	422	3845	36.4	100.0
	Total	8174	2389	10563	100.0	

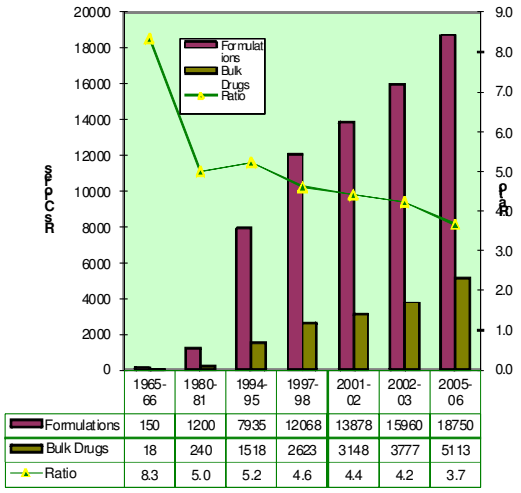
Note: States have been arranged in descending order of number of manufacturing units.

Source: NPPA, 2007

2.3.3 As noted above the production and manufacturing of bulk drug and formulation has increased manifold. As of 2005-06 the ratio of bulk drugs to formulations stood at 3.7%. Figure 2.3 provides a brief overview of production of both bulk drugs and formulations since 1965 to 2006.

Figure 2.3

Production of Indian Pharmceutical Industry and their ratio



	1965-66	1980-81	1994-95	1997-98	2001-02	2002-03	2005-06
Formulations	150	1200	7935	12068	13878	15960	18750
Bulk Drugs	18	240	1518	2623	3148	3777	5113
Ratio	8.3	5.0	5.2	4.6	4.4	4.2	3.7

Source: Moutushi Hati, 2007

2.3.4 The pharmaceutical industry also comprises of biotechnology firms which is a promising sector. Popularly called as the bio-pharma industry, it is noted by commentators that in India it can be said to be evolving as compared to the pharmaceutical industry as a whole. The estimated market size was pegged at US$120 million in 2003, compared with US$3.5 billion in domestic pharmaceutical sales (N. Lalitha, 2008). Although more than 50 per cent of the 170 biotech companies in India are agricultural based, the rest being split among health care and environmental companies, the bio-pharma industry owes 76% market segmentation within the biotechnology firms. The number of players involved in bio-pharma may be pegged at around 3 per cent of the total number of players operating in the pharmaceutical sector in India. Table 2.4 provides details of India's domestic bio-tech market segmentation. Among the top 20 biotechnology companies, at least 13 are bio-pharmaceutical companies. This suggests the opportunity waiting in the bio-pharma sector (Mueller, 2008).

Table 2.4: India's domestic Bio-technology market segmentation (2006-07)

Sl.no	Market segments	Figures in US$ Mn (%)
1	Bio pharmaceuticals	76
2	Bio agriculture	8.4
3	Bio services	7.7
4	Industrial products	5.5
5	Bio-informatics	2.5

Source: pharmexcil

2.4 Exports, Imports and the Balance of Trade

2.4.1 The Indian pharmaceutical industry is also a major exporter. As noted above, the growth since 1990's has been export led. As of March 2008, the export of formulations was calculated at Rs. 16,647.36 crores and bulk drugs at Rs 13,299.33 crores. The trend highlights that there has been almost an Rs 200-500 crores increase in export worth every year. 80% of domestic production consists of formulations and 85% are sold in domestic market. However, 60% of bulk drug production is exported (IDMA, 2009). Table 2.5 provides trends in exports of not just the modern pharmaceutical industry but also traditional medicines and indigenous systems practiced in India. A significant portion of the 200 countries that Indian pharmaceutical industry exports are targeted at are in the advanced regulated markets of US and western Europe (Department of Pharmaceuticals, 2009)

Table 2.5: India's Export of Bulk Drugs, Formulations, Ayurvedic, Unani, Homeo and Herbal Products.

(fig. Rs.Crores)

Commodity Name	Mar-03	Mar-04	Mar-05	Mar-06	Mar-07	Mar-08
Exports of Formulations	5,952.93	7,481.45	9,066.94	10,829.55	14,382.55	16,647.36
Exports of Basic Drugs, Fine Chemicals & Intermediates	2,493.36	7,207.79	8,091.69	10,740.51	11,868.29	13,299.33
Exports of Herbals	390.79	318.44	293.63	307.48	377.02	470.73
Medicants & Medicaments of Ayurvedic System	743.88	192.75	399.82	233.07	259.54	321.44
Medicants & Medicaments of Homeopathic System	8.19	10.30	2.11	1.87	2.74	3.05
Medicants & Medicaments of Unani System	0.00	2.08	1.89	1.13	0.70	1.13
Medicants & Medicaments of Siddha System	0.00	0.42	0.47	0.30	0.02	0.42

Source: DGCI&S

2.4.2 In terms of balance of trade (Exports-imports), while it was negative in 1990 to 1999-2000, the years 2000-2004 saw a reverse trend. But this trend has again been reversed, and the balance of trade during the year 2006-07 US$ 239.8 Million. Table 2.6 highlights the key trends in balance of trade in pharmaceuticals. Again, the share in world exports of Indian pharmaceutical products has increased from 0.87% in 1996 to 1.16% in 2006 (Report of the Taskforce, 2008). In terms of contribution to national economy, out of total exports by the pharmaceutical industry, around 3.56% was the industry's contribution to total exports.

Table 2.6 Exports and Imports of Drugs and Pharmaceuticals (1995-96 to 2006-07 in $ million)

Year	Export	Import	Balance of Trade
1995 – 96	911.6	1489.2	- 577.6
1996 – 97	1055.9	1493.2	- 437.3
1997 – 98	1207.3	1500.1	- 292.8
1998 – 99	1133.1	1166.1	- 33.0
1999 – 00	1343.4	1398.7	- 55.4
2000 – 01	1614.0	1338.2	275.8
2001 – 02	1733.3	1544.2	189.2
2002 – 03	2226.3	1906.3	320.1
2003 – 04	2324.8	2171.1	153.6
2004 – 05	2767.5	3034.6	- 267.1
2005 – 06	3250.8	3746.5	- 495.8
2006 – 07	4076.3	4516.1	-439.8

Source: *India Trade, CMIE* (**Joseph, 2008)**

2.4.3 The India's exports of pharmaceutical products registered a growth of 30.7%, reaching Rs 31,607.84 crore, in the first ten months of the financial year 2008-09, according to latest figures available from the Pharmaceuticals Export Promotion Council (Pharmexcil, Ministry of Commerce 2009). Indian pharmaceutical exports has increased from the said figure in the first 10 months of financial year 2008-09 from Rs 24,175.9 crore for the same period during previous year. The exports to United States (US) reached US$ 6.99 billion compared to US$ 6.08 billion during the same period in 2007-08. The growth of exports to US is 16.4 per cent, reveals the study. The highest growth in the 10 months exports was in December 2008 as compared to the same period of the previous year. The exports went up to Rs 4,934.43 crore in December 2008 which is 78.3 per cent higher than the Rs 2,766.78 crore recorded in the same month in 2007. The increase in exports was also high in November 2008, as it has recorded a Rs 2,988.72 crore with 34.1 per cent increase when compared to the exports in November 2007 (Rs 2,228.86 crore). However, the exports in January 2009 experienced a meagre 11.5 percent reaching Rs 2,916.99 crore when compared to Rs 2,616.72 crore in January 2008. The exports to US also found a decline of 10.1 per cent in January in US dollar terms- the reason being lower health spending in the US. During the periods of financial crisis news reports suggested that the Indian pharmaceutical exports are feeling the heat of the economic turmoil across the developed world (Mint, April 2009).

2.5 Market Shares and Net-worth of leading firms

2.5.1 Indian pharmaceutical firms (except Ranbaxy on account of its acquisition by Daichi Inc.) have shown increasing growth in total sales net worth (Dhar and Gopakumar, 2006). The top 250 firms among in the Indian pharmaceutical industry hold a market share of 70%. Among Indian firms, Cipla is leading with a sales turnover of Rs 5297 crore. Table 2.7 provides the total sales net worth of leading Indian pharmaceutical firms. At present there are 18 pharmaceutical MNCs operating in India, mainly through their subsidiaries. These are also listed on the Indian stock exchanges. This includes Ranbaxy Laboratories (subsidiary of Daiichi Sankyo of Japan with effect from November 2008), Matrix Laboratories (a subsidiary of Mylan Inc. from January 2007), and Fresenius Kabi Oncology (which acquired major stake during August 2008 of Dabur Pharma). Daiichi is holding over 65 per cent in Ranbaxy, Mylan is holding 71.16 per cent in Matrix and Fresenius over 91 per cent in Fresenius-Kabi Oncology Ltd. After the Daiichi take over, Ranbaxy is among the leading foreign firms in terms of sales, followed by others. Table 2.8 provides a list of sales turnover of all foreign companies and their subsidiaries in India last 7 years. There is vast difference among top three firms, which may be to the extent 1/5th among top 10 firms.

Table 2.7 Sales Turn Over of selected Indian Companies

Company	ownership	2003	2004	2005	2006	20007	2008	2009
Cipla Ltd.	CIPLA Group	1572.98	2055.66	2401.17	3103.81	3657.95	4295.24	5297.35
Dr. Reddy's Laboratories Ltd.	Dr. Reddy's Group	1607	1755.15	1637.95	2154.18	4196.69	3615.4	4531.5
Lupin Ltd.	Lupin Group	1008.49	1197.3	1218.58	1717.43	2051.7	2661.62	2993.85
Aurobindo Pharma Ltd.	Aurobindo Pharma Group	1192.74	1341.37	1161.83	1475.73	1991.03	2409.28	2885.25
Piramal Healthcare Ltd.	Piramal Ajay Group	1153.92	1444.51	1309.61	1508.46	1708.79	2001.32	2387.06
Sun Pharmaceutical Inds. Ltd.	Sun Pharmaceutical Group	789.83	892.89	1044.37	1353.02	1722.13	2427.35	2833.65
Cadila Healthcare Ltd.	Zydus Cadila Group	986	1136.9	1152	1339	1538.4	1758.5	1781.7
Wockhardt Ltd.	Wockhardt Group	741.64	767.08	881.55	928.36	1078.72	1146.3	1453.13
Orchid Chemicals & Pharmaceuticals Ltd.	Private (Indian)	542.76	713.4	689.3	883.18	934.19	1250.19	1203.22
Ipca Laboratories Ltd.	Ipca Laboratories Group	519.38	661.31	733.67	820.42	988.64	1119.96	1339.93
Alembic Ltd.	Alembic Group	566.98	614.7	572.98	666.45	722.58	1027.35	1120.49
Torrent Pharmaceuticals Ltd.	Torrent Group	409.48	490.49	540.34	744.33	895.17	1001.9	1188.72
Glenmark Pharmaceuticals Ltd.	Glenmark Pharmaceuticals Group	333.65	381.42	538.13	620.83	838.76	1408.71	873.79
Biocon Ltd.	Private (Indian)	276.98	535.94	688.43	725.75	888.77	905.07	938.8
Intas Pharmaceuticals Ltd.	Private (Indian)	293.24	381.14	458.66	624.02	782.29	973.85	1166.46
Divi'S Laboratories Ltd.	Private (Indian)	260.27	320.31	368.22	394.21	740.41	1047.55	1203.82
U S V Ltd.	Private (Indian)	403.94	561.45	513.71	581.62	659.24	700.55	851.86

*please note that Domestic formulation business of Piramal health care has been taken over by Abbot.

Source: CMIE, Prowess

Table 2.8: Sales Turnover of Selected Foreign Companies Operating in India

Name of the company	ownership	2003	2004	2005	2006	2007	2008	2009
Ranbaxy Laboratories Ltd.	Daiichi (F) Sankyo Group	3131.76	3888.98	3865.87	3284.03	3599.15	3656.2	3932.23
Glaxo smith kline Pharmaceuticals Ltd.	Glaxo (F) Group	1167.89	1209.5	1490.89	1593.86	1710.82	1761.39	1796.22
Aventis Pharma Ltd.	Aventis (F) Group	669.14	709.68	793.56	868.47	951.81	961.13	1070.38
Matrix Laboratories Ltd.	Private (Foreign)	416.93	557.41	664.23	788.48	775.43	974.27	1504.41
Pfizer Ltd.	Private (Foreign)	696.74	588.4	684.83	724.15	791.98	794.27	786.73
Novartis India Ltd.	Private (Foreign)	488.29	523.1	490.09	543.75	563.9	578.67	617.88
Abbott India Ltd.	Private (Foreign)	425.58	446.78	474.01	471.69	542.62	639.27	707.28
Merck Ltd.	Private (Foreign)	385.56	404.06	418.39	438.09	371.66	357.65	424.69
Strides Arcolab Ltd.	Private (Foreign)	NA	275.91	305.93	331.25	455.41	415.45	616.86
Wyeth Ltd.	Wyeth (F) Group	335.77	351.88	289.92	315.74	318.62	361.89	402.19
Astrazeneca Pharma India Ltd.	Private (Foreign)	153.2	196.11	210.89	246.42	293.68	330.51	374.34
Fresenius Kabi Oncology Ltd.	Private (Foreign)	NA	215.45	235.76	270.44	312.7	250.3	274.09
Organon (India) Ltd.	Private (Foreign)	188.87	180.99	160.66	190.97	203.67	163.16	166.9
Fulford (India) Ltd.	Private (Foreign)	94.7	130.51	131.79	151.97	155.04	174.38	190.44
Solvay Pharma India Ltd.	Private (Foreign)	68.61	106.94	127.73	141.91	157.49	183.18	212.88
Biddle Sawyer Ltd.	Glaxo (F) Group	36.72	36.49	35.19	34.58	32.47	35.25	35.44
Bayer Polychem (India) Ltd.	Private (Foreign)	NA	23.41	96.29	12.02	12.82	47.21	NA
Global Remedies Ltd. [Merged]	Private (Foreign)	NA	2.88	NA	4.34	7.41	7.23	5.42

Source: CMIE, Prowess, Database

2.5.2 In terms of profitability, the average stood at around 14.5% in the Indian pharmaceutical industry (foreign and multinational). Top firms share a ratio to sales at around 15-60%. Table 2.9 provides details on the profitability ratio of top firms as of 2008. The table reveals that on an average firms in the pharmaceutical industry are quite profit oriented. This can also be seen by comparing this sector with average profitability ratio in some other industries. When compared to Chemicals, food& Beverages, machinery, textiles, transport and equipments, the average profits accruing to the pharmaceutical industry are more than double in the recent years (Dhar and Gopakumar, 2006). Table 2.10 provides such a comparison.

Table 2.9 Profitability of Pharmaceutical firms stood at 14.5% in 2007-08 (MNCs and Indian)

Company Name	Owner	Sales (Rs. Crore)	Profit after Tax (Sales Rs. Crore)	Profit after tax (% of Sales)
Fresenius Kabi Oncology	Dabur Group	250.29	149.34	59.7
Biocon Ltd.	Private (Indian)	905.07	434.92	48.1
Pfizer Ltd.	Private	794.27	338.93	42.7
Sun Pharmaceutical Inds.	Sun	2427.35	1014.04	41.8
Biddle Sawyer Ltd.	Glaxo (F) Group	35.25	14.1	40.0
Divi'S Laboratories Ltd.	Private (Indian)	1047.56	353.56	33.8
Glaxosmithkline	Glaxo (F) Group	1761.39	537.65	30.5
Plethico Pharmaceuticals	Private (Indian)	555.14	158.34	28.5
Glenmark	Glenmark	1408.71	389.02	27.6
Global Remedies Ltd.	Private	7.2	1.82	25.3
Wyeth Ltd.	Wyeth (F)	361.89	81.48	22.5
U S V Ltd.	Private (Indian)	700.86	153.39	21.9
Merck Ltd.	Private	357.65	68.82	19.2
Astrazeneca Pharma	Private	330.51	61.46	18.6
Wockhardt Ltd.	Wockhardt	1188.95	213.88	18.0
Ranbaxy Laboratories	Ranbaxy-	3656.2	617.72	16.9
Natco Pharma Ltd.	Natco Pharma	237.89	40.05	16.8
Novartis India Ltd.	Private	578.67	97.23	16.8
Lupin Ltd.	Lupin Group	2661.62	443.38	16.7
Cipla Ltd.	CIPLA Group	4295.24	701.43	16.3
Dishman	Private (Indian)	367.45	59.56	16.2
Panacea Biotec Ltd.	Panacea Biotec	837	133.17	15.9

Source: CMIE, Prowess Database

Table 2.10 :Profitability of some of the major sectors in Indian Industry

Sectors	Dec-95	Dec-97	Dec-99	Dec-00	Dec-01	Dec-02	Dec-03	Dec-04
chemicals	5.8	4.8	4.8	4.2	3.5	4.4	5.8	6.3
Food & beverages	4.8	4.1	4.9	4.8	5.1	4.2	3.6	5.2
machinery	5.5	3.7	3.5	2.6	1.5	2.7	1.7	3.1
Textiles	5.6	0.6	-1.9	-1.0	-2.4	-2.9	0.9	-0.4
Transport equipment	5.8	7.3	3.1	3.3	1.0	3.3	5.0	6.3
Drugs and pharmaceuticals	8.8	7.5	6.6	7.5	10.0	12.4	11.3	13.4

Source: Dhar and Gopakumar (2006)

2.6 Inward and outward Foreign Direct Investment in India:

2.6.1 Post reforms foreign direct investments in the Indian pharmaceutical sector have seen an increasing pattern. Trends show that such a steady pattern. However, the data is not further segregated to know the qualitative investments that have accrued during the said years. Table 2.11 provides a detailed over view of FDI inflow in the pharmaceutical sector. Sector wise FDI inflows calculated for the period during 1991 and December 2006 suggest a FDI inflow of Rs 50,262 Million, amounting to 2.83% of the total FDI inflows (DIPP- Ministry of Commerce, 2007).

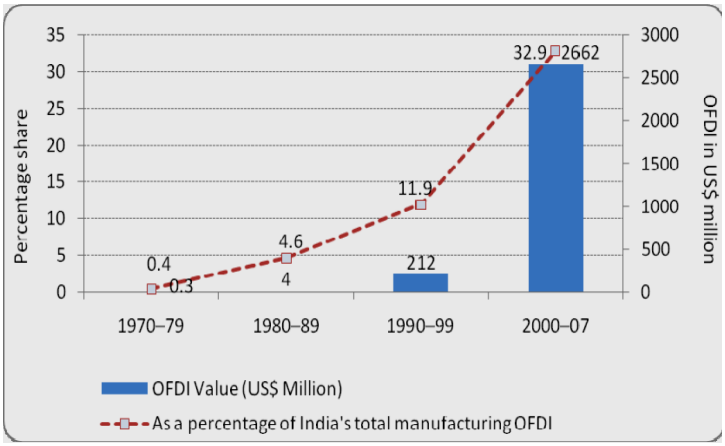
Table 2.11Approved FDI Inflows during 2000-2005

Periods / Year	FDI Inflows (US $ million)		Pharmaceuticals as % share of all sectors
	Drugs & Pharmaceuticals	All Sectors	
1991 – 1999 (Aug – Dec)	210	49836	0.42
2000 (Jan – Dec)	48	2851	1.68
2001 (Jan – Dec)	89	3673	2.43
2002 (Jan – Dec)	53	3815	1.38
2003 (Jan – Dec)	58	2401	2.40
2004 (Jan – Dec)	342	3758	9.10
2005 (Jan – Dec)	114	4295	2.65

Source: Pradhan and Alakshendra, 2006/07 (DIPP- GOI)

2.6.2 One interesting pattern that the Indian industry set was due to overseas acquisitions. Commentators have remarked that outward FDI is the new survival strategy due to the new policy regime in place post the TRIPS Agreement. Commentators believe that with the product patent regime in place, now firms' survival crucially depends on their abilities to develop new products and brand creating exercise (Rajan 2009, Pradhan 2008). According to Rajan the main motivations for overseas acquisitions are resource-seeking, technology and research & development (r&d)-seeking, brand name and expanding product mixes, market-seeking, risk diversification-seeking and efficiency-seeking (Rajan, 2009). Since Indian pharmaceutical firms with their inadequate product development capabilities are clearly at serious risk, an increasing number of Indian pharmaceutical firms are observed to be using acquisition as a strategy to overcome their limited innovation strength by accessing new products and their technologies, skills and new markets. However, such acquisitions present both challenges and opportunities for the Indian pharmaceutical industry. Figure 2.4 provides a detailed chart of the trends in overseas acquisitions.

Figure 2.4 Trends and Patterns in Outward FDI in the Pharmaceutical Industry



Source: Pradhan, (2008)

2.6.3 The total value of acquisition by Indian firms from the year 2000 up-to March 2008 is calculated at around US $ 2873.9 million. With 43 acquiring firms and a total of 105 deals, there were 28 target countries. Table 2.12 provides details of the same as under.

Table 2.12: Overseas acquisitions by Indian pharmaceutical firms

year	Acquisitions (US$ Mn)	In number		
	value	Acquisition deals	Acquiring Indian firms	Target countries
2000		2	2	2
2001		1	1	1
2002	12.8	6	3	5
2003	114.3	6	6	4
2004	68	10	8	8
2005	472.8	28	16	16
2006	1359	28	20	13
2007	773	19	15	13
2008	74	5	5	5
All years	2873.9	105	43	28

Source: Pradhan, (2008)

2.7 Mergers, Acquisitions and Alliances in the Indian Pharmaceutical Industry :

2.7.1 The pharmaceutical industry is witnessing increasing consolidation, which is likely to continue in the following years. Like the pre-1970 situation, it appears that the multinational drug companies are all set to repeat its success in capturing a larger pie of Indian markets. The past few months in 2009 have seen few public offers for acquisitions. Table 2.13 provides the details of select cases of MNC acquisitions in Indian pharmaceutical industry. Experts believe that a crash in the stock market over the last one year has helped the MNCs to increase their acquisition activities. In the recent past there has been an increase in number of public offers by the MNCs like Abbott India, Novartis India and Pfizer Ltd to raise their equity stakes (Mint, April 2009). For e.g. It is reported that Pfizer Inc, a US top pharma giant, has decided to raise its equity stake in its Indian arms from present 41.23 per cent to 75%. This may work to an investment of Rs 680 crore for Pfizer. Again, Novartis AG is planning to acquire an additional stake of up to 39 per cent in its majority owned Indian subsidiary Novartis India Ltd. At present it has a controlling stake of 50.9 per cent in its Indian arm. It is expected that this will increase the stake to over 90 per cent with investment of Rs 440 crore. Last year, during September 2008, Abbott India completed its buy-back offer. With this offer, the promoters have increased their stake from 65.14 per cent to 68.94 per cent. One of the major reasons that are identified by industry experts are the current economic crises. Again, in January 2009, Merck India expressed that the company is hopeful of signing a couple of acquisition deals later in the year 2009. French multinational Sanofi-Aventis' has also expressed that the company is looking towards consolidation opportunities in India (Mint, 2009). If news reports have to be relied upon, at least seven out of 10 foreign drug makers that have revenue of less than Rs 500 crores each will find this number rising to around Rs1,000 crore plus (Mint, 2009).

Table 2.13: select cases of MNC Acquisitions in Indian pharmaceutical sector

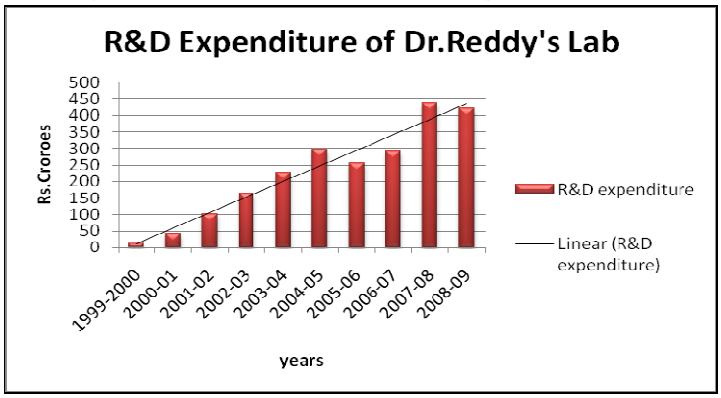
Target company	Acquirer	Country of origin	year	Amount (USD)
Matrix lab	Mylan Inc	US	August 2006	$736 million
Dabur Pharma	Fresenius Kabi	Singapore	April 20, 2008	$219 million
Ranbaxy Laboratories Limited	Daiichi Sankyo	Japan	June 11, 2008	$4.6 billion
Shantha Biotech	Sanofi Aventis	France	July 27, 2009	$783 million
Orchid Chemicals (injectible business)	Hospira	US	December 16, 2009	$400 million
Piramal Healthcare (domestic formulation)	Abbott Laboratories	US	21 May 2010	$ 3.72 billion

Source: compiled from various news reports.

2.7.2 In a recent move, global pharma major, GlaxoSmithKline has signed an agreement with Dr. Reddy's to develop and market selected products across an extensive number of emerging markets, excluding India. While the full terms of agreement are not clear, news reports suggest that GSK will gain exclusive access to Dr. Reddy's diverse portfolio and future pipeline of more than 100 off-patented, branded pharmaceuticals. These products and pipeline falls under the fast growing therapeutic segments such as cardiovascular, diabetes, oncology, gastroenterology and pain management. Under the terms of the agreement, revenues will be reported by GSK and shared with Dr. Reddy's as per the agreed terms. The products will be manufactured by Dr. Reddy's and licensed and supplied by GSK in various countries in Africa, the Middle East, Asia Pacific and Latin America. In certain markets, products will be co-marketed by GSK and Dr. Reddy's (Mint, 2009). However, Dr. Reddy's one of the major Indian firm investing in R&D surprised everyone when it decided to burry its prolific 15 old R&D model. 15 years ago Dr. Reddy's under the guidance of K. Anji Reddy (founder chairman) was a scientist whose visionary thoughts led to the experimentation of high risk and high capital intensive model of drug discovery among Indian generic firms. It is well acknowledged that any in new drug discovery, more molecules fail than succeed, and costs run into millions of dollars. Dr. Reddy's built well-equipped labs, and put together a team of highly paid Indian scientists. It also

created the Atlanta lab to research novel targets, but Dr. Reddy's continued focus on generics to capture the lucrative market did reportedly put it on the R&D back front. Two major reasons have been manifested for Dr Reddy change in R&D strategy- first, R&D is a high risk business and without appropriate human resource and investor confidence- this was very clear from investor concerns expressed in Dr. Reddy's case. Second, it is reported that Dr. Reddy's has it intends to save $10-15 million in fiscal 2011 from the revamp. Figure 2.5 shows the growth of R&D investments of Dr. Reddy over a period of time. In 2008-09, Dr. Reddy's spent Rs 409 crores on R&D (including on generics), up 18 per cent over the previous year, however, the future investment after the GSK tie-up is uncertain (Kamath, G, 2008).

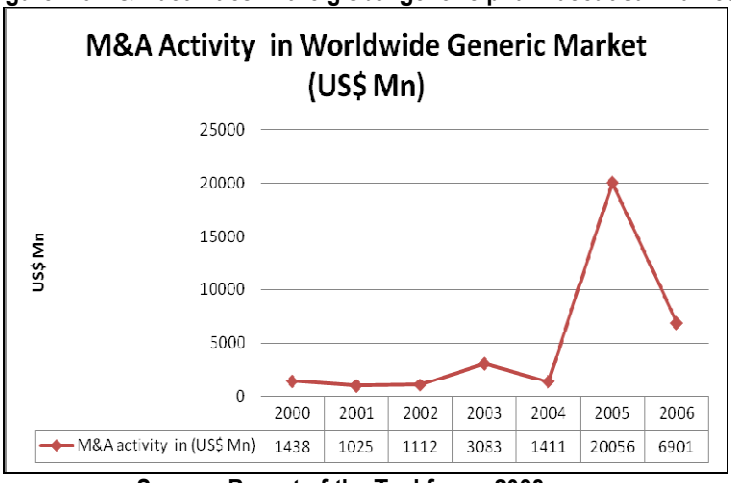
Figure 2.5 R&D expenditure of Dr.Reddy's Lab



Source : CMIE, Prowess database

2.7.3 Mergers and acquisitions in the past show some interesting trends and incisiveness. However, only few commentators have collected exhaustive data and analyzed the trends and patterns. These patterns in fact correspond to global pattern in consolidation of generic firms through Mergers and Acquisitions (M&A). The following graph (figure 2.6) provides the trends in global M&A activities. However, these trends do not relate to consolidation in R&D based companies worldwide. It may be noted that during the period 2000-2006, the global generic industry witnessed around US$ 35000 Million of M&A value, suggesting increasing trends in consolidation not just in research based pharmaceutical industry but in the generic industry.

Figure 2.6 M&A activities in the global generic pharmaceutical markets



Source: Report of the Taskforce, 2008

2.7.4 Data on M&A is very limited. However, some studies can provide anecdotal evidence of M&A activities and behavioural patterns during pre merger and post merger period. Post liberalization and until 2005, there were around 64 mergers and 63 acquisitions in the pharmaceutical industry (Beena, 2006). The study shows a

domination of domestic firms over foreign firms in case of mergers. It is noted that out of the total 32 merging firms, 20 belonged to the domestic sector and in the case of merged firms; it is 38 and 20 respectively. Domestic firms are merging with the domestic firms, which constituted 64 percent of the total number of mergers and many foreign subsidiaries merged with other foreign subsidiaries, which constitute 26 percent of the total number of mergers. Table 2.14 provides details of the size-wise classification of mergers.

Table 2.14: Size-wise Classification of Mergers

Size	Merging		Merged	
	No.	Percent	No.	Percent
Large (> 1000 Million)	28	59.57	1	3.57
Medium (10-1000 Million)	18	38.3	27	96.43
Small (< 10 Million)	1	2.13	0	0
Total available	**47**	**100**	**28**	**100**

Source: Beena 2006

2.7.5 The study also noted that almost all the merged firms were medium sized, i.e. 27 out of the 28 firms come under medium sized category. Medium sized firms were getting merged with large sized firms. About 64 percent of the mergers came under this category (Beena, 2006). Commentators note that the preference for medium sized firms by the large sized merging firms may be due to several reasons such as the ownership of well-known brands in some therapeutic markets, well established marketing networks and their market share-even though they are not the market leaders. The study also noted that most of the mergers in the pharmaceutical industry were horizontal type. Table 2.15 provides the details of the type of mergers in the Indian industry.

Table: 2.15
Types of Mergers in the Indian Pharmaceutical Industry

Type	Number	Percent
horizontal	52	82.25
vertical	9	14.75
Total available	**61**	**100**

Source: Beena, 2006

2.7.6 There are high instances of cross-border acquisitions, and unlike in case of mergers they are acquisitions by foreign companies. Large number of acquisitions occurred among the foreign owned firms. It is noted that foreign firms are increasingly willing to raise their stakes in the Indian subsidiary. The reasons being a favourable investment policy of the government and a conducive patent law regime for marketing new technology products (Mint, 2009). These acquisitions have occurred where firms already had some managerial tie-ups (Beena, 2006).

2.7.7 The study also notes certain examples of firms that had such managerial tie-ups and subsequent acquisitions that occurred. They are: Solvay Healthcare acquired 44.52 per cent of equities in Solvay Pharmaceutical India; the promoters of Syncom Formulations India have acquired 5.22 per cent of equities, Abbott Laboratory, USA acquired 51 per cent of equity holdings in Abbott Laboratory India Ltd. etc. In many cases, firms have acquired a small portion of the assets and later on opted for merging with the same firms. Some of such cases are the mergers of Boehringer Mannheim with Nicholas Piramal India Ltd. (NPIL), Roche Products with NPIL, Sumitra Pharmaceuticals with NPIL, MJ Pharmaceuticals with Sun Pharmaceuticals, Vorin Laboratory with Ranbaxy Laboratory, Rhone Poulance with NPIL, Matrix Laboratory with Ranbaxy Laboratory etc (Beena, 2006). Table 2.16 provides a detailed list of acquisitions among categories of firms.

Table: 2.16 Acquisitions in the Pharmaceutical Industry

category	ownership	No.	percent
I	Domestic-Domestic	17	32.08
II	Foreign-Foreign	21	39.32
III	Foreign--Domestic	6	11.32
IV	Domestic -Foreign	8	15.09
V	Foreign-Domestic foreign	1	1.9
VI	Total available	53	100

Source: Beena, 2006

2.7.8 There were also alliances within the pharmaceutical industry during this period. Most alliances were on account of marketing motives. It is noted that 34 out of the 62 alliances, which accounts for 55 percent of the total number of alliances were exclusively for marketing purpose (Beena, 2006). They study notes that marketing and manufacturing including contract manufacturing. Marketing and others includes technology, capital utilization, market entry, Research and Development and availing raw materials etc. Table 2.17 provides details of motivations for building firm-firm alliances.

Table 2.17 Motives for alliances

Motive	No.	Percent
Marketing	34	54.84
Marketing and manufacturing	13	20.97
Marketing and others	7	11.29
R&D and Technology	4	6.45
Not specified	4	6.45
total	62	100

Sou**rce: Beena, 2006**

2.7.9 It may be noted that motives for joint R&D and technology for alliances constitutes only 6.45%. This has much to state about the quality of such an alliance, which at times may not be at advantage from a broader industry perspective. According to the above given data it is the marketing activities, which constitutes the chunk of possible motives not high-end use of technology and human resource. Thus such alliance may not be useful from the point of technology spillovers that accrue through such alliances.

2.7.10 The performance of merged firms' pre and post merger provides some interesting trends. As a natural consequence of mergers, there is bound to be an increase in scale and scope of enterprise activities and reducing costs of the firms merged. However, it also leads to more market concentration and can be a cause for higher pricing. No such perforce-price studies have been conducted in India to the knowledge of the authors revealing the effects of mergers and acquisitions in India. Indeed, a price based evaluation would be difficult to assess mergers/acquisitions. However, using certain performance indicators, commentators have noted that overall performance has increased among the merged firm (Beena, 2006). But such data does not explain the impact of such mergers on the market and implications for consumer welfare. Table 2.18 provides the pre and post-merger performance based on 11 indicators.

Table: 2.18: Performance Indicators of Firms Pre and Post Merger

Performance indicators	Period (average values)		Change
	Pre-merger	Post-merger	
Gross profit margin	13.97	18.22	Increased
Net profit margin	7.11	11.42	Increased
Return on capital employed	15.79	18.08	Increased
R&D intensity	1.47	2.3	Increased
Advertisement intensity	1.11	1.29	Increased
Marketing intensity	3.39	3.7	Increased
Cost intensity	95.35	92.48	improved
Export intensity	11.66	23.15	Increased
Import intensity	12.84	17.14	Increased
Capacity utilization	98.09	82.57	Decreased

Source: Beena, 2006

2.7.11 It must be noted that all indicators except capacity utilization show a positive trend. However, contrary to results of other studies concerning performance of firms during the pre-merger and the post merger period in other sectors which came to a conclusion that profitability of such firms declined during post merger period, the data above shows that profitability of the firms during the post merger period has increased. Thus points out to the unique price setting strategies in the context of the pharmaceutical industry. Data on product diversification in the pharmaceutical industry post mergers shows that number of products in different therapeutic categories have generally increased. But the data does not show the trends in pricing and marketing strategies adopted by such firms after mergers. Table 2.19 briefly analyses the change in product diversification among the merged firms.

Table: 2.19 Product diversification of merging firms (1990-2005)

Firm	Number of therapeutic categories		Change (No)
	1990	2005	
Aventis	8	12	4
Cadila	14	10	-4
Glaxo Smith Kline	9	15	6
Lupin	6	9	3
Nicholas Piramal	9	12	3
Novartis	10	12	2
Pfizer	7	13	6
Ranbaxy	9	9	0
Sun pharma	5	8	3
Torrent	11	10	-1
TTK pharma	2	3	1
Unichem	8	9	1
Wyeth	9	12	3

Source: Beena, 2006

2.7.12 One of the most interest and closely watched acquisition deal in the recent is Daiichi's acquisition of Ranbaxy Inc., in 2008. Japan's Daiichi Sankyo Co. acquired Ranbaxy Laboratories Ltd., which was India's largest pharmaceutical company, in November 2008. The deal created a lot of concerns among experts and popular media. Some regarded the deal as a consequence of Ranbaxy failing in its vision to remain as a competitive generic company. While others appreciated that deal and opined that it would create more efficiency among the merged firms. Daiichi Sankyo Co. agreed to pay more than $4 billion for a controlling stake in Ranbaxy in June, and the transfer of

63.92% of Ranbaxy's equity shares to Daiichi. The **Box** below provides incisive details about the Daiichi-Ranbaxy acquisition and discusses some issues concerning the deal and its implications for competitiveness of the pharmaceutical industry in India.

Daiichi-Ranbaxy Acquisition Deal

Ranbaxy was formed as joint venture with a European Pharmaceutical company in 1961. It was bought over in 1966 by Bhai Mohan Singh. Till 90s the company mainly concentrated on reverse-engineering for its growth. The success of the company as a major generic player in the world market is reflective of the policies adopted post-1970 by the Indian government. With the opening up of the Indian economy and changing patent law landscape, including other business factors forced the company to have a re-look at its strategies. The company then started aggressively looking out for tie-ups/joint ventures with foreign pharmaceutical companies and also to take over some good Indian companies in the same line of business. The company has entered into licensing arrangements with international companies for marketing their patented drugs in the country. Ranbaxy Laboratories is one of the top leading pharmaceutical companies in the country. Almost half of its revenues come from antibiotics and antibacterial products. However, of late, the company is slowly shifting its focus to cardio-vascular and anxiety-related drugs (Life style drugs). The company has been focusing more on international markets, new tie-up, new products and R&D activity. Currently it holds 6 US patents and 79 pending applications. Expenditure on R&D in (Rs. Mln) as of December 2008 stood at Capital: 558 and Revenue 4155.46 (Annual Report 2009). The company posted a profit of 5,713.3 in December 2008, when compared to 9865.6 posted in December 2007. Ranbaxy has come under close scanner of the US FDA which banned many of its products due to non-compliance of standards. However, similar investigations in other countries found no such violations.

In November 2008, Daiichi Sankyo of Japan acquired Ranbaxy Laboratories at US $4 billion for a controlling stake of 63.92% of Ranbaxy's equity shares (position as of December, 2008). Daiichi paid Rs737 ($15.42) per share. Pursuant to the change in the ownership of the Company, the Board of Directors of the Company was re-constituted on December 19, 2008 (Annual Report 2009). As per the Company's 2009 annual report *"…[t]he coming together of Ranbaxy and Daiichi Sankyo is a path-breaking confluence that, in one sweep, catapults the new, empowered entity to the status of the world's 15th largest pharmaceutical Company. Individually, the two pharmaceutical giants are formidable - one, India's largest generics Company and the other, among the largest innovator companies in Japan*". This possible motive for the acquisition seems strategizing market position, combined with strengths of both generic market networks and skills in innovation.

Many dubbed the deal as panic selling by Ranbaxy unable to visualize and strategise its position in the changing market landscape. Others noted that the deal was not about creating synergies but about creating the best out of the then prevailing share prices. However, this deal has raised a lot of questions about future competitiveness of the Indian generic industry in the light of possible change in generic pharma strategy by Daiichi. Some commentators have suggested that Ranbaxy being a firm that immensely benefited out of national policies should not have been allowed to be acquired by a foreign stakeholder (Kumar Nagesh, 2008). Citing regulations for protecting domestic industries by other countries, it is argued that Ranbaxy being a national industry, a law prohibiting such acquisitions is much needed. They remark that considering that India's fledgling technological capabilities are attracting global attention, blocking such deals would be desirable. It is feared that Ranbaxy's case may become a trendsetter for many such future deals. On a broader industrial policy perspective, a couple of deals have the potential to jeopardize the national capability in the industry.

Post acquisition, it has been a rough ride for Ranbaxy. It posted a huge loss in 2009 and ended its financial year with a loss of Rs 915 crore, against a profit of Rs787 crore it posted last year. Ranbaxy Laboratories will launch in India an anti-hypertensive drug, Olvance - the first product from its parent Daiichi Sankyo's portfolio to be introduced through it. It is noted that the launch of Olvance marks the beginning of a "productive engagement" that will harness the respective strengths of Daiichi Sankyo and Ranbaxy to establish a much stronger platform for Ranbaxy in India (Mint. 2009).

2.7.13 Some estimates state that given the current momentum of growth the Indian pharmaceuticals market is estimated to expand to US$ 25 billion by 2010[33] basically emphasizing that mergers and acquisitions are possible at R&D level, manufacturing level and at the marketing level (Shukla 2006). They attribute to the rise in consolidation activities in India primarily due to the new patent law amendments and also because it would be difficult for

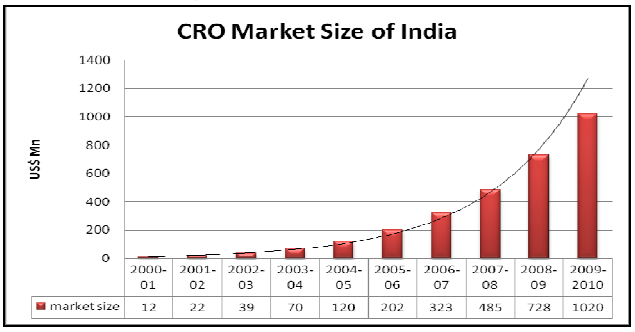
[33] Data is from *Frost and Sullivan* as quoted by Shivani Shukla *Pharmaceuticals Practice, (2006)*

western MNCs to singlehandedly penetrate into Indian markets.[34] Some major motivations for Indian companies to merge that could be identified are:[35] achieving critical mass in production; diversification into new areas; enhance product and IP portfolio; and for increasing market share.

2.7.14 While mergers and acquisition has been the consolidation strategy among pharmaceutical companies, existing innovative generic firms have also resorted to other survival strategies. Many studies have noted that India is emerging as a fastest clinical-trial hub. This has led to the exploration new synergies within the industry and companies are eying a huge market. As per some commentators engaging in clinical trial presents a huge opportunity and can be a good strategy for survival in the post-2005 regime. Contract R&D services like custom synthesis, clinical trials, clinical data management, bioequivalence testing, stability testing, chemistry and biology services presents a good opportunity for Indian companies (Taskforce Report, 2008). Since India has a huge population with a variety of disease syndrome [considered as prime indicator for clinical trials] to participate in clinical trials and the country also has proven capabilities in medical skills, hospital beds and IT capability, it is argued that such an opportunity must be exploited to its advantage. The costs of clinical trials in India are around one-tenth of their levels in the U.S. and it is estimated that there could be investments worth US$300 million in India by 2010. Already major drug producers are already conducting trials in India include Pfizer, estimated to have some 20 ongoing clinical trials; GSK, with seven trials; Eli Lilly, with 17 trials; plus AstraZeneca and Novartis as well as Chiltern. Thus leading contract research organizations (CROs) such as Quintiles, SFBC International and ICON Clinical Research have extensive operations in India. (taskforce report, 2008)

2.7.15 The figure 2.7 gives an idea about the market size of the contract research organisation facilitating clinical trials in India. The estimates show that the market will develop in to an approx. US$1000 Million opportunity by 2010. While there are varying figures of clinical trials being conducted in the country, a few have been mapped by some commentators. Table 2.20 provides a list of clinical trials conducted in India and the research area of such trials up to 2006. A recent note by Department of Pharmaceuticals notes that as on 31 March, 2009, 442 projects were announced in the drugs sector entailing an investment of Rs. 32,718 crores. 258 projects worth approximately Rs.20,011 crores among them were under implementation. While 13 new projects worth Rs.1855 crores were announced during the quarter ending March, 2009, one project was completed and two were shelved during the quarter.

Figure 2.7: CRO market size of India



Source: Report of the Taskforce, 2008.

Table 2.20 List of Clinical-Trials in India including area of Research

Firm	Number of Trials	Areas
Bristol Myers Squibb	20	CVS,CNS, Diabetes, Cancer, Hep B
Eli Lilly	17	Diabetes, Cancer, CNS
Pfizer	14	CVS,CNS, Diabetes
Glaxo SmithKline	12	CNS, Arthritis, Cancer, Visceral Leishmaniasis
Aventis	11	CVS, Cancer, Diabetes, gastroentritis

[34] *Ibid*
[35] *Ibid*

AstraZeneca	9	CVS, CNS, Cancer
Novartis	8	Hypertension, Hepatitis, CVS
Merck	7	Fungal Infection, HIV, Cancer, Diarrhoea
Bayer	5	CVS
Boehringer ingeheim	2	CVS

Source: Jha, 2007

2.7.16 Some commentators have remarked that a "fragmented domestic market marked by a lower degree of domestic competition is not conducive for global competitiveness and hence, policy measures are needed to encourage mergers and acquisitions among domestic firms to offset the scale disadvantage and to overcome the trap of low R&D intensity" (Pradhan, 2006). They argue that increases in average firm size through M&As until the concentration index of the Indian pharmaceutical industry rises significantly, may result in improving India's competitive advantages in the pharmaceutical sector. They also argue for Government policies that encourage overseas acquisitions by the Indian companies for brands, technology and market access can also be important for strengthening firms' technological capabilities and to adhere to the demand for data protection (Pradhan, 2006).

2.8 Innovation, R&D and Patents: Performance of the Indian Pharmaceutical Industry

2.8.1 *"The innovator has for enemies all who have done well under the old law."*[36] It is often argued that innovation capabilities in the Indian pharmaceutical industry are rising at an exponential rate. Increasing R&D expenditures, technology absorption and benefiting from the spillovers have provided some key players in the industry an opportunity to familiarize in the state of with the state of art technology. The percentage spending on R&D has been increasing. However, the R&D intensity when compared to other major global players is very low. Pre 1990s public sector was the major source of R&D investments. In the case of innovation, the contribution of the CDRI, Lucknow and Hindustan Antibiotics has been among the most notable. Table 2.21 provides a detailed overview of key achievements in inventing new products and processes.

Table: 2.21 Major achievements of the Indian Drug Industry in developing new drugs

S.No	Name of the Drug	Pharmacological Classification	Name of the Discoverer
1	Hamycin	Topical Anti – fungal	M/s Hindustan Antibiotics, Pune.
2	Centimizone	Anti-thyroid	Central Drug Research Institute, Lucknow
3	Enfenamic Acid	Anti-inflammatory Agent	Regional Research Laboratory, Hyderabad.
4	Nitroxazepine Hydrochloride	Anti-depressant	M/s Hindustan Ciba-Geigy, Mumbai.
5za	Azabiperidol	Neuroleptic Agent	M/s Hindustan Ciba–Geigy, Mumbai.
6	Tinazoline	Nasal decongestant	M/s Hindustan Ciba–Geigy, Mumbai.
7	Centbucridine	Local Anaesthetic agent	Central Drug Research Institute, Lucknow
8	Satranidazole	Anti-amoebic	M/s Hindustan Ciba–Geigy, Mumbai.
9	Amoscanate	Anthelminitic	M/s Hindustan Ciba–Geigy, Mumbai.
10	Kyasavur Forest Disease (KFD) Vaccine	Vaccine	Virus Diagnostic Laboratory, Shimoga (Karnataka)
11	Gugulipid	Lipid Lowering Agent	Central Drug Research Institute, Lucknow.
12	Centchroman	Post –Coital Contraceptive	Central Drug Research Institute, Lucknow.
13.	Centpropozon	Anti-depressant	CDRI, Lucknow
14.	Bulaquin	Anti-Malaria	CDRI, Lucknow.

Source: Seventh Report of Standing Committee on Pharmaceuticals 2005 – 06.

2.8.2 Many studies have noted that R&D in the pharmaceutical industry is on the rise. As of 2006 R&D expenditures studies have shown an upsurge in R&D. It stood at 530 crores. However, the R&D expenditure data is not

[36] *Niccolò Machiavelli (1469-1527)*

disaggregated. Hence the exact figures on investments in discovery and research and in clinical trials cannot be obtained. Table 2.22 explains the surge in R&D by Indian companies from 1993 to 2006.

Table: 2.22 R&D Expenditure by Indian Pharmaceutical Industry

year	Major spenders: No of cos	Major spenders: R&D exp as % of sales	Other cos: No of cos	Other cos: R&D exp as % of sales
1992-93	7	1.78	40	0.86
1994-95	14	2.42	64	1.15
1995-96	13	2.98	74	1.42
1996-97	16	2.80	73	1.23
1997-98	15	3.06	66	0.94
1998-99	15	3.10	71	0.86
1999-2000	18	3.17	70	0.94
2000-01	21	3.88	68	1.16
2001-02	24	3.86	74	1.33
2002-03	25	4.72	72	1.18
2003-04	28	5.79	81	1.23
2004-05	28	7.83	73	1.40
2005-06	28	8.79	65	1.20

Source: Sudip Chaudhuri 2007

2.8.3 The percent-age R&D investment to sales varies around 12.69 % to 1.75 %. Ranbaxy Ltd (before Daiichi acquisition) was the largest R&D spender among Indian companies. In 2007, it spend around Rs 462 Crores on R&D. Dr. Reddy labs was the next with R&D at Rs 293 crores amounting to 7.07% of total sales. Thus we may see that there are varying degrees of investments currently ranging in between Rs. 35 crores to 300 crores. Although the % investments may seem higher, it does not connote a higher level of investment in absolute terms. Table 2.23 gives a detailed structure of R&D expenditures to sales in India. Some few MNEs have also shown interest in investing in R&D in India. However, there is no clear disaggregated data available on actual R&D spent and the area in which such research is being undertaken. Table 2.24 provides details of MNC R&D investments in India for the year 2007-08. It is interesting to note that domestic-grown Ranbaxy which invested 460.51 topped the list last year. Matrix Labs, a public limited company listed on the major stock exchanges in India and engaged in the manufacture of Active Pharmaceutical Ingredients (APIs) and Solid Oral Dosage Forms, is the second highest R&D investor in India pegging at around Rs 120 crores.

Table: 2.23 Research and development expenditures to sales of Top companies (2007-2008)

Rs(in Crore) & (As % of Sales)

Company Name	Owner	R&D	R&D as % Sales
Dr. Reddy's Laboratories Ltd.	Dr. Reddy's Group	333.45	9.2
Cipla Ltd.	CIPLA Group	232.3	5.4
Lupin Ltd.	Lupin Group	193.37	7.3
Cadila Healthcare Ltd.	Zydus Cadila Group	161.8	9.2
Sun Pharmaceutical Inds. Ltd.	Sun Pharmaceutical Group	144.39	5.9
Wockhardt Ltd.	Wockhardt Group	126.74	10.7
Aurobindo Pharma Ltd.	Aurobindo Pharma Group	117.51	4.9
Torrent Pharmaceuticals Ltd.	Torrent Group	113.17	11.3
Panacea Biotec Ltd.	Panacea Biotec Group	107.67	12.9
Piramal Life Sciences Ltd.	Private (Indian)	99.03	N.A.

Orchid Chemicals & Pharmaceuticals Ltd.	Private (Indian)	70.9	5.7
Glenmark Pharmaceuticals Ltd.	Glenmark Pharmaceuticals Group	65.91	4.7
Biocon Ltd.	Private (Indian)	64.65	7.1
U S V Ltd.	Private (Indian)	59.02	8.4
Alembic Ltd.	Alembic Group	46.24	4.5
Sun Pharma Advanced Research Co. Ltd.	Sun Pharmaceutical Group	44.71	N.A.
Ind-Swift Laboratories Ltd.	Ind-Swift Group	44.69	2.3
Ipca Laboratories Ltd.	Ipca Laboratories Group	42.92	3.7
Piramal Healthcare Ltd.	Piramal Ajay Group	35.28	1.8
Unichem Laboratories Ltd.	Private (Indian)	32.71	5.5

Source: CMIE Prowess

Table: 2.24 R&D of MNCs Operating in India (2007-2008)

(In Rs. Crore) & (As % of Sales)

Company Name	Owner	R&D	R&D (% Sales)
Ranbaxy Laboratories Ltd.	Ranbaxy-Daiichi Group	460.51	13
Glaxosmithkline Pharmaceuticals Ltd.	Glaxo (F) Group	5.81	0
Matrix Laboratories Ltd.	Private (Foreign)	119.70	12
Aventis Pharma Ltd.	Aventis (F) Group	4.53	0
Pfizer Ltd.	Private (Foreign)	24.58	3
Abbott India Ltd.	Private (Foreign)	3.55	1
Novartis India Ltd.	Private (Foreign)	0.76	0
Strides Arcolab Ltd.	Private (Foreign)	37.5	9
Wyeth Ltd.	Wyeth (F) Group	0.79	0
Merck Ltd.	Private (Foreign)	1.48	0
AstraZeneca Pharma India Ltd.	Private (Foreign)	2.46	1

Source: CMIE Prowess

2.8.4 However, it is argued that the R&D intensity of Indian companies when compared to established global majors is minuscule. Studies have pointed out that with such low intensity, the industry as a whole may not be in a position to attain competitiveness in R&D (Dhar and Gopakumar, 2006); (Chaudhuri, 2007). Even while the ratio of R&D to sales may be close to that of the Indian firms, in these rations can be deceptive when compares to global sales and profitability of such major in absolute terms. Table 2.25 following table provides for R&D intensity of global majors.

Table 2.25: R&D Intensities of Global Pharma Companies in 2008

Rank	Company	Country	R&D intensity %
1	Roche	Switzerland	19.1
2	Pfizer	USA	16.5
3	Johnson & Johnson	USA	11.9
4	Novartis	Switzerland	17.4
5	Sanofi-Aventis	France	16.7
6	GlaxoSmithKline	UK	15.2
7	AstraZeneca	UK	15.9
8	Merck	USA	20.1
9	Eli Lilly	USA	18.8
10	Bristol-Myers Squibb	USA	16.8
11	Schering-Plough	USA	19.1

12	Wyeth	USA	14.8
13	Takeda Pharmaceutical	Japan	20.1
14	Amgen	USA	20.2
15	Boehringer Ingelheim	Germany	18.2

Source: www.innovation.gov.uk/rd_scorecard/index.asp

2.8.5 In terms of R&D output, existing surveys have tried to quantify it through introduction of new chemical entities under clinical trials and filing and grant of patents. It may be noted that Indian companies engaged in R&D do not perform at all levels of research. Table 2.26 provides a list of select R&D outputs in terms of stages of research.

Table 2.26: NCEs under Clinical Trials, Indian Pharmaceutical companies on 2006-07

Company	NCE	Indication	Development stage
Cadila Healthcare	ZY11	Anti-inflammation, pain	Phase I
Cadila Healthcare	ZYH2	Diabetes	Phase I
Cadila Healthcare	ZYH1	Dyslipidemia	Phase II
Dabur	DRF 7295	Anti-cancer	Phase II
Dr Reddys Labs	DRF2593	Diabetes	Phase II completed (partner Rheoscience, Denmark)
Dr Reddys Labs	DRL11605	Obesity	Phase I (assigned to Perlecen)
Dr Reddys Labs	RUS3108	Atherosclerosis	Phase I (assigned to Perlecen)
Dr Reddys Labs	DRF10945	Dyslipidemia	Phase II (assigned to Perlecen)
Dr Reddys Labs	DRF1042	Anti-cancer	Phase II (partner Clintec International. UK)
Glenmark	GRC8200	Diabetes	Phase II
Glenmark	GRC6211	Osteoarthritis, pain	Phase I
Glenmark	GRC3886	Asthma/COPD	Phase II
Lupin	LL3348 (herbal)	Anti-psoriasis	Phase II
Lupin	LL4858	Anti-TB	Phase I
Lupin	LL2011	Anti-migraine	Phase II completed
Lupin	LL4218	Anti-psoriasis	Phase I completed
Nicholas Piramal	P276	Anti-cancer	Phase II
Nicholas Piramal	PP04 (herbal)	Anti-fungal	Phase II
Nicholas Piramal	PP05 (herbal)	Arthritis	Phase II
Orchid	BLX1002	Diabetes	Phase II
Ranbaxy Labs	RBx9841	Urological disorders	Phase I
Ranbaxy Labs(jointly with MMV)	RBx11160	Antimalarial	Phase II (In India, Thailand and Africa)
Sun Pharmaceutical Industries	NCE	Anti-allergy	Phase II (in USA independently with a CRO)
Wockhardt	WCK771	MRSA, resistant infection	Phase II
Wockhardt	WCK1152	Respiratory infections	Phase I

Source: Sudip Chaudhuri, 2007

2.8.6 On the national front, since India opened up to the product patent regime, it had to put a mail-box system in place to review those applications. These applications are under examination process after 2005, when India amended its law to extend it patent regime for pharmaceutical products. A brief review of patents filed in India would show a surge in number of patent applications. Tables 2.27 and 2.28 below show field wise details of patent applications

filed and granted. There has been an increase in drug patent applications from 2316 in 2004 to 2316 in 2009. Similarly the number of drug patents granted also has gone substantially.

Table 2.27 Patent applications filed in the last five years in India patent office

Year	Chemical	Drug	Food	Electrical	Mechanical	Computer/ Electronics	Bio-technology	General	Other fields (See-App-E1)	Total
2004-05	3916	2316	190	1079	3304	2787	1214		2659	17466
2005-06	5810	2211	101	1274	4734	5700	1525		3150	24505
2006-07	6354	3239	1223	2371	5536	5822	2774		1621	28940
2007-08	6375	4267	233	2210	6424	4842	1950		7110	35218
2008-09	**5884**	**3672**	**340**	**2319**	**6360**	**7063**	**1844**	**2946**	**6384**	**36812**

Table 2.28 Patents granted in the last five years in India patent office

Year	Chemical	Drug	Food	Electrical	Mechanical	Computer/ Electronics	Biotechnology	General	Other fields (See App- F-1)	Total
2004-05	573	192	67	245	414	71	71		278	1911
2005-06	1140	457	140	451	1448	136	51		497	4320
2006-07	1989	798	244	787	2526	237	89		869	7539
2007-08	2662	905	154	1067	3503	1357	341		2474	15316
2008-09	**2376**	**1207**	**97**	**1140**	**3242**	**1913**	**1157**	**1318**	**3611**	**16061**

Source: Annual report (2008-09), India Patent and Trademarks Office

2.8.7 In terms of trends in patent grants, Indian applications have seen an upsurge. The total grants during the years 2000-05 stood at 174. As of 2005, total patents grants for Indian applicants by top 10 Indian companies stood at 221 at the USPTO. Table 2.29 provides the list of USPTO patent grants at the US as of 2005. It can be noted that the Council for Scientific and Industrial Research (CSIR) topped the list of US grants in pharmaceuticals in the year 2006. Distribution of Indian patenting organizations in terms of patent grants show that CSIR topped in terms of grants in the US by having in its portfolio around 46 patents. In many ways, Government participation in the R&D activities came in the aftermath of the report presented by the Pharmaceutical Research and Development Committee (PRDC) that was established in 2000 (Dhar and Gopakumar, 2006). One of the focus areas of the PRDC was the increase in spending by the Government on the R&D. Complementing the focus areas that the PRDC had identified was the increase in the R&D collaboration between the Government-owned research laboratories (mostly under the CSIR) and the industry (Dhar and Gopakumar, 2006).

Table2.29 Patenting by Indian pharmaceutical companies in USPTO

First name assignee	Before 1989	1990-94	1995-99	2000-05	Total
Ranbaxy Laboratories Ltd	0	7	13	45	65
Dr Reddy's Laboratories Ltd	0	0	10	33	43
Dabur India Ltd	0	0	1	27	28
Orchid Chemicals & Pharmaceuticals Ltd.	0	0	0	18	18
Panacea Biotec Ltd	0	0	6	8	14
Lupin Ltd	0	0	9	3	12
Torrent Pharmaceuticals Ltd	0	0	0	8	8
USV Ltd	0	0	1	7	8
Biocon India Ltd	0	0	0	7	7
Wockhardt Ltd	0	0	0	7	7
Aurobindo Pharma Ltd	0	0	0	6	6
Sun Pharmaceutical Industries Ltd. 0	0	0	0	5	5
Total	0	7	40	174	221

Source: Sudip Chaudhuri, 2007.

2.8.8 However, as some studies have pointed out the percentage of patents filed by Indian inventors abroad have been quite low. For example in the year 2002, 40 USPTO grants constituted 25 % of all US patents granted to Indian

inventors. This constituted around 2.2% of all pharma patents granted by the USPTO during that period. The same lower percentage of Indian applications of pharma patents is seen in the EPO space, too. Table 2.30 clearly shows these trends.

Table 2.30 Number of pharma patents filed by Indians at USPTO and EPO

Year	US Patent Grants			EPO Patent Applications		
	Number	All Indian (Per Cent)	All Pharma (Per Cent)	Number	All Indian (Per Cent)	All Pharma (Per Cent)
1980-84	12	14.5	0.09	1	100	0.00
1985-89	23	16.9	0.13	0	0	0.00
1990	11	28.2	0.26	1	0	0.01
1991	14	36.8	0.37	4	100	0.06
1992	18	36.7	0.39	1	50	0.01
1993	11	16.7	0.21	1	0	0.02
1994	9	12.9	0.13	1	50	0.01
1995	17	19.5	0.17	3	100	0.04
1996	24	19.7	0.38	3	100	0.04
1997	40	23.0	0.52	3	33	0.03
1998	44	21.7	0.59	9	50	0.09
1999	43	15.9	0.54	23	43	0.23
2000	70	23.3	0.95	35	55	0.33
2001	63	19.8	1.20	36	47	0.36
2002	40	25.0	2.20	16	27	0.31

Source: Lanjouw J., Margaret Macleod, 2005.

2.8.9 The capabilities of Indian generic companies to move up the value chain are also reflected in the DMF and ANDA filings. DMF refers to Drug Master File (document containing complete information on an API). It is known as European Drug Master File (EDMF) or Active Substance Master File (ASMF) and US-Drug Master file (US-DMF) in EU and US respectively. The DMF contains factual and complete information on its subject's chemistry, stability, purity, impurity profile, packaging and the GMP status of any APIs. In some countries it is a voluntary requirement. ANDA refers to the Abbreviated New Drug Application, which is filed in the United States for a generic drug approval. They are based on existing licensed medication or approved drug by the US Federal Drug Administration. The ANDA contains data which when submitted to US FDA, provides for the review and ultimate approval of a generic drug product. Once approved, an ANDA applicant may manufacture and market the generic drug product to provide safe, effective generic substitutes. Both DMF and ANDA filings can be a vital source of information on generic substitutes available, which also brings forth the research skills in coming out with such products. Figure 2.8 and 2.9 below provide Indian companies' status of DMF filings and ANDA filings in the US. This can be considered as one indicator of skill of Indian generics to come out with substitutes.

Figure 2.8: Comparison of drug master files(DMFs) (Type II) by India, China and world (1998-2007) (figs.Nos)

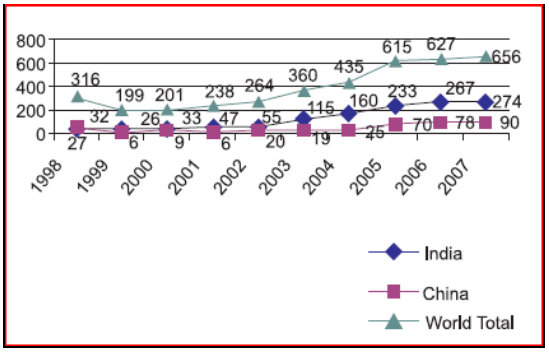
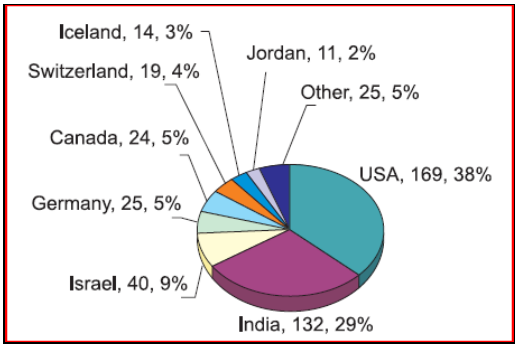


Figure2.9 : Final ANDA approvals by country (2007) (figs.Nos)



Source: Annual Report (2008-09), Department of Pharmaceuticals

2.8.10 On the pharma bio-tech front, the output of R&D in terms of patents has not been encouraging. Although Indian companies have acquired a lot of process skills, they lag in terms of product development (Narayanan, 2002). However, as commentators also remark that since the industry is at a nascent stage, it is evident that the companies are all concentrated on producing the generics alone which would help poor patient populations across the world. They also remark that Indian companies are constrained by the fact that they are not backed by adequate venture capital fund (Narayanan, 2008).

2.8.11 It may be noted that pharma patents granted since 90s increased steadily. However, Ranbaxy was the only company who could get 8 patents from 1995-2000. However, since then, barring some exceptions, the total number of pharma patents has risen each year and 68 were awarded in 2007. On the biotech front, since they have been granted since 2001 their rise has happened only more recently from 2003. However, they do not show a consistent rise. There are appreciable fluctuations in the patents granted (Sriramkumar Sundaramoorthy *et. al.* (2009).

2.8.12 The study conducted on US patent grants to Indian pharma and biotech companies has much to tell about the nature and quality of inventions that such patents have produced. Relying on citation index of USPTO (where higher the number of citations of a given patent, the more valuable it is as a basis for future work), it is concluded that although such companies have received large number of citations by non-Indians, they yet are far from being fundamental or breakthrough discoveries in nature (Sriramkumar Sundaramoorthy *et. al.* 2009). Table 2.31 illustrates the trends in citation of Indian grants at the USPTO.

Table: 2.31 US Patents of Indian Biotech and pharma companies by Citation relevance

Company	Patent number	Date of grant of patent	Number of citations	By self or associated company	By others
Cadila Laboratories	5616593	1 April 1997	19	0	19
Dabur Research Foundation	6048847	11 April 2000	12	3	9
Dr Reddy's Research Foundation	6054453	25 April 2000	17	11	6
Dr Reddy's Research Foundation	5985884	16 November 1999	13	7	6
Dr Reddy's Research Foundation	5889025	30 March 1999	16	5	11
Dr Reddy's Research Foundation	5885997	23 March 1999	13	10	3
Dr Reddy's Research Foundation	5801173	1 September 1998	11	5	6
Panacea Biotec	5858371	12 January 1999	15	0	15
Panacea Biotec	5716609	10 February 1998	11	3	8
Ranbaxy Laboratories	5763646	9 June 1998	13	1	12
Sami Labs	5861415	19 January 1999	17	0	17
Total number of citations			**157**	**45**	**112**
Percentage of citations			**100**	**29**	**71**

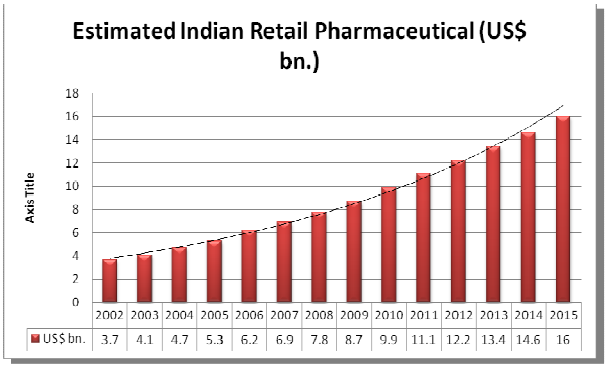
Source: Sriramkumar Sundaramoorthy *et. al* (2009)

2.9 The Pharmaceutical Markets in India: Flagging the dynamics of relationship

2.9.1 The pharmaceutical market in India ranks among the top twenty markets in the world with the potential to move to top 10 by 2015. This market is being viewed as essential by pharmaceutical companies exploring new opportunities for growth. The retail pharmaceutical market size in India is estimated at US$7.8bn in the year 2008, and is expected to grow at a high CAGR of 9.9 percent till 2010 and thereafter at a CAGR of 9.5 till 2015 (Taskforce report, 2008). There are around 60000 brand formulations currently in the market. Drug markets are basically characterized in to Over the Counter Drugs (OTC) and prescription based drugs. Figures 2.10 and 2.11

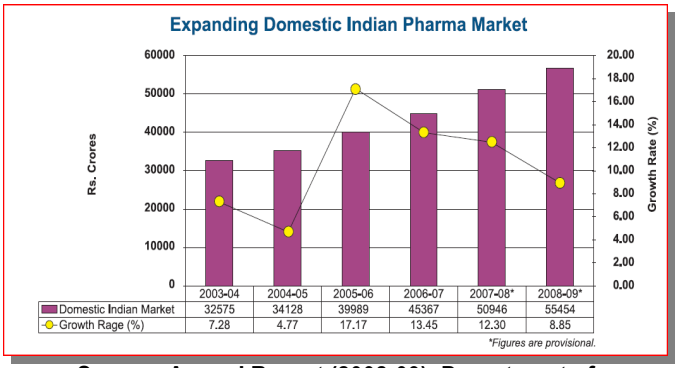
provide an overview of pharmaceutical market in India.[37] An overview of the growing domestic market is also provided by the Department of Pharmaceuticals. According to this the domestic pharmaceutical market has crossed Rs.55 thousand crores in 2008-09 from Rs. 32575 crores in 2003-04.

Figure 2.10



Source: Taskforce Report (2008)

Figure 2.11



Source: Annual Report (2008-09), Department of Pharmaceuticals

2.9.2 In India the prescription drugs are listed under Schedule H. There are about 570 molecules in this category that are stocked in a total of 5 to 8 lakh retail chemists. The Department of Pharmaceuticals notes that the pharmaceutical sector in India provides a total employment is about 340,000, and an estimated 400,000 doctors and 300,000 chemists are serving an over 1 billion customers market (DoP, 2009). It is in common knowledge that many chemists sell prescription drugs even without written prescription (as discussed later).

2.9.3 While this report has focused on issues concerning prescription drugs where competition concerns are immense, a brief overview of OTC market would be beneficial. The Drugs and Cosmetics Act and its appended Rules, governs the sale of prescription only drugs as listed in schedules H and X. Another category of drugs listed in Schedule G (mostly antihistamines) do not need prescription to purchase but require the following mandatory text on the label: "Caution: It is dangerous to take this preparation except under medical supervision". Drugs falling in these 3 schedules are currently not advertised to the public under a voluntary commitment by the pharmaceutical industry (OPPI, 2008). However, currently, non drug-licensed stores (e.g. non-chemists) can sell a few medicines classified as 'Household Remedies' listed in Schedule K of the Drugs and cosmetics Act in villages whose population is below 1000. As of 2005 the Indian OTC segment was pegged at Rs 4500 crore it could be considered as 17000 cores if cosmeceuticals & neutraceuticals are also included. The CAGR for Indian OTC markets is currently hovering between 12 and 15% and this is much faster than OTC market growth of most development countries.

2.9.4 Due to changing trends and consumer awareness of OTC drugs, the OTC market is contemplated as future growth driver. What makes the OTC market interesting is the fact that many of such drugs can be registered as 'Ayurvedic Medicines'. They are also regulated under Drugs and Cosmetics Act and Rules, but they do not require a drug licence they can be sold by non-chemists. Further, there are no price controls on ayurvedic drugs. Some of the top OTC brands in India (e.g. Vicks VapoRub, Amrutanjan Balm, Zandu Balm, Iodex , Moov Pain Cream, Itch Guard Cream, Eno Fruit Salt, Vicks Cough Drops, Halls Lozenges, etc.), are registered as 'Ayurvedic Medicines' because of their plant-based natural active ingredients (OPPI, OTC Profile, 2008).

2.9.5 However, India does not have an OTC list of Drugs. A recent note on Pharmabiz suggests that preparation of such a list is under consideration by the DCGI. It states: "The proposal to have a list of over the counter (OTC) drugs has been under the consideration of the government for some time now. A committee appointed for the purpose has been working on it for some years. A list of OTC drugs is understood to have been now finalised by this

[37] 'OTC Drugs' are drugs that are legally allowed to be sold 'Over the Counter', i.e. without the prescription of a Registered Medical Practitioner in India. In India, though this phrase has no legal recognition, all the drugs that are not included in the list of 'prescription only drugs' are considered as non-prescription drugs (or OTC drugs), See Drugs and Cosmetics Act.

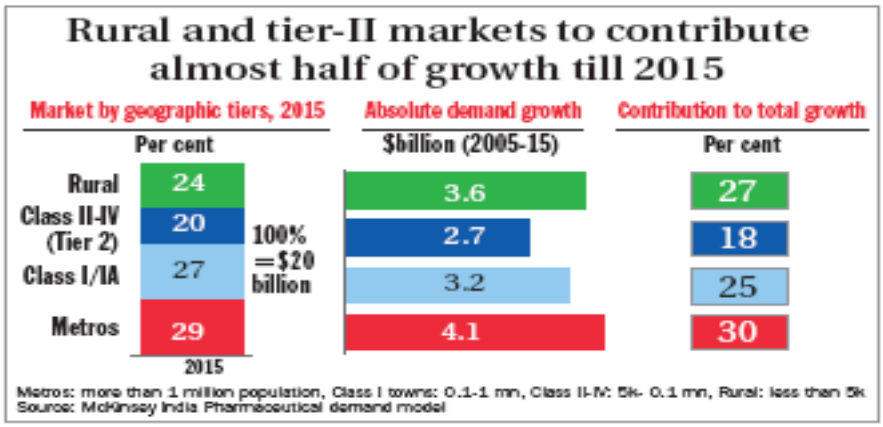
committee. The main objective of having a list of OTC drugs is to widen the access of at least medicines which do not require a prescription or medical supervision, to larger sections of the society. Apart from expanding the access to modern medicine, such a move is also expected to bring down the medical costs to some extent. Despite having 5-8 lakh retail chemists in the country, even commonly used medicines are not available to a large section of the rural folk of India today. There is not going to be any major change to this situation in the coming years, as the expansion of retail chemists' network is not taking place in the rural areas at desired level. By placing widely used painkillers, balms and cough syrups under OTC, they can be sold at the counters of grocery stores and other shops without a drug licence. Numbers of such trade channels are considerably larger and widespread than retail chemist shops. For pharmaceutical companies and some of the FMCG corporations, marketing of OTC medicines is thus going to be a huge business opportunity. Entry of Hindustan Lever into pharmaceutical marketing with its recent launch of a cough syrup and Ranbaxy's declared plan to go for a major expansion of its OTC products are indications of this new business interests".

2.9.6 It further states: "A key issue here is the safety in using OTC drugs. As these drugs will be taken without any medical advice, label comprehension with regard to disease symptoms, directions for use, warnings, etc is extremely important. Tendency to take higher doses of an OTC medicine and its use for longer periods are possible dangers associated with them. Generally labels on OTC products also do not indicate specified doses for children. All these call for a drastic change in the labelling practices of OTC medicines if they have to be sold outside medical shops. Firstly, labelling of OTC medicines has to be in local languages and all the instructions have to be in simple and easily understandable words. At present, very few pharma companies are printing labels in local languages. Some basic knowledge about medicines is also crucial amongst the traders who will be selling OTC products. It is extremely important, therefore, that the Drug Controller General of India has to lay down a separate set of rules or guidelines for OTC marketing. The companies which will be entering into manufacturing and marketing of OTC products also have the responsibility of following fair trade practices in this business".

2.9.7 However, Indian Drug Manufacturers' Association (IDMA) is of the opinion that the products to be sold through OTC route should an absolute minimum as the country does not have the required infrastructure nor qualified pharmacists. Low literacy and education amongst the consumers, especially in relation to consumer drugs information of medicines also makes it all the more necessary to be extremely cautious on this front (IDMA, 2005). However, the OPPI has asked for more drugs in the category of OTC.

2.9.8 The retail market in India posted a healthy growth of 10% in May 2009 over the previous month. The total annual total basis (April 08 to May 09), the organized pharma retail market grew by 10.4% to Rs 36,048 crores, which was slightly higher than the previous month's value of Rs 35,675 crores, according to consulting company, ORG-IMS data (TOI, 2009). Some reports also predict that by the year 2015, India will be among the top 10 global pharma markets by value (McKinsey Report, 2007). It is also predicted that it will add revenues the fastest after the US and China, which is $14 billion in drug sales, more than double the country's pharmaceutical market in 2005. The reasons for the expected rise in the market are that Indians are expected to spend far more on healthcare (McKinsey, 2007). It is also noted that changing health patterns and susceptibility of Indians to chronic diseases would mean that by the year 2015, millions more will suffer from chronic, costly-to treat diseases such as diabetes, asthma and cancer than being currently seen. (McKinsey Report, 2007). However, it is not that this rise in markets is solely due to urban populations and spending. It is expected that the rural and second tier cities will contribute to half of the Indian retail markets (McKinsey Report, 2007). Table 2.36 explains the estimated rise in market shares in rural and II tier retail pharmaceutical markets in India.

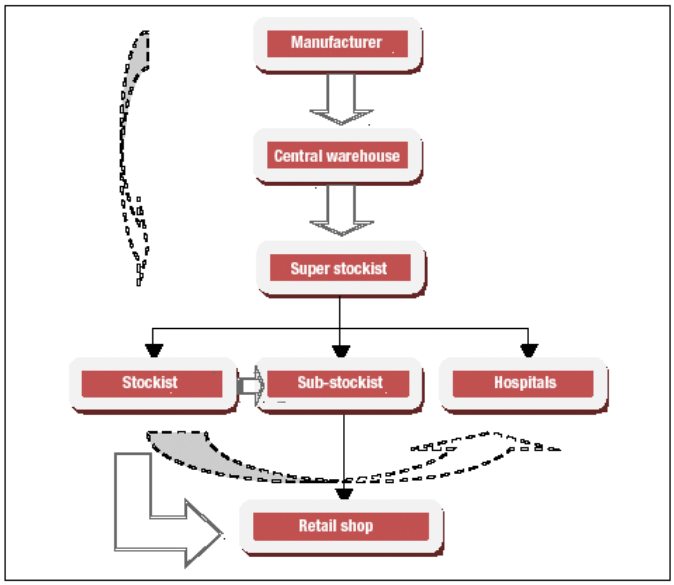
Table: 2.32



Source: McKinsey Report, 2007

2.9.9 Pharma Retail in India is fast changing due to the entry of organized players. The sector that is growing at 27% annually. Drug distribution in India has witnessed a paradigm shift in the recent years. Before 1990, pharmaceutical companies used a different distribution system, in which they established their own depots and warehouses that now have been replaced by clearing and forwarding agents (CFAs). These organizations are part of the distribution chain, and are primarily responsible for maintaining storage (stock) of the company's products and forwarding it to the stockists on request. Most companies keep one to three CFAs in each Indian state. On an average, a company may work with a total of 25–35 Stockists/regional distributors can simultaneously handle more than one company (usually, 5–15 depending on the city area), and may go up to even 30–50 different manufacturers. The stockist, in turn, after 30–45 days (a typical credit or time limit) pays for the products directly in the name of the pharmaceutical company. The CFAs are paid by the company yearly, once or twice, on a basis of the percentage of total turnover of products. Figure 2.12 clearly describes the drug distribution model in India. (Bio-pharma International, 2008).

Figure 2.12: Current Distribution Chain in India



Source: Bio-pharma International (2008)

2.9.10 The distribution network indicates that manufactured product passes through the company-owned central warehouse, which supplies it to the CFA or super stockist. From the CFA the stocks are supplied either to the stockist, substockist, or hospitals. The retail pharmacy obtains products from the stockist or substockist through whom it finally reaches the consumers (patients). Certain small manufacturers directly supply the drugs to the super stockist. However, the profit margins although officially declared by the NPPA gives retailers 16-20% (16% for scheduled and 20% for non-scheduled), it may not be correct at the ground level. Firms may often provide greater discounts to retailers for allow brand promotion and to augment sales. Table 2.33 provides a clear picture of margins at various levels in the pharmaceutical supply chain.

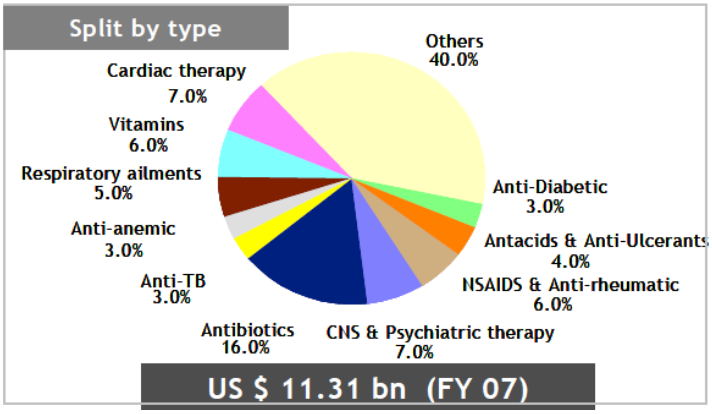
Table 2.33 Margins at various levels of distribution system

Levels	Margins
Clearing and Forwarding (C&F)agents	1-10 on the total turnover + other expenses
Stockiest or distributors	8% on scheduled drugs 10% on non-scheduled drugs
Retailers	16% on scheduled drugs 20% on non-scheduled drugs
Source: www.nppaindia.nic.in/index1.html	

2.9.11 As of May 2009, there was little change in the top rankings of companies. Cipla occupied the top position in terms of market share, followed by Ranbaxy and GlaxoSmithKline on the third position. Piramal Healthcare was ranked fourth, followed by Zydus Cadila which moved to the fifth position. Zydus displaced Sun Pharma, which had moved to the fifth position in April. The sale segment also saw some movements as far as the top 20 companies were concerned with Dr Reddy's Labs, Wockhardt-Merind and Emcure gaining one rank each, to move up to rank 11, 14 and 16 positions respectively, according to ORG-IMS retail market reports (TOI, 2009).

2.9.12 The position of brands among sales points to drug demand for specific brands. Amongst medicine brands, pain killer drug Voveran maintained its top position. Iron supplement Dexorange and lipid lowering medicine, Strovas leaped three ranks and jumped to rank five and 20 respectively. Oral rehydration salt Electral, pain killer Spasmo-proxyvon and Asthalin (for managing asthma) were the highest gainers, moving four ranks each to nine, 15 and 16 positions respectively. Among the top 20 products, antibiotic drug Taxim, Liv-52, antibiotic Mox, Taxim-O, gained one rank each and moved up to ranks eight, 11, 13, and 17 respectively. Aciloc gained seven ranks and entered the top 20 list at rank 18 during as of May 2009 (TOI, 2009). It may be noted that some of such brands are OTC brands. The market for therapeutic segment is dominated by average sales in cardiac therapy, followed by psychiatric therapy, vitamins, respiratory ailments etc… Figure 2.13 provides an overview of percentage product segmentation in Indian therapeutic market.

Figure 2.13



Source: Padmashree Sampat, 2007

2.9.13 The pharmaceutical markets present an interesting saga of extent of competition in the prescription drug market. A recent study (Jha, 2007) rightly notes that individual market shares of the companies does not reveal the actual intensity of competition as such competition takes place within therapeutic segments which cater to distinct diseases of any population. The study based on retail formulations data for the month of February 2006 from ORG IMS calculates the level of competition that can be observed for some drugs, including drugs like ciprofloxacin, which is a drug under DPCO. It must be noted that these drugs are not under patents, but still the intensity of competition may be quite low. The table below shows that the prices within various therapeutic categories reflect an oligopolistic structure despite generic competition. The study rightly notes that reason being that prescription drug market cannot be a perfectly competitive market or even close to it is because the consumer and the decision-maker for consumption are not the same people. The study also notes that the share of advertising and marketing expenditure as a proportion of total sales of the drug companies is much higher than their R&D expenditure as a proportion of total sales. (Jha, 2007). Table 2.34 illustrates the nature of competition in various therapeutic segments. It reveals that top 4 brands have high percentage of shares in the market, quite reflective in the market concentration in certain brands. While this may just be anecdotal, it reveals the deceptive nature of existence of competition in prescription drug market. It is when there exist substitutable generic brands as competitors.

Table: 2.34 Extent of Competition in Therapeutic Segments

Name of the Drug	Therapeutic Category	No of Brands	Share of Top 4 Brands (Per Cent)
Ciprofloxacin	Quinolones	200	60
Levofloxacin	Quinolones	45	48
Chloroquine	Anti-Malaria	43	93
Quinine	Anti-Malaria	24	85
Rh Adults	Anti-Tuberculosis	63	79
RHEZ FD (Rifampicin +Isoniazid+ Pyrazinamide)	Anti-Tuberculosis	40	70
RHE(Rifampicin +Isoniazid+ Ethambutol)	Anti-Tuberculosis	42	65
Atorvastatin	Statins	75	47
Simvastatin	Statins	25	84
Lovastatin	Statins	15	98

Note: *The drugs categories include all dosages and forms of individual brands.

Source: Jha, 2007

2.9.14 India's domestic retail market recorded a growth of 15% and has grown by nearly 10% during January-December 2008. As per ORG IMS data Cipla gained the largest retail market share, followed by Ranbaxy and GlaxoSmithKline at third position, according to consulting company, ORG-IMS. Piramal Healthcare was ranked fourth, followed by Zydus Cadila at the fifth slot in terms of market share. As of January, pain killer drug, Spasmo-Proxyvon was the highest gainer in ranks, amongst the largest selling drugs moving up from the 24th slot in December to the 18th. The other major gainers are vitamin supplement Revital, having moved up from the 11th slot in December to seventh position in January, and iron supplement Dexorange, gaining four ranks (rank 11 as per January '09). Zinetac used to treat ulcer moved up three slots to the 14th position, up from rank 17 in December. Among the therapeutic areas, cardiovascular segment recorded a 14% growth, while anti-infective medicines grew 10% during the month ending January 2009.

2.9.15 A recent 2008 initiative of the Department of Pharmaceuticals to set up generic stores in every district of the country popularly called as Jan Aushadhi project has for now taken off well. At least 30 such stores have already come up during last six months. Now, the project is facing trouble as the supply of drugs to the stores has become erratic. The public sector drug units which are expected to play a key role in ensuring regular supply of generic drugs to these stores are not able to deliver drugs in time. Indian Drugs and Pharmaceuticals Ltd and other four public sector units were to coordinate the supply of drugs from its own plants and other PSU drug units. Initially, these stores are expected to come up in 12 states and in the second and third phases, they were to come up in all the remaining states. The project is an excellent initiative with right social agenda of making essential drugs available at affordable prices.

2.9.16 Commentators and experts note that it is possible that large pharmaceutical companies and pharmaceutical trade may try to defeat this initiative as the success of generic stores is bound to hit their profitability. As the price control in the pharmaceutical industry has almost failed, opening generic stores is probably one way the prices of essential drugs can be brought down.[38]

2.9.17 According to the Indian Retail Druggists and Chemists Association, in 1978, there were roughly 10,000 distributors and 125,000 retail pharmacies in India. Today, the total number of stockists in India is around 65,000 and the number of pharmacies is about 550,000, an increase of 4-6 folds respectively. It is expected that retail pharmacists, despite of spatial monopoly, will face intense competition in generic drugs. However, without proper control on prescription habits of doctors and unethical practices in the ethical drug market, it is doubtful if Government's Flag ship programme will attract a wide consumer base.

2.10 Drug Promotion and Drug Advertising in India

2.10.1 Drug promotion in India or elsewhere has always attracted controversy. All advertising is inherently unethical. (Thawani, 2002). Unlike other commodities where consumers are choosers, prescription practices in the drugs category is driven by drug promotion. The very nature of prescription drugs market is ethically driven- hence it is also called as the "ethical drug" market. In 1998, the World Health Organization (WHO), in an attempt to support and encourage the improvement of health care through the rational use of drugs and to curb unethical marketing practices, came out with a landmark "Ethical criteria for medicinal drug promotion".[39] It is an outline document which defines drug promotion as "all the information and persuasive activities by manufacturers and distributors in order to induce the prescription, supply, purchase and/or use of medicinal drugs". However, as per the WHO this criterion does not constitute legal obligations; governments may adopt legislation or other measures based on them as they deem fit. It also advises that other groups may adopt self-regulatory measures based on them.

2.10.2 Drug promotion also includes the activities of medical representatives, drug advertisements to physicians, provision of gifts and samples, drug package inserts, direct-to-consumer advertisements, periodicals, telemarketing, holding of conferences, symposiums and scientific meetings, sponsoring of medical education and conduct of promotional trials. It is well understood that the pharmaceutical companies do have trade interests in promoting their products for disseminating information about the drug it produces, but it should do so in a fair, accurate, and ethical manner. The blurring boundaries of what constitutes fair practices are of intense debate in issues involving drugs promotion.

2.10.3 Many studies have noted that drug companies are involved extensively in promoting their brands by paying huge kickbacks and the relationship between actors in the distribution network is almost always based on perverse set of incentives (Angell M., 2005). Studies have also identified the variety of ways and means in which the drug industry influences doctors and the doctor's in turn due to their fiduciary position are susceptible to perverse incentives. In the year 2008, the pharmaceutical industry in India spent a total of Rs 4941.15 crore, in which Advertising expenses were 823.57 and drug marketing 2470.44 crore Indian rupees.

2.10.4 The Indian Medical Council Act, 1956, and the Code of Medical Ethics, 2002, govern the conduct of physicians in India (as discussed in chapter III). There are voluntary resolutions of various industry associations providing necessary guidance on drug promotion, but they have not been effective. In fact, there seems to be no logical reason that the voluntary codes which aim at restricting or regulating drug promotion is in direct conflict with the interests of drug industry. In totality, all measures currently available under law have largely remained ineffective to

[38] interviews with Guha and Zafarullah Chaudhuri April 2009

[39] Criteria for Medicinal Drug Promotion (WHO) Available at: http://apps.who.int/medicinedocs/collect/edmweb/pdf/whozip08e/whozip08e.pdf
The criteria that follow have been prepared in compliance with the above on the basis of a draft elaborated by an international group of experts. Following the WHO Conference of Experts on the Rational Use of Drugs held in Nairobi in November 1985, WHO prepared a revised drug strategy which was endorsed by the Thirty-third World Health Assembly in May 1986 in resolution WHA39.27. This strategy includes, among other components, the establishment of ethical criteria for drug promotion based on the updating and extension of the ethical and scientific criteria established in 1968 by the Twenty-first World Health Assembly in resolution WHA21.41.

deal with the collusion crises in the prescription drug markets. An editorial in one of India's reputed medical journal notes that "The International Federation of Pharmaceutical Manufacturer's Association which had first suggested a self regulatory code of pharmaceutical marketing practices in 1981, adopted the revised version in 1994. There seems to be obvious double standards in adoption of the code. While in the developed countries, these firms often publish reasonably ethical advertisements which are published in medical journals, the very same companies promote the same drug for different indications in developing countries".

2.10.5 Advertising, as distinct from promotion is generally used as a direct measure to popularize a particular drug or a remedy. It is governed by the Drugs and Magic Remedies Act (discussed in chapter III). The Drugs Enquiry Committee, 1930 under the chairmanship of Sir R N. Chopra was the first authoritative attempt by the Government to look which scrutinized the pamphlets of drugs which made spurious claims. However, not much has been achieved since then except the introduction of the Drugs and Cosmetics Act, 1955 has "largely remained unenforced due to the apathy and general disinterest of the health care fraternity and the industry refuses to be cowed down by legislative enforcements" (Thawani, 2002). For example: Hamdard Dawakhana filed a writ to the Supreme court of India asking it to declare the direction for recalling 40 drugs as bad in law- as basically violating their right to free speech and right to carry on trade and business. But the petition was dismissed (Thawani, 2002)

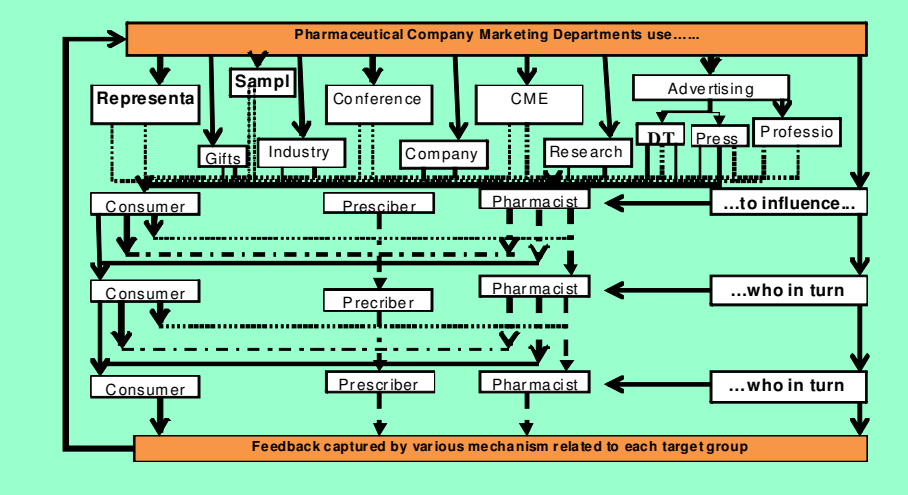
2.10.6 It is well recognized that in case of prescription of a drug- where the doctor is decision maker for the ultimate user - the patient, the industry has a powerful influence on prescribing habits (Lancet, 1993). The industry is often blamed for its marketing practices, which has been considerable covered and discussed in western literature (Angell, 2005). It is noted that while doctors uniformly deny that their understanding of drug is influenced by the activities of industry, there is considerable evidence to support the efficacy of the personal encounter with a medical representative in shaping doctors' attitude towards drugs (Bhat, 1993)

2.10.7 While delivering information to the doctors about new drugs, including its usefulness and efficacy may have pro-competitive effects, marketing strategies adopted by firms may downplay the demand side and hence raise prices for consumers. There is an essential difference between promotion and information. How doctor decide which drug to prescribe to his patients is at the heart of controversy. Popular news reports and mapping of recent incidence of collusion between the profit-oriented pharmaceutical companies, pharmacists and doctors, it is noted that these actors are routinely wooed with gifts ranging from mobile phones to sponsored weddings. Interviews conducted during the course of this study reveal that it extends from sponsored conferences in five-stars to high-value gifts like motorcycles and cars. There are even cases where pharma companies have helped doctors set up small nursing homes. However, there is no concrete evidence to point specific people, institutions or companies, since these interviews were held in confidence**.** A list of three collected news items published in the Times of India on drug promotion does portray various facets of drug promotion in India (See Annexure II).

2.10.8 Such incidences have long been noted in the medical fraternity, but have rarely been thoroughly investigated. In this study, based on earlier studies and reports, investigate such practices from a horizontal and vertical agreement point of view. This is despite the fact that inappropriate prescriptions could lead to dangerous side effects, medical complications and needless expenses for patients. It has also been noted that medical associations have allegedly warned pharmaceutical companies, that they you don't sponsor our conference they will boycott your drugs. Some experts and commentators are also of the view that breakthrough drugs that enter the market early are promoted through scientific information. But 'me too' drugs and irrational formulations have to be pushed vigorously, resulting in excessive sampling, lavish conferences and obscene gifts (Angel, 2005). Some interviews also reveal that drug companies sponsor weddings and birthdays of doctor's kith and kin.[40] However, currently there is, at present, no legal requirement of continuing medical education or periodic recertification in India.

[40] Interview with Amitava Guha and Zafarullah Chaudhuri, April 2009.

Diagram : Drug Promotion Matrix in India



Source: Amitava Guha (2009)

2.10.9 The diagram above provides a bird eye's view of drug promotion activities in India and how various actors are linked in the supply chain markets. It reveals that drug manufacturers promote their products through:

- Representative visits
- Free samples
- Gifts
- Conference travel (including pleasure trips)
- Continued Medical Education Funding
- Research Materials/journals and other promotional literature

2.10.10 A study conducted by Madhiwalla and Pai (2007) on drug promotion in India[41] notes that:

> "[d]octors stated that they received information on new drugs primarily through visits by MRs who use flip charts for this purpose. These flipcharts show the benefits of their drugs over the drugs of other companies. They also provide results of studies carried out by them on the drug's efficacy." According to the doctors, MRs rarely mentioned drug interactions and adverse reactions but they were otherwise generally satisfied with the information provided and accepted the MR's role. "Everything is told in a precise way... medical representatives are well versed with their products and quite capable of answering the doctor's questions".

2.10.11 The above paragraph highlights that medical representatives are a major source of promoting drugs. Hence it would be pertinent to see if medical representatives are governed by any guidelines or regulations (as discussed in chapter III). Interviews reveal that doctors normally are averse to seeing medical representatives during working hours since they would lose as much time in seeing their patients. However, medical representatives are trained to ensure that they have appointments for at least few minutes- which MRs try to do during early hours- when doctors are considerably free. On an average a doctor may see two or three medical representatives every day. MRs use a

[41] Roy, Madhiwalla and Pai, Drug promotional practices in Mumbai: a qualitative study, Indian Journal of Medical Ethics, 2007 April-June 4(2)

variety of techniques to enforce upon the doctors the brand name that they promote. This is done by giving token gifts like pens, scribbling pads with brand name, prescription pads with brand names etc…[42] This is also noted by a study[43] which states:

> "MRs were required to give small gifts to doctors, to keep their brand in the doctor's memory. These "brand reminders" varied from desktop items to minor medical equipment, including prescription pads and rubber stamps (with the names of drugs manufactured by the company). It was also reported that some companies employed marketing professionals to build a personal rapport with the doctor by remembering occasions such as birthdays. Further, pharmaceutical companies stated that they did not differentiate between qualified and unqualified physicians in their promotional practices".

2.10.12 Medical representatives are under constant pressure to push for higher sales- they reason why they resort to providing perverse set of incentives to the doctors. The sales driven motivations for MRs warrant that MRs resort to activities that can call ethics of promotion into question. Studies have indicated that promotional materials provided by pharmaceutical companies through their representative cannot be entirely relied upon. Source of primary literature on drug promotion are articles published in peer-reviewed journals, secondary literature includes abstracts of various types of published literature and third, reference from text books and other standard literature (Shetty VV et. al, 2008). Commentators point that few physicians are equipped with skills to critically evaluate and appraise it (Sheety VV et. al, 2008). It is noted that lack of proper methodological understanding among physicians to evaluate these drugs is the prime reason for them being swayed away with arguments presented in promotional literature (Shetty VV et. al, 2008). It is suggested that physicians must see if a new drug is relevant to their practice in terms of population studied, the disease and the need for new treatment (Shetty VV et. al, 2008).

2.10.13 Quoting G. J Kyle, Guha (2009) states that "the web of direct and indirect commercial influences that can be exerted on the prescribing process into a single visual representation. Prescribers make decisions about whether to prescribe or not, and if so, which drug to prescribe, within the paradigm of these commercial influences. The power of a coordinated marketing campaign utilizing multiple influencing factors, or channels of influence, can be seen". Guha (2009) is of the firm conviction that unethical practices in the ethical drug industry represent an ugly face of modern that demand creating pharmaceutical markets where physicians have perverse incentives to engage with the pharmaceutical industry. Guha (2009) quotes a famous passage from a Blumenthal's article in NEJM (2003), which states "when a great Profession and the forces of Capitalism interact, drama is likely to result. This has certainly been the case where the profession of medicine and the pharmaceutical industry are concerned. On display and the grandeur and weakness of the medical profession-it's noble aspiration and its inability to fulfil them".[44]

2.10.14 Guha (2009) has also collected various materials used for drug promotion. It is startling to note the claims made by drug companies of their brands and the ways and means in which prescription is being generated, unregulated (for details see annexure III). Claims involve projecting the prescription drug as the best available product, including claims that the product has highest prescription. Some products are being promoted based on effectiveness trials conducted by the same companies marketing them. Other products are promoted based on reward schemes and offers. The WHO guideline on ethical drug promotion states that "[s]cientific data in the public domain should be made available to prescribers and any other person entitled to receive it, on request, as appropriate to their requirements. Promotion in the form of financial or material benefits should not be offered to or sought by health care practitioners to influence them in the prescription of drugs". It may be clearly noted that above practices of luring doctors through gifts, rewards, schemes, including delivering large amount of free samples are in violation of

[42] Interview with a doctor (confidential)
[43] Roy, Madhiwalla and Pai, Drug promotional practices in Mumbai: a qualitative study, Indian Journal of Medical Ethics, 2007 April-June 4(2)
[44] David Blumenthal: New England Journal of Medicine, 21st October, 2004

general ethical guidelines laid down by the WHO. Thus it can be concluded that drug promotion strongly influences prescribing behaviour, but doctors underestimate this influence. Company funding of doctors, of educational events, and of research are important elements in this influence. Medical representatives do not receive any formal training on drug promotion[45]

2.10.15 The study notes that out of diverse interventions to control or counter the influences of promotion, the only ones that have been found effective are government regulation, training of students (both before and after graduation), media exposure of abusive promotion, and free and abundant provision of reliable non-commercial therapeutic information to professionals and the public. Research and policy questions to be addressed include the development of effective methods of educating doctors about drug promotion, the impact of guidelines on promotional gifts, and the development of effective guidelines for managing conflicts of interest in research. The effects of different regulatory frameworks also urgently need to be compared. Governments and other organisations that introduce policies to regulate promotional activities need good evidence of the advantages and drawbacks of different systems.[46]

2.10.16 No medical journal in India can survive without the advertisements of a drug. The pharmaceutical industry spends heavily on advertising in journals with a wide circulation meant for a clinical specialist or general practitioners. However, in India, the basic journals e.g. clinical pharmacology, pathology find it difficult to manage themselves, because of lack of advertisements.[47] Besides the advertisement, the many western journals also carry full text of approved information on a drug. This practice could help the journal in generating additional revenue and also help the reader in getting balanced information on a drug.

2.10.17 Hospitals pharmacies can also be a source of huge revenues. Many hospitals chains in India have their retail outlets. However, these are incorporated as different companies. The case of hospital pharmacy is that they can largely exploit spatial monopoly. There is no concrete hospital data in India. Even interviews conducted during the study could not reveal factual data concerning the same. A study had carried status of pharmacy practice was evaluated at six hospitals in India.[48] It notes that common drugs were available at private hospitals but the pharmacies at government hospitals had fewer than half of the needed drugs. It notes that selection of the best generic drug appeared difficult because the bioavailability and pharmacokinetic data generally were not available. The hospitals did not have formularies. No unit dose and intravenous admixture services had been implemented. The patient profiles were not maintained. The pharmacists did not appear to provide any professional, educational, or clinical services to patients or physicians. Serum concentrations of drugs were not measured for monitoring therapy. A lack of clinical education and training of pharmacists, lower status and salaries in the hospital pharmacy compared with industry and government, and overall limited resources appear to be the important reasons for the present status of pharmacy practice.[49]

2.10.18 The pharmaceutical sector despite its obvious importance of the sector to the economy is that there has not been any study aimed at assessing the extent to which anticompetitive practices that are potentially susceptible to challenges under the Competition Act, 2002. While the CUTS Study draws some anecdotal evidence, and there have been news reports in popular media, including medical and other journals highlighting the nexus between different actors in the supply chain emphasizes the need for a comprehensive study examining various issues is relevant for the purpose of this study. There is evidence of inefficient allocation of resources in the distribution of pharmaceutical products as studies available indicate that the profitability margins of different actors is quite high and keep huge mark-ups for non DPCO drugs and non-scheduled drugs in the pharmaceutical industry in India. This has implications on competition in the sector and unfair enrichment through wealth transfers.

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[45] Roy, Madhiwalla and Pai, Drug promotional practices in Mumbai: a qualitative study, Indian Journal of Medical Ethics, 2007 April-June 4(2)

[46] Drug promotion database

[47] Roy, Madhiwalla and Pai, Drug promotional practices in Mumbai: a qualitative study, Indian Journal of Medical Ethics, 2007 April-June 4(2)

[48] Kotwani A. et al. *Prices & availability of common medicines at six sites in India using a standard methodology.* Indian J Med Res 125, May 2007, pp 645-654

[49] *Ibid*

2.10.19 Many problems may occur when consumers find it difficult to evaluate the qualities of the products, as is the case in the pharmaceutical products. The problem is that the information asymmetries may prevent effective brand name generics from competing with innovator products, generic-generics competing with brand name generics and innovator drugs etc… In the pharmaceutical sector, it is known that the innovator drug is the standard of quality; the issue is not whether the innovator is effective, the issue is whether the generic is as effective as the innovator. There is a real danger, therefore, that consumers/ physicians who find it difficult/ costly to evaluate the qualities of generics might develop a strong preference for innovator medication, especially for the consumer who has had a bad experience with one generic medication in the past and decided to shun all generic medication.

2.10.20 The study also highlights the information structure of the pharmaceutical sector. It reveals the high degree of information asymmetries among consumers in pharmaceutical sector as it shows that a non-negligible proportions of consumers are without information that would be relevant to their decision making process. A 2007 study conducted by Centad on Consumer Drug Information also reveals the issues concerning consumer information asymmetries and the low level of awareness among consumers concerning the drugs they consume (Centad, 2007a). The extent of information asymmetries is an obvious candidate for the source of market power that exists in the distribution of pharmaceuticals and is therefore an area of concern for the CCI. The major objective of this sample study is to identify informational asymmetries and examine the extent to which business enterprises could exploit them to acquire, maintain or extend market power. The study recommends measures to address anticompetitive practices prevalent in the sector.

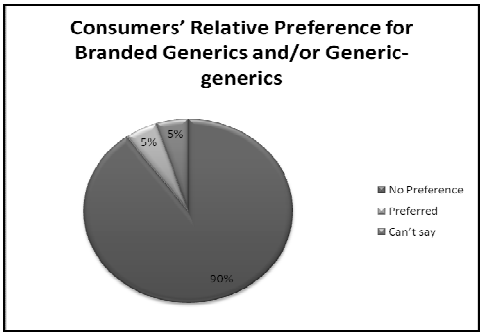
2.10.21 Market power of business enterprises is the central pre-occupation of competition law enforcement authorities. While having market power is not in violation of the competition laws in many jurisdictions across the world, but acquiring market power through unfair means is susceptible to a competition investigation. The massive pharmaceutical sector inquiry being launched by the European Competition Commission is testimonial of this assertion. To make this discussion simpler, we refer to *active* market power as that which accrues to businesses through their own deliberate conduct. To the contrary, *passive* market power can be referred to that which accrues to businesses due to actions (or inactions) of independent parties. Competition law is designed to curtail the abuse of active market power which poses a threat to the competitive environment. While the focus on active market power is justified, there is little reason to suspect that passive market power is any less threatening to competition. Indeed, it is well established that the consumers' ability (and willingness) to shun unreasonably high priced products is an important feature of competitive markets. When consumers lose this ability because of say, ignorance of lower priced alternatives, firms are able to abuse passive market power and maintain prices above competitive levels.

2.10.22 It is noted by many studies that information asymmetries in a market can be exploited by firms to acquire, maintain and extend market power. Since the information structure of the market could facilitate the abuse of both active and passive market power, understanding the information structure is of fundamental importance in promoting competition in markets. The pharmaceutical sector has attracted the attention of both practitioners and academic economists alike. For practitioners, the fundamental preoccupation is how to make pharmaceuticals accessible to more final consumers, given the intimate link between access to pharmaceuticals and the quality of the consumer's life.

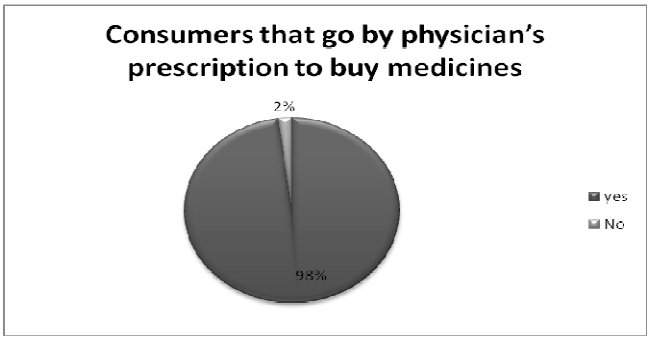
2.10.23 The attitudes and opinions of major stakeholders about the substitutability of prescription medication vary intensely. There is evidence to suggest that consumer preference for branded and generic prescription medication is related to relative prices, reputation and budget constraints. The Indian pharmaceutical market has three types of substitutable drugs being sold. The first category includes originator drugs (patented or newly innovated) - they have a brand name. The second category includes brand name generic drugs. The third category is generic-generic drugs- which are sold without a brand name. Perception survey conducted as part of this study suggests that the following:

- Consumers' Relative Preference for Branded Generics and/or Generic-generics.

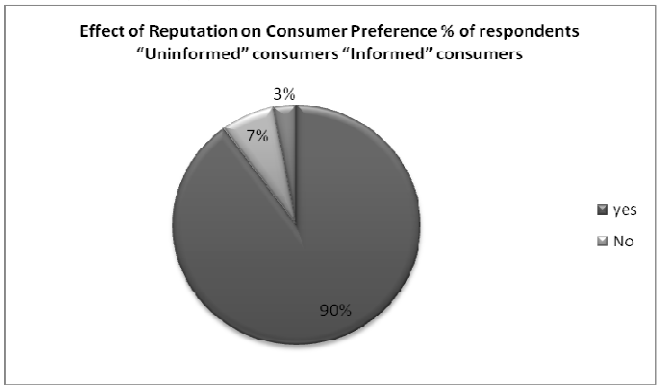
Consumer Response	Per cent
No Preference	90%
Preferred	5%
Can't say	5%



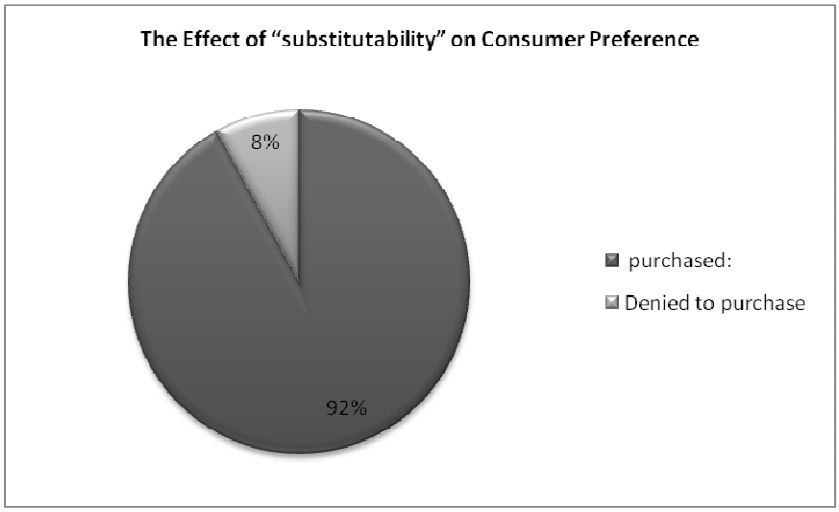
- 98% Consumers that go by physician's prescription



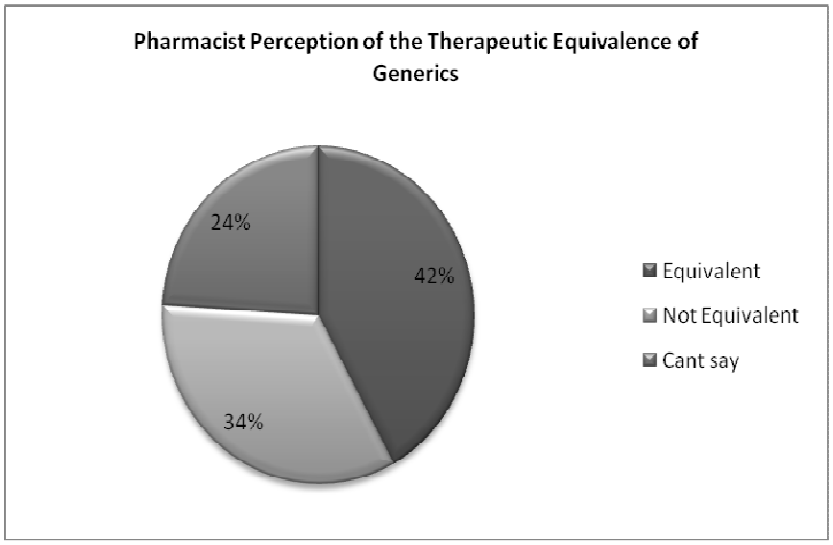
- Effect of Reputation on Consumer Preference % of respondents "Uninformed" consumers "Informed" consumers- Yes: 90% No: 7% can't say 3%



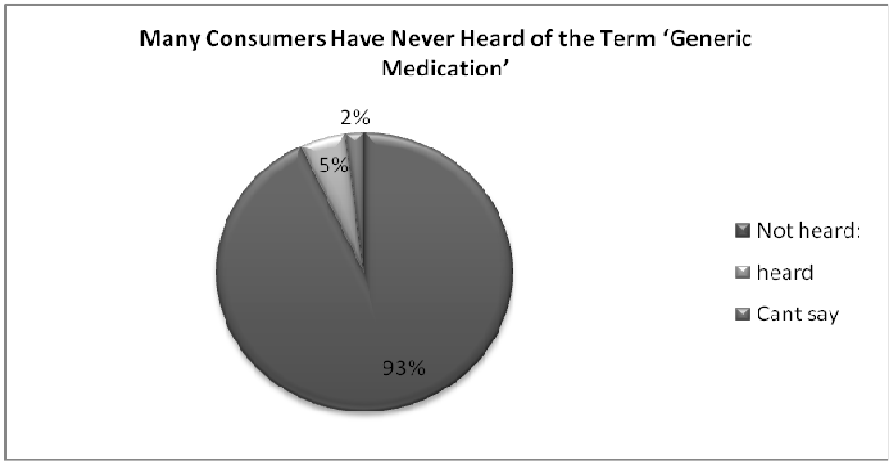
- The Effect of "substitutability" on Consumer Preference for % of respondents. Consumers denied to purchase 92%; purchased: 8%



- Pharmacist Perception of the Therapeutic Equivalence of Generics % of respondents. Equivalent: 42% No: 34% Cant say: 24%



- Many Consumers Have Never Heard of the Term 'Generic Medication'. Not heard : 93% Heard: 5% can't say: 2%



2.10.24 Thus the weak options for consumer choice is a source of passive market power in prescription drugs market. Harriott (2005) demonstrated that the importance of simultaneously modelling information acquisition and

information dissemination, in terms of furthering our understanding of the nature of markets with asymmetric information. The main point of his research was that whenever there is asymmetric information in a market, there will always be an incentive for the uninformed to acquire information and consequently incentives for the informed to disseminate information. To understand these markets, one must explicitly take account of the information acquisition and dissemination mechanisms, as failing to do so might eliminate important interaction effects between the two mechanisms on the market. He demonstrates this point in making a contribution to the on-going debate on the effect of advertising on competition. This study examined the extent to which there are differences in the *perceived* therapeutic effects of branded and generic medication among consumers, physicians and pharmacists.

2.11 Drug Procurement in India

2.11.1 Drug procurement in India is done largely by the government. However, it is not more that 10% of the overall expenditure on health. Hence it constitutes a small but significant figure in consumption of pharmaceuticals in India. The overall expenditure on drugs spent by the GOI in 2008 stood at Rs. 18890 crore vis-à-vis a total expenditure of 1962636 crore spent on health. This represents 9.63% of total health expenditure spent on drugs (see Annexure IV for more details).[50] Drug procurement on behalf of the government is undertaken by various ministries, primarily the health ministry. There are special programmes undertaken by the government. They are also actively involved in procurement.

2.11.2 Good procurement is a key to access to quality and appropriate medicines. "Operational Principles for Good Pharmaceutical Procurement", a guide developed by the WHO can be a good starting point in developing best practices in procurement. Drug procurement is generally done to achieve the following objectives:[51]

- the most cost-effective drugs in the right quantities.
- Select reliable suppliers of high quality products.
- Ensure timely delivery.
- Achieve the lowest possible total cost.

2.11.3 The NIPER study noted down 12 guiding principles of good pharmaceutical procurement, grouped in four categories, which include A) Efficient and Transparent Management B) Drug Selection and Quantification C). Financing and Competition D) Suppliers Selection and Quality Assurance. Readers are invited to refer to the NIPER study for a detailed examination of the Delhi State, Orissa State, AP State models and the Tamil Nadu model. Prior to 90's drug procurement in most states was decentralized. However, problems in shortage and wastage have led to centralization of drug procurement in most states. There is considerable difference between retail prices and tender prices under procurement schemes. It is noted that difference in retail v tender price may vary for more than 1000% (Selvaraj, 2009). Table 2.35 provides an overview of price variations in detail.

[50] Saktivel selvaraj – TPSA workshop (2009)
[51] Niper Study on Drug procurement (2006)

Table:2.35 High drug price - retail and tender price

Disease conditions	Therapeutic drug	Formulation	Strength and No.	Retail Price (Rs.)	TNMSC price (Rs.)	Price difference (%)
Cancer	Cyclophsphamide	Endoxan-N	50mg;10	36.35	13.218	275
Cancer	Fluorouracil	Fluracil	5ml	11.67	1.001	1166
Child and infectious disease	Chloramphenicol	Chloromycetin	250mg;10	30.76	4.4	699
Child health	Phenytoin Sodium	Dilantin	100mg;10	131.55	9.75	1349
COPD and Asthma	Betamethasone	Walacort	0.5mg; 10	3.55	1.043	340
COPD and asthma	Salbutamol	Asthalin	4mg;10	5.21	0.522	998
CVD	Verapamil	Veramil	40mg;10	5.02	4.392	114
CVD	Atenolol	Aten	50mg;14	25.75	1.2	2146
Diabetics	Insulin NPH	Actrapid	10ml	129.28	86.85	149
Diabetics	Glibenclamide	Daonil	5mg;10	6.60	0.454	1454
Injuries	Bupivaccine HCl	Sensorcaine	0.5%;20ml	34.34	15.5	222
Injuries	Ketamine	Ketalar	50mg;10ml vial	89.50	15.15	591
Japanese encephalitis	Ceftriaxone	Lyceft	1g;vial	90.00	16.11	559
Lymphatic Filariasis	Diethylcarbamazine	Banocide	50mg;10	3.88	0.707	549
Malaria	Chloroquine	Melubrin	250mg;10	4.36	2.233	195
Maternal health	Carboprost	Prostodin	1amp	80.13	68.5	117
Maternal health	Ferros Sulphate	Ferrochelate-Z	150mg;10	19.94	0.495	4028
Mental health	Chlorpromazine	Chlorpromazine-NP	25mg;10	5.95	1.81	329
Mental health	Alprazolam	Alprocontin	0.5mg;10	22.55	0.442	5102
Tuberculosis	Rifampicin	Rifacilin	150mg;100	99.68	66.6	150
Tuberculosis	Pyrazinamide	PZA-Ciba	500mg;10	42.46	5.188	818
Others	Rantidine	Consec	150mg; 10	7.51	2.205	341
Others	Dopamine	Dopinga	5ml	25.00	6.05	413
Others	Ciprofloxacin	Ciplox	200mg;100ml	27.00	6.41	421
Others	Paracetamol	Calpol	500mg;10	8.78	1.24	708
Others	Diclofenac Sodium	Diclonac	50mg;10	11.03	0.686	1608
Others	Diazepam	Calmpose	5mg;10	13.70	0.4	3425
Others	Dexamethosone Sodium Phosphate	Decdan	2ml	10.36	0.222	4667
Others	Cetrizine	Alerid	10mg;10	31.50	0.561	5615

Source:For Retail Price—Monthly Index of Medical Specialities, India, August, 2004
For TNMSC Price—Tamil Nadu Medical Services Corporation (TNMSC). Available from URL: http:/www.tnmsc.com/system.html

Source: Sakthivel Selvaraj (2009)

2.11.4 The study has examined the most popular drug procurement model of the Tamil Nadu Medical Services Corporation, popularly called as the "Tamil-Nadu model". Established in 1995, the model has proved to be one of the most efficient ones in drug procurement. The success of the TNMSC model is because it has larger involvement of multi-stakeholders in selection and finalization of the drug requires to be procured. The tendering process is based on the TN Transparency in Tenders Act, 1998 and rules of 2000. The TNMSC initially finalized the list of essential drugs to be procured largely as per the WHO's Model List of essential drugs. TNMSC has 271 items of drugs and medicines on its list, accounting for around 90% of the budget outlay for the purpose, leaving other drugs of small quantities to be purchased locally by the institutions from out of the remaining 10% budget. The TNMSC follows WHO's recommendation for the use of the international non-proprietary name (INN, commonly known as generics) for each drug. This is a major source of generic competition since brand preference is not allowed. In order to ensure the procurement of only quality drugs at competitive prices, an open tender system is followed and purchases are made only from manufacturers and not through agents or distributors. It is important to note that the TNMSC model requires participation from only such manufacturers that have a GMP certificate and also have a market standing for at least three years. A minimum turnover is also fixed in order to eliminate the very small firms since such firms may fail to keep delivery commitments. It is interesting to note that the TN model allows for a flexibility margin of 15% as earnest bid required from the small scale industry. Excessive dependence on one supplier is abated as the next two lower suppliers willing to match the lowest price are also approved.

2.11.5 After due advertisement, tenders are sought in two covers- one for the technical bid and other for the price bid. There are clear guidelines and forms for submission of both the bids. Once the bids are received, as series of finalization and evaluation process is undertaken. While there is general downward trend in prices, studies show that the year 2007-2008 saw an increase in prices of more than 50% of drugs procured.[52] It is noted that competition is low in case of high-priced specialty drugs. The reason is also that there are very few companies participating/ manufacturing speciality drugs. A detailed overview of price variation and competition in speciality drugs is provided in table 2.36.

[52] Draft study, Maulik Chokshi (2009)

Table 2.36 Expenditure on and competition in speciality Drugs under the TNMSC model

Drug Code	Name of drug	% of total expenditure 2007-2008	Number of Companies	Price variation
G293	Temozolamide cap USP	52.52	2	99998-170000
G111	Geftinib tab	7.87	1	22121-79740
G92	Etoposide cap	3.92	3	1945-5625
G168	Linzolide tab	3.07	3	2750-3925
G15	Amiodrone	1.61	2	142-278
G209	Ofloxacin tab	1.24	15	73.74-178
G127	USP	1.17	2	265-441.95

Source: Maulik R. Chokshi (2009 draft) TN Public Drug Procurement Model

2.11.6 The implementation of the Government of Tamil Nadu of the TNMSC model in drug procurement and management has improved availability of drugs in nearly 2000 government medical institutions throughout the State.[53] The competitive procurement system has resulted in savings in the outlay on drugs to the extent of 36% of the allocation. This would surely ensure bringing down of state budgets on health.

[53] NIPER study (2006)

THE REGULATORY WEB OF THE PHARMACEUTICAL SECTOR IN INDIA: ITS IMPLICATION FOR EX ANTE COMPETITION

3.1 Patent Law and *Ex ante* Competition policy in Pharmaceuticals

3.1.1 Intellectual property rights are a form of statutory monopolies granted to ensure disclosure of inventions and creative outcomes which would have otherwise remained secret. Patents protect technical embodiments of inventions and are considered to be the strongest form of legally granted monopolies amongst the various categories of intellectual property rights. Since it is the strongest form of market intervention, it is bound to have certain effects on competition (Ghidini, 2006, p. 13; FTC, 2003). Patents are a category of legal monopolies granted to inventions that have legally subscribed level of novelty, inventive step and industrial capacity. Monopolies in the form of patents can be strongest in the absence of substitutes for the product or consumer behaviour working in favour (passive market power) of the patented product due to information asymmetries in the market. However, the debate about optimality in patent scope in terms of patent breadth (scope of claims through interpretation, including patent eligibility and patentability thresholds) and length of patent duration has traditionally been controversial.[54] As Ghidini notes[55]:

> "It is noteworthy that more contemporary authorities such as Chamberlin, Scherer, Scotchmer express not dissimilar concerns about the anti-competitive effects generated by a system of patents (and intellectual property rights in general): the more so vis-à-vis the oligopolistic scenarios in which the current innovation process are typically situated, especially in the "network industries". Of course today there is greater awareness that patent rights relate to a specific technical solution and not the type of utility (and consequently not to a field of activity, as in the case of a real monopoly right)".

3.1.2 It is often argued that patents generate consumer welfare by introducing new products in the markets and thus making creative destruction as an on-going process. Further, from a transactional perspective patents also provide markets for technology (Arora, 2008). It is also argued that patents are necessary, especially in the pharmaceutical industry (with linear innovation model) (Malerba and Orsenigo, 2001). Even the most ardent critiques of the patent system believe that patents are of immense importance for the private pharmaceutical industry, without which many breakthrough inventions might not have occurred at all (Scherer, 1998 Taylor and Silverston, 1970). However, strong and broad patents do exclude competition for a certain period of time (Orsi and Coriat, 2005). It must be noted that the patent system has grown out of enough flexibilities until the TRIPS Agreement of 1995, which has now set the common minimum binding standards for all WTO member countries. Developed countries have used such flexibilities from time to time depending upon policy needs and their development context. From a policy perspective, it may be noted that many developed countries had even excluded product patents on pharmaceuticals until 1970s.[56] However, it is now argued by many that such policy space has considerably reduced post-TRIPS and this situation can have immense implications for access and affordability of medicines (Musungu, 2006).

3.1.3 It wouldn't be an over statement to emphasize that there are many positive elements in the modern patent system. However, it has always remained as a second best choice- mainly to prevent market failure through an interventionist approach. As explained by Prof. Fritz Machlup in the illustrious review of the American patent system, notes: "since we have had a patent system for a long time, it would be irresponsible, on the basis of our

[54] NBER (2000)
[55] (Ghidini, 2006, p. 13)
[56] For example, Switzerland, Italy etc which introduced product patents in pharmaceutical only at the beginning of 1970s

present knowledge, to recommend abolishing it.' (Machulp, 1958 p. 76). The experience of the developed countries in the last three decades also reflects the limitation of the modern patent system in promoting uniform economic growth (EPO, 2007). It is not conclusively, nor empirically being demonstrated that the patent system has a positive role in local innovation in developing economies (WIPO, 2008; CIPR, 2002). In fact, some have argued that it is a mere extension of first world standards for monopolies into developing country context (Abbot, 1989). However, considering that there are flexibilities in the TRIPS agreement, including limitation and exceptions and non-voluntary uses, it remains to be seen how the patent law and jurisprudence evolve and interact with larger policy concerns of access to medicines at affordable prices to Indian consumers.

3.1.4 The Patent Act 1970 follows a distinctive approach in identifying the patentable subject matter under section 3. This provision has substantially remained unchanged even after the recent amendment in 2005 (third amendment 2005). While the important definitions are given in section 2 & 3 of the Act, they collectively contribute in identifying inventions that are not eligible for patent protection. One of the main objectives of excluding certain subject matter from patents scope or to exclude patentability by keeping a high threshold of patent law thresholds is the protection of public interest involved in identifying and limiting the areas that require monopoly protection (Gopalakrishnan, 2009). Among other important policy levers that have a wider import, provisions relating to research exemption, *Bolar* exemption, parallel imports, government use, compulsory licensing are also discussed in this report. Since the 1970s, as noted above, in the case of pharmaceutical patents, local production of generic drugs and cheaper access to essential drugs formed part of the strategy to place limits on the nature and scope of patent law protection. But certainly, considering TRIPS being the watershed, this position stands altered. This report examines few issues in Indian patent law provision, including the interpretations that have developed through case laws.

3.1.5 ***Scope of Patentability and Patent-eligibility: The Section 3(d) Conundrum****:* Many expert reports and commentators have emphasized that patents should be granted to noteworthy inventions by maintaining a higher level of inventive step (CIPR, 2002).[57] This, they argue, would exclude certain category of inventions in incrementally modified drugs (IMDs) from the protective gear of the patent system. There is firm consensus that new chemical entities do need patent protection. However, a persistent inquiry in connection with IMDs has been about the approach that the India would take to iron out from section 3(d) inventions that are patentable and those that are not patentable by fixing the correct benchmark. This remains solely a matter of domestic policy choice. Moreover, Article 27.1 of the TRIPS Agreement does not define these standards in any concrete terms and hence countries have flexibilities in determining the nature of protection (Gopalakrishnan, 2006). However, as argued by some commentators, it does not give a *carte blanche* to WTO member countries to arbitrarily set such standards so as to violate the provisions in the TRIPS agreement, either directly or indirectly excluding a category of inventions (Basheer, 2005).[58] It is also argued that the same time that in case of pharmaceuticals, it a stricter interpretation of patents claims and scope is warranted to weed out patents on incremental modifications, second uses and other derivatives that do not represent significant innovation and to prevent "ever greening".[59] (Correa, 2006).

3.1.6 Section 3(d) is one of the most intensely and widely discussed, though much controversial provision in the Indian Patent Act, 1970 as amended in 2005. Section 3 (d), which has been reintroduced as a safeguard clause to avoid broad patents in the area of pharmaceuticals. Section 3(d) reads as follows**:**

[57] As a prominent commentator points out "patents should be granted only for inventions that are really novel, that are really non-obvious or really have a substantial inventive step, that are really useful or really technological, and that are really enabled" (Barton, 2004).

[58] The main criticisms against it are relating to TRIPS compatibility and potential negative impact on indigenous innovation (Mueller, 2007). However, since it is not of much relevant to this report, the issue of TRIPS consistency is not discussed.

[59] As a commentator notes "ever-greening refers to a variety of legal and business strategies by which technology producers with patents over products that are about to expire, retain rent from them by either taking out new patents (for example over associated delivery systems, or new pharmaceutical mixtures) or by buying out or frustrating competitors, for longer periods of time than would normally be permissible under the law" (Faunce and Lexchin, 2007)

> *…the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance* or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> *Explanation*.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, *unless they differ significantly in properties with regard to efficacy*;

3.1.7 Although the major intent of this provision is to prevent what is normally called as "ever-greening" in the pharmaceutical patent circles, it has not lived up to the certainty that is expected out of the legal provision. The word "efficacy" used in the section has been of intense confusion. The "enhanced efficacy" criterion is a variant of the application of the inventive step criterion. While the purpose of this provision seems to exclude certain forms of inventions by using a higher patent law threshold of inventive step, there is no prima-facie clarity on what is excluded through this exercise. Hence since its inception it has landed in troubled waters and the courts have been asked time and again to come out whether or not some form of invention in hand is patentable. However, it is noted by experts that 3(d) is not a mere "paper tiger".[60] Out of 68 cases so far where a pharmaceutical patent application was opposed by generic companies and/or public health groups, the patent office rejected the patent in 46 cases (i.e. approximately 68% of the time). In these 46 rejections, around 60% (28) were based on failure to comply with section 3(d).[61] This briefly illustrates the importance of section 3(d) in preventing "evergreening" of pharmaceutical inventions.

3.1.8 This provision excludes mere discovery of new forms (derivatives) of known substances from patentability unless they result in the enhancement of known efficacy of the substance. This "efficacy" provision is further explained to mean differing "significantly in properties with regard to efficacy". This restriction is aimed at circumventing ever-greening of patents. However, there is distinction between what amounts to ever greening and what are generally called as incrementally modified drugs is tricky. Ever-greening is a routine business strategy to delay generic competition (EU Competition Commission, 2009). For example, the EU commission report notes:

Box: 2 Findings of the European Competition Commission's Inquiry into the Pharmaceutical Sector

"The strategies observed include filing for a large number of patents in relation to a single medicine (so-called "patent clusters", up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding more than 200 settlement agreements with generic companies which partly restrict generic entry and lead in certain instances to value transfers from the originator to the generic company and intervening in national procedures for the approval of generic medicines. The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer".[62]

3.1.9 Hence this is a significant provision, and when interpreted using higher standards of patentability, can successfully work in improving generic competition by weeding out pharmaceutical inventions unworthy of patents. However, much is desired from the legal certainty that this provision must have. It is widely noted that originator companies (R&D based pharmaceuticals) resort to a variety of practices to extend the commercial life of patents. One way of doing this is to file multiple patents on variants. This is also confirmed by the EU Competition commission sector inquiry where it notes that 'originator companies use a variety of instruments to extend the commercial life of their medicines. The results of the sector inquiry suggest that the behaviour of companies contributes to the generic delay".

[60] Basheer S. www.spicyIP.blogsot.com
[61] Basheer S. www.spicyIP.blogsot.com
[62] EU Competition Commission, 2009, p. 521

3.1.10 Section 3 (d) also excludes from patentability, new methods of using known substances. This makes the Indian law different from the U.S. and the European systems, which have no similar provision in their patent laws. There is much criticism with respect to the term "efficacy", since 3(d) is silent in providing the much needed guidance. However, irrespective of an unsettled position in law- which will surely be clarified through case law developments, 3(d) is surely a public-health safeguard. International business community, mainly propelled by the pharmaceutical MNCs, has time and again proclaimed that 3(d) results in dis-incentivizing pharmaceutical inventions in IMDs.[63] But no study has conclusively proved through economic evidence that pharmaceutical innovation would be reduced locally in the presence of section 3(d).

3.1.11 By taking the infamous Glivec patent case, it is demonstrated that section 3(d) can work effectively by excluding many forms of incrementally modified drugs. Box … provides a brief overview of the case.

Box: 3 The Novartis Invention in Glivec and Section 3(d): The Jury is not yet out!

Dr. Brian Drucker along with two Novartis researchers created and tested a number of molecules to find out the target for a cancer causing kinase enzyme. Their efforts paid success with the invention of 'Imatinib' free base. Novartis filed patents covering Imatinib, including all pharmaceutically acceptable salts (US Patent Number: 5521184, titled: "Pyrimidine derivatives and processes for the preparation thereof"- filed in April 1993 and issued in May 1996). Improvements in the imatinib free base led to the conversion of it into a salt form called 'imatinib mesylate' Subsequent research by Novartis proved fruitful with the invention of 'Glivec'- a beta crystalline form of imatinib mesylate- which was the most stable version of a particular polymorphic form. Since its first acceptance by the US FDA, Glivec has proved effective in patients and Novartis has claimed that around 40 patents covering the polymorph has been granted in various countries. Novartis filed a mail-box application in 1998 in India ("Crystal modification of A N-Phenyl-2-Pyrimidineamine derivative, processes for its manufacture and use", Application No.1602/MAS/98- July 17, 1998). As the EMR regime was then in place in India, Novartis applied for EMRs pending the patent grant. Litigation on the validity of EMRs resulted in Novartis being sued by CIPLA and Ranbaxy in Madras and Mumbai High courts.[64] The Madras and the Mumbai High courts gave contrary decisions on the same subject matter. The Madras HC held the EMR valid by relying on Novartis GIPIP programme which doled out Glivec free of cost to patients who could not afford it in India. The Bombay HC emphasized that public interest warranted that generic producers should not be hit by the grant of EMRs especially when the validity of the invention is being seriously questioned by the courts. But none of the courts took resort to examining the application in question. This classically highlights the tension prevailing on the very validity of the invention applied for a patent.

Post -2005 amendments and with the opening of the mail-box applications, the Glivec patent application was challenged at the patent office by NGO and Cancer Patients Association on grounds of lack of novelty, obviousness, wrong priority and as violative of section 3(d). The patent office denied the patent on the above grounds. Novartis then moved the High court of Madras by filing writ petitions to declare that 3(d) was unconstitutional and also that it was in violation of India commitment under the TRIPS Agreement. The Madras High Court declined to give any judgment on the issue of TRIPS consistency stating that it lacked jurisdiction in the matter. On the issue of constitutionality, the court stated that section 3(d) was perfectly constitutional. It said that there was enough "in-built materials in the amended section and the Explanation itself, which would control/ guide the discretion to be exercised by the Statutory Authority. In other words, the Statutory Authority would be definitely guided by the materials to be placed before it for arriving at a decision"[65]

Further, in answering the question as to what amounts to "enhancement of known efficacy", the court invoked an interpretation by confirming that "efficacy" amounted to therapeutic efficacy.[66] It concluded by stating that it is scientifically

[63] USIBC, 2009

[64] Novartis AG v Adarsh Pharma & Anr., 2004 (29) PTC 108 (Mad). *Injunction confirmed in* Intas Laboratories Pvt. Ltd. v Novartis A.G. 2005 (1) CTC 27. For the Mumbai HC decision see, Novartis AG v Mehar Pharma & Anr., 2005 (30) PTC 160 (Bom).

[65] In *Novartis AG v. Union of India*, (W.P. Nos.24759 and 24760 of 2006 decided on 06.08.2007)

[66] *Ibid* It noted: "Dorland's Medical Dictionary defines the expression "efficacy" in the field of Pharmacology as "the ability of a drug to produce the desired therapeutic effect" and "efficacy" is independent of potency of the drug. Dictionary meaning of "Therapeutic", is healing of disease - having a good effect on the body." Going by the meaning for the word "efficacy" and "therapeutic" extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease / having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though preceded by research, - we state - for any Patent applicant to place on record what is the therapeutic effect / efficacy of a known substance and what is the enhancement in that known efficacy. The amended section not only covers the field of pharmacology but also the other fields. As we could see from the amended section, it is made

possible to distinguish between properties of derivatives and the substance already claimed.[67] The Madras HC transferred the petition on the issue of reversal of the patent office's order to the Intellectual Property Appellate Body (IPAB) to be decided on merits. It is pertinent to note that as per the Madras HC judgment in Novartis Glivec will not qualify for a patent since the invention in question must show discovery of a "better therapeutic effect" and that the disease must have a good effect on the body. The Madras HC decision places an inherent limitation on derivatives, including inventions that provide for increased heat stability and novel drug delivery systems, and hence such inventions would not pass the 3(d) threshold (Basheer, 2008). The draft manual of the Intellectual Property Office presumably upholds this interpretation. The Draft Manual of Patent Procedure and Practice 2008 also quote from the Madras High Court decision in *Novartis case* for explaining the term "efficacy". In the light of the discussion above, it must be noted that 3(d) limits the treatment of "efficacy" to therapeutic efficacy.

Pursuant to the Madras HC judgment, the IPAB rendered its much awaited decision on 26th June 2009. While the IPAB came out with the right decision to deny the patent, it reasons are completely flawed. Unfortunately, the IPAB found that there exists and inventive step in the Glivec patent application. It notes: "We also believe that without a thorough research such a discovery could not have been possible. The Appellant has surely made a technical advance as compared to the existing knowledge by way of demonstration of polymorphism, isolation, characterization of beta (and alpha) crystal forms of imatinib mesylate, identifying suitable properties in the beta crystal form useable in the making of oral solid drug formulation for curing cancer". Reversing the patent office's decision finding of lack of inventive step, the IPAB further noted that: "It is the fact that no one could predict the possibility of existence of polymorphism in imatinib mesylate before the impugned application. There was no motivation also by an uninventive man to try for finding out different polymorphic forms and their relative properties suitable for preparing for solid dosage formulation for cancer drug. Thus, we cannot agree with any of the Respondents that the Appellant's alleged invention lacks inventive step. IPER and the decision of the Board of Appeals and Interferences of USPTO also upheld existence of inventive step. We thus reverse the R 8's decision on inventive step in his impugned orders". In clear terms, the IPAB cleared the patent on the issue of inventive step by relying on USPTOs inference of what should constitute inventive step.[68]

However, on the issue of section 3(d), the IPAB denied the grant of patent noted that "We have also already observed that bio-availability is not the same as therapeutic efficacy [paragraph 9(xviii) supra]. Therapeutic efficacy is different from advantageous property of a drug [paragraph . 9(xxi) supra] Appellant cannot make its own conclusion on the meaning of efficacy [paragraph 9(x) supra]. Imatinib mesylate as such and its beta form are therapeutically same substances [paragraph 9(xxiv) supra] and also beta form of imatinib mesylate and imatinib are same substances with regard to efficacy [paragraph 9(xxv) supra]. It is also observed that imatinib mesylate is a known substance [paragraph 9 (xvi) supra]. From our above observations we have convincingly come to the conclusion that by demonstrating enhanced bio-availability of 30% which also is obvious, because of increased solubility of the salt in water, the Appellant could not show any actual enhancement of known efficacy for its subject compound with respect to either imatinib or imatinib mesylate as the known substance. Thus, we obviously can finally conclude that Appellant has failed on account of efficacy requirement for its beta crystalline form of imatinib mesylate under section 3(d) of the Act".

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applicable to even machine, apparatus or known process with a rider that mere use of a known process is not an invention unless such a known process results in a new product or employs at least one new reactant. Therefore the amended Section is a comprehensive provision covering all fields of technology, including the field of pharmacology. In our opinion, the explanation would come in aid only to understand what is meant by the expression "resulting in the enhancement of a known efficacy" in the amended section and therefore we have no doubt at all that the Explanation would operate only when discovery is made in the pharmacology field."

[67] The court said: 'Scientifically it is possible to show with certainty what the properties of a "substance" are. Therefore when the Explanation to the amended section says that any derivatives must differ significantly in properties with regard to efficacy, it only means that the derivatives should contain such properties which are significantly different with regard to efficacy to the substance from which the derivative is made. Therefore in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the Patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy".

[68] It is also interesting to note that in *Pfizer Inc. v. Apotex Inc.* 480 F. 3d 1348 (Fed. Cir. 2007), a post KSR decision from the US Federal Circuit, discounting the physical properties of improved stability and tablet processing, the court focused only on whether there was any therapeutic effect. It could be seen that the post KSR decisions tend to set the non-obviousness standards for inventions relating to pharmaceuticals and biotechnology higher.

This leads one to conclude that there is a lot of consistency in what the IPAB has decided with reference to the inventive step criterion and with respect to section 3(d). The only reason that the IPAB has given based on the reading of section 3(d) is by drawing the difference between therapeutic efficacy and other advantageous property of a drug. The obvious inference seems to be drawn from the Madras HC decision in 2007. The IPAB however has added no value in real terms in explaining why 30% bioequivalence as claimed by Novartis does not merit a patent. It remains to be seen how the appeals court would decide on this matter.

The most deleterious effect of the IPAB decision comes from the IPAB's reasoning on why the Novartis patent is unworthy on other grounds. The IPAB notes: "Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India [See also paragraph 9(xix) above]. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances. This is also one of the different public interest provisions adopted in the patent law at the pre-grant level, as we see, are also permissible under the TRIPS Agreement and to accommodate the spirit of the Doha Declaration which gives to the WTO member states including India the right to protect public health and, in particular, to promote access to medicines for all. This is also reflected in the said Novartis AG v. Union of India and others (2007) 4 MLJ 1153"
There seems to be apparently no reason for the IPAB to refer to the TRIPS agreement or the Doha Declaration and it permissibility of section 3(d) or any other provisions in the Act. As far as the intention of the provision is concerned, the IPAB's reasoning is flawed inasmuch as it states that "section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances". This contradicts with its own position of dissecting the inventive step criterion and examining it separately irrespective of what section 3(d) requires. It also contradicts with the Madras High Court's decision which emphasized that section 3(d) does not make any such distinction. Even while the policy reason for introducing section 3(d) may be to ensure greater access to medicines, the IPAB sitting in judgment as a technical Board on a technical issue of the whether or not the invention claimed in the Glivec application is patentable, should not have even referred to such extraneous factors. One may wonder whether this part of the decision forms the ratio of the case of was it just an opinion- in the nature of *obiter.*
Further, the most troubling part of the decision appears in the IPAB's discussion on the GIPAP programme of Novartis which provides free distribution of Glivec to Cancer patients. The IPAB notes:
"We are fully conscious of the Appellant's benevolent GIPAP program for free distribution of GLEEVEC to certain cancer patients. But as per information furnished in its written counterargument by R 3 that when the Appellant was holding the right as EMR on GLEEVEC it used to charge Rs. 1,20,000/- per month for a required dose of the drug from a cancer patient, not disputed by the Appellant, which in our view is too unaffordable to the poor cancer patients in India. Thus, we also observe that a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well. Considering all the circumstances of the appeals before us, we observe that the Appellant's alleged invention won't be worthy of a reward of any product patent on the basis of its impugned application for not only for not satisfying the requirement of section 3(d)of the Act, but also for its possible disastrous consequences on such grant as stated above, which also is being attracted by the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder among other things We, therefore, uphold the decision of R 8 on section 3(d) of the Act to the extent that product patent cannot be made available to the Appellant, but the Appellant cannot be deprived of its fruit of research for developing a process for preparing the beta crystalline form of imatinib mesylate".
One would wonder why such a discussion actually figured in the context of 3(d). Is unaffordability of the drug an additional criterion satisfying section 3(d) of the Act? The appeals court is likely to strike down this reasoning. But it remains to be seen if the appeals court could give a more palpable reasoning by interpreting the patent eligibility and patentability criterion in the light of Section 3(d) of the Act. The jury is not yet out!

3.1.12 From an *ex ante c*ompetition point of view the above discussion makes it clear that attempt has been made in the amended patent law in India to confine patent protection only to those inventions that maintain a high quality and also to ensure that many areas of public interest remain outside the purview of patent monopoly. This trend is also witnessed in decisions post KSR in the US.[69] The amendments to the Indian Patents Act, 1970 clearly reflect a

[69] This is also clearly reflected in the recent observation of the US Supreme Court in *KSR International v. Teleflex* 550 US 398 (2007). It noted: "We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a

nuanced approach to avoid pitfalls by granting patents to minor variations of inventions. These latest amendments are influenced by the standard laid down by the Supreme Court in *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries* (1979) 2 SCC 511), based on the provisions of the Act before amendment. While it is controversial if the appellate courts would consider the Supreme Court's seminal decision in that case due to change in definitional provisions of the Act, it would not be totally since the spirit of patent law and policy since the inception of the 1970 Act. The Supreme Court laid down strict standards for patenting new invention, that too if the invention is an improvement of existing technology. The observation of the Court is quite pertinent:

> It is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an "inventive step". ***To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before.***[70]

3.1.13 The recent judicial trend in case law developments show the emergence of a complex set of problems in determining principles of infringement, especially in the pharmaceutical patent law context. It is pertinent to note that the availability or non-availability of injunctions is important from a competition policy perspective because it is a measure to promote or defeat introduction of generic products in the market and the incentive to continue with production. It can also have a spiral effect of generic production if injunctions are skewed in favour of the originator industries. A nuanced law and policy framework on injunction in balancing the conflicting interests involved in a patent litigation is a must. Patent law in India has no specific mention about the principles to be followed in finding out the infringement of rights, especially in cases where the validity of the patent is challenged on the basic grounds of lack of novelty and inventive step- which are so fundamental to the very issue of why patent grants must be *per se* valid. Same is the case with the principles to be followed in granting temporary reliefs such as injunction, that too when the patent is only recently acquired.

3.1.14 It is pertinent to note the influence of foreign judgments in the development of Indian patent jurisprudence. While applying the general norms in the Civil Procedure Code, the courts have been trying to evolve new norms based on the experiences from other jurisdictions, which may at times swing the pendulum in different directions. The problem is acute in case of recently granted patents of which the validity is questioned since the patent law is silent on these aspects. One of the important and interesting issues is regarding the norms to be followed while granting temporary injunction in cases where the allegation is infringement of a recently granted patent. This issue was addressed by the Gujarat High Court in *Cadila Pharmaceuticals Ltd., v. Instacare Laboratouries Pvt. Ltd.* 2001 PTC 472 (Guj). The argument was that the patent was granted to the plaintiff in India in March 2000. Thus in a suit for infringement of patent, the defendants opposed the grant of temporary injunction and challenged the validity of the patent on the ground of lack of novelty. It was argued by the defendant, *inter alia,* that since the patent is of

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new threshold from which innovation starts once more. And as progress beginning from higher levels of achievements is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Where it otherwise patents might stifle, rather promote, the progress of useful arts".

[70] The observation of the Court on the standard of inventive step quoting from Encyclopedia Britannica is worth quoting:

> A patentable invention, therefore, must involve something which is outside the probable capacity of a craftsman — which is expressed by saying it must have 'subject-matter' or involve an 'inventive step'".
>
> "The expression "does not involve any inventive step" used in Section 26(1) (*e*) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of patent law. The **"obviousness" has to be strictly and objectively judged"**.

recent origin and the defendant entered the market in 2000 itself, there is considerable doubt as to the validity of patent and the request for the injunction must be rejected. In what may be explained as a block exemption in favour of patent infringers who have already placed the infringing product in the market, the Court interestingly observed that :

> If, *prima facie,* the process evolved by the appellant is not found to be patentable, the defendant cannot be restrained from using the said process for its products and marketing them. In the present case, as referred to herein above, the defendants have already entered the market with their products…sometime in the month of December 2000. It should, therefore, also not be proper to restrain them from continuing to market its products which have already entered the market for quite a few months.

3.1.15 The decision has raised questions about the presumption of validity of patents because the Court did not accept the argument of the plaintiff that the Patent Certificate is a *prima facie* evidence of the validity of patent, merely on the basis of which temporary injunction could be granted. Now the question is if the judgement should be interpreted to mean that the alleged infringer in the market with the product immediately after the grant of patent to the plaintiff is a clear indication that the information regarding the product and process are already in the public domain? It is so because it is only because of such information can the defendant comes up with the products quickly. Thus, the counterfactual is that if the defendant comes up with the product after a long time of the grant of patent it may give credence to the conclusion that the product may be a violation of the patent (Gopalakrishnan, 2009). This case amply justifies why there shouldn't be a presumption in favour of patent validity.

3.1.16 In a path breaking decision of the Delhi High Court recently in *F. Hoffman-la Roch Ltd., v. Cipla Ltd.* 2008 (37) PTC 71 (Del.), first handled by a single judge and then went in appeal to the division bench, the question of spelling out nuanced legal position emerged. In this case the plaintiff was granted a patent in India on 23.2.07 for the cancer drug "Erlotinib". After approval from the Drug Controller, the same was marketed in the trade name "Tarceva". The plaintiff came to know that the defendant was planning to launch the same drug and sought for injunction. It was argued by the defendant that they obtained approval for marketing the drug in October 2007 and started marketing it from December 2007 under the brand name "Erlocip". It was also contended that the invention of the plaintiff lack novelty and is not an invention as per section 3(d) of the Patent Act. While rejecting the application for injunction the Court though found that the plaintiff has an arguable case relied its impact on the large number of cancer patients who are not parties to the suit. This view has also found favour in the division bench's decision on appeal. However, it is difficult to understand if the court based its reasoning on price of the patented drug or on presumed invalidity of the patent granted. The observation of the Court is important:

> Therefore, this Court is of the opinion that as between the two competing public interests, that is, the public interest in granting injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant's product which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus irreparable injury would be caused if the injunction sought for is granted.

3.1.17 ***Adequate disclosure and Spurring competition*:** Another area that needs specific attention is the disclosure requirement. Disclosure of inventions is central to the arguments that patents are in public interest. The *quid pro quo* for the grant of patent is the adequate disclosure of the invention to the public. This also enables to find out the exact nature of the invention and to determine its limits. The object behind the same is to make it clear to the public and the users the boundaries of the patent right so that it is possible for them not to violate the rights and also to

freely develop new technology based on it. Increasingly, this has not been satisfied at the time of grant of patent. The speed in which patent is granted and the pressure of the work in the patent office and the demand to grant the patents at the earliest, restrain the patent office from finding out whether the disclosure is adequate and full.[71] Adequate disclosure creates legal certainty which is important for generic competition. Though it is possible to revoke the patent on the ground of insufficient disclosure, considering the cost involved, many patents may remain unchallenged (due to the cost involved in litigation, many patents remain unchallenged).[72] The Indian Patent Act insists for different kinds of disclosure before the patent is granted. In addition to the full and complete disclosure of the invention in the specification, there is also the requirement to provide technical information including the deposit of the invention in case of biological materials and also the source of origin of the materials. It is absolutely important that these conditions are insisted on and strictly monitored to ensure the quality of the invention and to give the details of the boundary of the patent as far as possible.

3.1.18 ***Pre and Post grant oppositions as Safety Valve for Patent quality:*** Opportunity for adequate and early oppositions at the patent office does promote competition by weeding out patents that are unworthy of grants (Pai, 2009). This provision will go a long way in ensuring *ex ante* competition by allowing any stakeholder to challenge patents and hence keep a check on quality of granted patents. However, it is not a full proof mechanism. (Pai, 2009). A right to oppose the patent application before granting – pre-grant opposition –is a provision peculiar to Indian law (Section 25(1). However, developed countries in the past did resort to pre-grant opposition for strategic reasons. The use of the provision depends upon the ability of such stakeholders to constantly litigate in the courts of law. It allows "any person" to file an opposition to an application for patent after its publication, but before grant of patent on various grounds like wrongful obtaining of the invention by the applicant, prior publication of the claims in India or elsewhere, invention already claimed in another application, public knowledge about the invention prior to the application, obviousness, non-fulfilment of patentability standards, insufficient disclosure, non-disclosure or wrongful disclosure of source or geographical origin of biological material used for the invention, non-disclosure or wrongful disclosure of traditional knowledge having regard to which the invention is anticipated.

3.1.19 The main intent of the provision is to provide an opportunity to interested groups to prevent invalid and illegal inventions being granted patent and also ensure that only inventions with good quality are conferred patent. It is interesting that this pre-grant opposition procedure is being made use of by rival industries as well as vigilant consumer groups (Mueller, 2007). The Madras High Court in *Indian Network for People living with HIV/AIDS v. Union of India* (MANU/TN/1217/2008) held that the person filing the pre-grant opposition shall be heard by the Controller before disposing the application and deciding to grant the patent. This has temporarily entombed the legal debate concerning mandatory nature of India's pre-grant patent opposition hearings. In this keenly awaited verdict by public health advocates, generic industry and the big pharma alike, the court interpreting section 25 (1) of the Patents Act, 1970 (as amended), said that the use of the word "shall" suggests the mandatory nature of hearing to be complied by the patent controller on request made by any person. The court relied on the logic of "quasi-judicial" nature of the pre-grant proceedings. Given that in a pre-grant opposition, the Controller by applying his mind decides over a controversy of whether or not to grant a patent, any lax in giving an opportunity of hearing to either of the parties goes against the seminal principle of natural justice: '*audi alteram partem'*- no person shall be condemned unheard. As per the court, "when law consciously confers right on a person to object at a pre-grant stage, that right must be protected in the way it has been granted, namely the right to object with a right of hearing"**.**

3.1.20 The court also noted that wider public interest concepts like preserving public health, nutrition and affordability of medicines were well grounded in the principle of providing an opportunity for hearing at the pre-grant stage. For the same reason, it noted: "grant of patent virtually confers the right of monopoly, which is a right in rem [against the world]" granted in favour of the patent applicant. Consequently, "before such a right is granted, law has

[71] Rational Ignorance at the Patent office (Mark lemley)

[72] Article on Litigation costs and litigation outcomes in patent disputes

provided that right of objection to any person". To cut the long story short, without stressing on aspects of 'quality' of a granted patent, the court has however shown some tacit unease. It appears that the court was deeply concerned about the presumed validity of patents granted without hearing objections at the pre-grant stage and the long term implications that flow from a legally unsustainable grant.

Box: 4 Maintaining Patent Quality: Why the Patent Office must Evaluate Options

Some recent law and economics scholarship in comparative patent jurisdictions has provided empirical evidence for how innovation is stifled when patent offices' grant patents of questionable validity.[73] "Questionable patents"- as they so called- are those that are more likely to be invalid when challenged in the court of law, or contain claims that are overly broad. With a rush in applications to the patent offices, it is evident that patent examiners spend less time to cautiously evaluate them- a trait not really unique to the Indian patent office. In other jurisdictions, new models for ensuring patent quality, viz., patent peer review and patent law reforms that provide for a mandated opposition at patent offices, are up on the cards. Hence, it is not completely irrational to present valid skepticism of the patent office's ability to carefully scrutinize all applications based on legal thresholds at an early stage. There is no gainsaying in the fact that for an over-burdened patent office, heeding to every pre-grant opposition hearing may not sound a good proposition. This primarily being an administrative concern, it may still be resolved by an increase in staff capacity, demand management, better use of technology and by keeping the pre-grant process time bound. Nevertheless, an early stage patent opposition would only help the patent office to grant qualitative patents and reduce the burden of socio-economic costs of unwarranted grants.

3.1.21 When viewed from a competition law and policy perspective, the problem of some patents stifling innovation markets and delaying generic competition has increasingly come under scanner of the Competition/Antitrust authorities across the world.[74] The United States Federal Trade Commission was among the early critics, which in a 2003 report on 'competition and patent law and policy', highlighted that questionable patents can deter or raise the costs of innovation, and also that in industries with incremental innovation, questionable patents can increase defensive patenting and licensing. This may prove anticompetitive. Invalidity proceedings are on rise, and today, there are more chances than ever that in most cases generic companies who challenge secondary patents prevail in pharmaceutical patent litigation.

3.1.22 This is confirmed by a very recent 2009 pharmaceutical sector inquiry preliminary report published by the EC Competition Commission. Revealing some more startling facts about patent acquisition and enforcement strategies in the pharmaceutical sector, it states: "one commonly applied strategy [in the pharmaceutical sector] is filing numerous patents for the same medicine (forming so called "patent clusters" or "patent thickets")….. the important objective of this strategy is to delay or block the market entry of generic medicines." It further states, "Patent clusters can lead to uncertainty for generic competitors as to whether and when they can start to develop a generic medicine without infringing one of the many (new) patents, even though patent holders admit internally that some of these patents might not be strong".[75] Pre-grant oppositions could in fact prevent the abuse of patent system by granting quality patents and avoid wasteful litigation at some later stage.

Box: 5- Public Notice Function of Patent System: Why Pre-grant Oppositions Matter!

The failure of public notice function of the patent system has led to a host of new legal and policy challenges- what some scholars would want to call as "patent failure".[76] Semantics apart, the argument is: since patents are currently interpreted using different rules of claims interpretation at different stages in the legal process, the outer boundaries of a patent are almost vague. This uncertainty created due to improper drafting of patent claims and varying styles of claims interpretation cannot be remedied unless litigated by third parties. Consequently, this impedes third parties freedom to operate and innovate. While both- the patent applicant and the patent examiner- have first-hand information and the best means to clarify patent claims, they do not have an incentive to create certainty in the claim meaning for the benefit of third parties. Thus pre-grant opposition could facilitate better understanding of how patent offices' interpret patents and thereby create more legal certainty for third parties at an early stage. This indeed strengthens the legal and doctrinal foundations of the patent system. But pre-grant opposition could also lead to potential delays and protracted litigation at the patent office. It

[73] Patent failure (2008)
[74] US FTC Report 2003,
[75]
[76] Patent failure, 2008

may also lead to creation of a bad prosecution history in against the patent holder. But the whole object of the patent system and the quality lever depends on the competitive market structure to make valid oppositions. Hence prosecution histories in such cases can only strengthen the patent system. Further, the opposition can certainly be time-bound to avoid unwarranted delays at the patent office.

3.1.23 Though post-grant opposition under section 25 (2) is based on the same grounds, only "person interested" are allowed to file it. It has to be filed within one year of publication of grant of patent. *The Supreme Court in J. Mitra v. Asst. Controller of Patent and Design (*MANU/SC/3435/2008), the court examined the scope of these provisions while examining the sections dealing with appeal from the orders of the Controller and observed thus:

> There is, however, a radical shift due to the incorporation of Section 25(2) where an interested party is granted a right to challenge the patent after its grant. The ground of challenge under Section 25(1) is identical to Section 25(2) of the said 1970 Act. However, Section 25(1) is wider than Section 25(2) as the later is available only to a "person aggrieved". The main difference between Section 25(1) and Section 25(2), as brought out by Patent (Amendment) Act, 2005, is that even after a patent is granted, a "post-grant opposition" can be filed under Section 25(2) for a period of one year. The reason is obvious. In relation to patent that are of recent origin, a higher scrutiny is necessary. This is the main rational underlying Section 25(2) of the said 1970 Act….

The above discussed judgments are indicative of the judicial approval of the legislative intent in protecting the public interest in maintaining patent quality while granting patent. One pertinent question is whether or not patents that are not of adequate quality create market power for the purposes of competition law and hence necessarily protect public interest. It may be argued that since such patents may not have market value, it would hardly make any difference in terms of increasing or inhibiting competition, and hence neither patent law nor competition law should concern itself with issue of patent quality. The prospective theory of patents at least alludes on this aspect. However, this argument is unsustainable since filing of numerous patents that are unworthy or grants or fail validity when challenged in the courts of law does inhibit competition, especially generic competition in pharmaceuticals, by creating uncertainty about the technical scope of the invention and thereby impedes freedom to operate and innovate around the patents. If interpreted by keeping in view the prime objects of patents law- to promote adequate disclosure and to provide incentives for innovation, the provision on pre and post grant opposition will surely help in ensuring *ex ante* competition by allowing blocking patents to be appropriately screened.

3.1.24 ***Research Exemption:*** The usefulness of research exemption is of great importance for follow-on inventions and to conduct experiments based on patented technologies without requiring prior licensing or permission. It is one of the statutorily granted exceptions to patent rights for the benefit of third parties. Research exceptions in the field of patent laws can have tremendous scope for competition through faster diffusion of technologies. The growth of industries and the increase in the number of inventions led to the demand for recognizing express provisions to facilitate the future research and developments (Gopalakrishnan, 2009). The exception for teaching and research using the patented technology is the outcome of this process. Irrespective of the objectives of the research (whether it is for commercial or non commercial), exception was granted in case of research. However, as of today, if any element of commercial activity is involved in utilizing the research output, the developed countries require that permission should be taken from the holder of patent (Kevin Iles, 2005). The decisions from the developed countries particularly from US and England are testimony to this, however they need not be decisive. The decisions for US Court in *Madey v. Duke University (*307 F.3d 1351 (2002))[77] and *Integra Lifesciences I, Ltd.*

[77] The observation of the Federal Circuit in *Madey* is worth quoting here:

> In short, regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very

v. Merck KGaA (331 F.3d 860) [78] reflect the limited interpretation given by the court, which may not be helpful in a developing country situation warranting access and innovation not just by the incumbents in an oligopolistic setting but also by small firms and start-ups wanting to penetrate into the innovation markets.

3.1.25 Section 47(3) of the Patents Act, 1970 deals with research exception. The importance of having a strong research exemption is important in the context of complementary and sequential research, especially in the bio-medical industry. The provision in the Indian Act is broadly worded. The words "for the purpose merely for experimental or research including the imparting of instructions to pupils" include three types of activities; experiment, research and imparting instructions. The exemption permits the 'making or using' of the patented invention for these purposes. The word "merely" qualifying the three categories of activities exempted under this exception needs some analysis. The literal meaning of 'merely' is 'just', 'only', 'simply', 'purely' etc. makes clear the intention for which the patented invention is made or used. The section does not connote any finding of impact of the patent holders rights (Gopalakrishnan, 2009). As long as the intention of making or using the patented invention is for experiment, research or teaching it is permitted and no permission is needed from the owner of the patent. Hence the activities of the user even for furthering his economic interest from experiment, research or teaching are covered under this exception (Gopalakrishnan, 2009).

3.1.26 There are two potential problems which a strong research exemption can solve. One is the tragedy of anticommons in the bio-medical industry and about patenting upstream research tools and such patent blocking downstream research. Experts owe the problems concerning blocking patent due to the phenomenon of the tragedy of anticommons.[79] The tragedy of the anticommons refers to a problem that might arise when multiple owners each have a right to exclude others from a scarce resource, and no one has an effective privilege of use. Commentators emphasise that there are two mechanisms by which a government might inadvertently create an

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> narrow and strictly limited experimental use defence. Moreover, the profit or non-profit status of the use is not determinative.

The example given by the court for acting for 'commercial gain' renders almost all cases of research and experimental use infringement. The court has stated:

> For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

The logical result of *Madey* allows the courts to find out some commercial application or purpose behind every use of the patented technology by the defendant and thus renders the research exemption literally not useful.

[78] In *Integra Lifesciences I, Ltd. v. Merck KGaA*, again, the Federal Circuit court took a restrictive interpretation. However, in the dissenting judgement Judge Newman has stated that "the subject matter of patents should be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or "design around" it. Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology." The US Supreme Court, in *Merck KgaA, Petitioner v. Integra Lifesciences* 545 U.S. 193 (2005) resorted to an expanded interpretation of research exemption. In that case use of patented inventions for pre-clinical research was held not to constitute infringement even when the result is not submitted to the Food and Drug Administration for regulatory approval. However, as neither the Federal Circuit nor the Supreme Court in *Merck* opined on the common law experimental use exemption, the law laid down in *Madey v. Duke,* for the time being, states the current rule of the law, enunciating an extremely narrow scope of the common law exception. Thus the US standard of exception now seems to be very much limited confining only to research for curiosity and self satisfaction. This position is extremely restrictive in its approach and has come under constant criticism with reference to its practical utility.

[79] Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research* Science 1998 May 1; 280: 698-701.

anticommons through some form of intervention or non-intervention. One is by creating too many concurrent fragments of intellectual property rights in potential future products; and second by permitting too many existing patent owners to stack licenses on top of the future discoveries of users. Commentators theorize that patenting of gene fragments and of receptors useful for screening potential pharmaceutical products are two situations in which too many concurrent fragments may result in anticommons.

3.1.27 If a tragedy of the anticommons were to emerge, it might endure because of the transaction costs of rearranging entitlements, heterogeneous interests of owners, and cognitive biases among researchers, the authors suggest. The authors suggest that policy-makers should seek to ensure coherent boundaries of existing patents and to minimize restrictive licensing practices that interfere with product development. Otherwise, they conclude that more patent rights may lead paradoxically to fewer useful products for improving human health.[80] Recent amendments in the Swiss law pertaining to research exemption may provide better guidance in creating a suitable and optimal law and policy for biotechnology based patenting activity to grow, but yet to provide place for subsequent innovation in that area[81]. In many ways, it's a formula for allocating rights in research and scoping the monopoly incentive to incumbent firm in favour of subsequent innovator.

3.1.28 It is pertinent to note that there are special problems concerning research tool patents on bio-medical inventions. Some expert academics in the US have conducted an empirical study of the implications for innovation of patenting and licensing practices in the pharmaceutical and biotech industries.[82] The authors conducted filed interviews which were 70 interviews with IP attorneys, business managers and scientists from 10 pharmaceutical firms and 15 biotech firms, as well as university researchers and technology transfer officers from 6 universities, patent lawyers and government and trade association personnel." The authors found that patents on research tools have increased, but have not significantly hindered drug discovery. The increased complexity of the patent landscape, they concluded, has not resulted in a tragedy of the anticommons. They noted that some university research has been delayed by restrictions on the use of patented genetic diagnostics, and that there have been some delays or access restrictions to research tools or other foundational discoveries. In some instances, research was re-directed to areas where there were fewer patents. Overall, however, the researchers found that no valuable research projects were halted as a result of limited access to a research tool. The experts cautioned, however, that the potential exists and ongoing scrutiny is warranted. They also concluded that firms and universities use a range of strategies to avoid breakdown and restricted access to research tools, including taking licenses, inventing around patents, infringement -often informally invoking a research exemption, developing and using public tools and challenging patents in court.

3.1.29 Section 47 (1) of Indian Patent Act provides for an exemplary exception in Indian law for the limited government use of the patented invention without any authorization from the owner of patent. This include importing or making of the patented invention by or on behalf of government for government use. Section 47(4) further provides for use of process patent by or on behalf of government for government use and import of patented dugs for the use of government and distribution through government hospitals and dispensaries for public purpose. While the use by government for public purpose without permission and payment of royalty is controversial in many countries due to impact on the right of the patent holder for normal exploitation, a specifically carved out interpretation of the Government use provisions may perhaps withstand any such challenge. This exception is in the patent law since the 1970 Act remains intact without any practical use by the Government. The pertinent question is that since the Act does not define the appropriate authority within the Government, it is not clear which department of the Government must be authorized to use them. Since the provision, especially relating to drug importation relates to assessment of demand and supply factors in pharmaceuticals, the health ministry should logically be the appropriate authority.

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[80] Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research* Science 1998 May 1; 280: 698-701.

[81] Swiss Research Exemption (EPIP, 2008).

[82] John P. Walsh, Ashish Arora & W esley M. Cohen *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M . Cohen & Stephen A. Merrill eds. 2003),

3.1.30 ***Parallel Importation and Legal Importation:*** Since the TRIPS agreement under Article 6[83] leaves enough scope for countries to adopt measures on exhaustion, the Indian policy makers seeing the flexibility in the international law framed a unique yet controversial provision in favour of international exhaustion, more so in the nature of legal importation without authorization of the right holder. The provision in the patent law so was included to ensure that patented products are not priced beyond to purchasing capacity of the Indian consumers, Section 107A (b), reads: "importation of patented products by any person from a person who is duly authorized by under the law to sell or distribute the product shall not be considered as an infringement of patent rights," This was included in the Act to facilitate import of products patented in India from other countries where they were legally produced.

3.1.31 It must be noted that prior to the amendment in 2005, the Indian legal provision, as introduced in 2002, was only authorizing parallel importation of patented product "from a person who is duly authorized by the patentee to sell or distribute the product". This provision was incapable of covering all forms of parallel import and legal imports. The 2005 Act included the words "who is duly authorized under the law to produce and sell or distribute the product". The broader scope of the provision is indeed the intention of the legislature. The issues here is about the scope of this provision since the idea of parallel import is to facilitate products that are not infringing products manufactured in some other country to enter in the Indian domestic market while the patent is in force in India through distributors not authorized by the owner of patent. Since the patent owner can locally produce or import his patented article, any other person importing a non-patented article from a foreign market to the Indian domestic market where the article is patented can be contentious. Section 107 A (b) authorises an independent distributor who has no licence from the owner of patent to import the products into India, by enjoying the legal right of parallel import, to purchase the same product distributed by a licensed manufacturer of another country where there exists a valid patent for the product and bring it to India and sell it in the Indian market. One interesting question is if such an importation of legally produced but foreign unpatented goods should be permitted since they are in direct conflict with the patent holder's right of importation. However, it is clear that such an importation provision is verily available in case of a grant of compulsory license in other countries from where the article is imported.

3.1.32 ***Regulatory Review Exception:*** Use of patented invention for generating data for manufacturing and marketing approval by regulatory authorities is another exception introduced in the Patent Act in 2002 and 2005 in the context of introducing product patent for pharmaceutical products. According to Section 107A(a) the act of making, constructing, using, selling or importing a patented invention for the sole purpose of generating information is not considered as infringement of the patent rights. This is popularly called as the regulatory review exception or as the Bolar exception. However, a recent Delhi High Court decision has provoked a great deal of excitement and concern about the interface between drug regulation and patent laws (discussed in drug regulation section)

3.1.33 ***Compulsory Licensing under the Indian Patent Act:*** Before we set the tone for a discussion on compulsory licensing provisions in India, it is important to note an automatic route available for generic production exists for all those who made investments in drug production prior to the year 2005. This was specifically introduced to avoid any form of closure of generic production due to alleged violation of patents applied through the mail-box system.

3.1.34 Traditionally compulsory licensing provisions were used to prevent the owner of an intellectual property right from refusing to exploit his right in a country where intellectual property protection is granted, or from enjoying an absolute monopoly by forcing him to permit competition from other producers, subject only to reasonable payment of royalty or license fee. It is the well established fact that the maximum benefit of the patent system will be enjoyed by a country granting patent if the invention is worked in that country by actual manufacture and distribution. This will ensure not only industrial development and employment generation but also progress in science through research and development. It was also a concern that in case the invention is not worked in the country where a patent has been granted, the owner of patent would use the patent monopoly to expand his

[83] Article 6 of the TRIPS states "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

market for selling the patented products manufactured in some other country. In the early stages of the development of the patent system the patent used to be revoked on the ground that patented invention was not worked in the country to satisfy the obligations of grant of patent. The demand for recognizing importation of patented product as right of patent owner was resisted at the international level to retain the freedom of the countries to introduce appropriate measures to prevent the abuse of patent monopoly detriment to the industrialization of the country. Countries used different strategies to ensure actual manufacture of the invention locally. Grant of compulsory licence was considered as one effective method for ensuring this. The Paris Convention recognises right of countries to impose compulsory licenses "to prevent abuses of the exclusive rights conferred by the patent, for example, for failure to work."

3.1.35 India is one country who has made use of not only the flexibilities available in the TRIPS agreement, but also the changes accepted by the WTO Ministerial Conference in its Doha Declaration and the consequential amendment proposed to the TRIPS agreement, and created different types of compulsory licenses. Still some hold the view that complete flexibilities available were not properly exploited/ utilized by India. India's compulsory licensing provisions are considered by some others as the "broadest and most comprehensive of all the world's patent systems". Nonetheless, the provisions have very rarely been made use of in India. The reason for it could be attributed to the lack of necessity of the only competent industry in India at that time, that could make use of the provision, viz., the pharmaceutical industry. The refusal of product patent for inventions pertaining to this field and the comparatively short period of protection etc., allowed them to manufacture these products using indigenous processes enabling them to effectively compete with the patent owner. Thus it was not necessary for them to undergo the laborious process of obtaining a compulsory license. However, the situations have undergone a sea change after 2005, i.e, after introducing product patent for pharmaceutical substances in India.

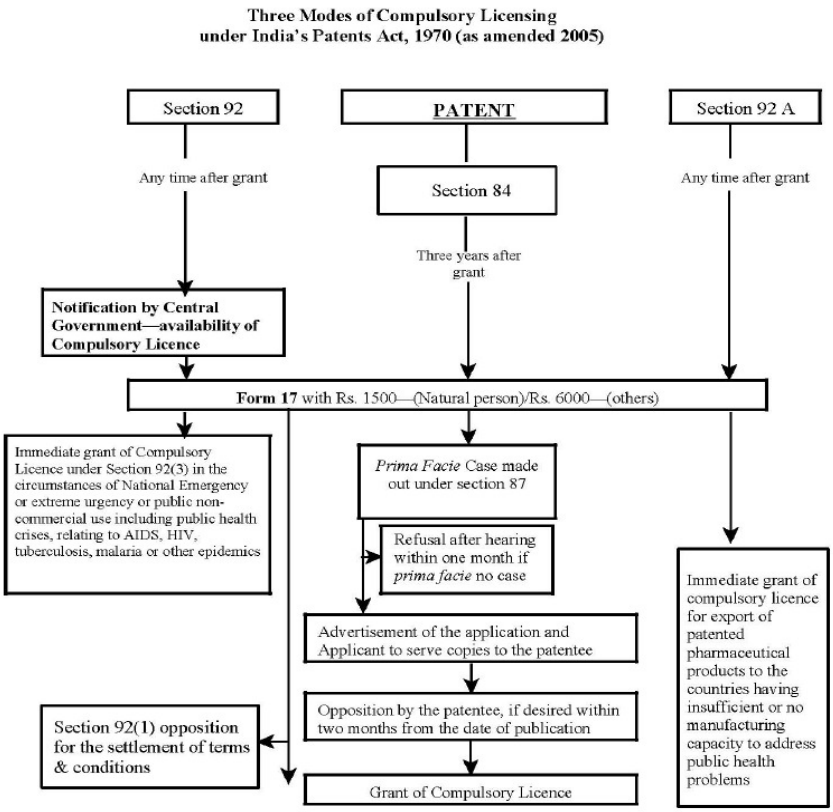
3.1.36 It is important to note that the general principles of working of patent in India are well articulated in the chapter dealing with compulsory licence. Section 83 makes it clear that the patent must be worked in India on a commercial scale; cannot enjoy the monopoly only by importation of the patented product; protection and enforcement of patent right must contribute to promotion and dissemination of technology; should not act as an impediment to public health and nutrition; the use of patent should not unreasonably restrain trade or adversely affect international transfer of technology and make the patented invention available at affordable price to the public. Based on these principles the compulsory licensing provisions available under the Indian Patent Act could be broadly classified into (a) General compulsory licensing provisions, (b) Provision relating to pharmaceuticals patents in case of emergency and (c) Licence to export pharmaceuticals to countries with insufficient manufacturing capabilities.

3.1.37 The general compulsory licence provisions are largely based on Paris Convention and hence are in conformity with TRIPS obligations. The grounds on which compulsory licence can be requested after the expiry of three years of granting of patent by a person interested are: (a) reasonable requirement of the public have not been satisfied; (b) patented invention not available to the public at reasonably affordable price and (c) not worked in the territory of India. The section also explained the circumstances that result in not satisfying the reasonable requirement of the public. This is largely based on the general principles of working of the patent given in section 83 of the Act. Protection of the existing trade and industry, development of new industrial activities, promotion of export, availability of the product at affordable price, prevention of unreasonable terms in voluntary licence like grant back, packaging, prevention on challenge etc., exploitation of the market based only on import etc. are the circumstances covered in this provision.

3.1.38 These grounds will help to make the patent used for the economic and industrial development of India. There are basically three modes in acquiring compulsory licensing in India. The first mode is by satisfying criterion laid down under section 83. Here compulsory license can be granted after 3 years by satisfying certain conditions and a lengthy procedure. However, such a procedure can be parted with only through a government notification under

section 92. Another form of compulsory license is under section 92A, which is exclusively for an export market. The following chart explains the three modes of compulsory license (Mueller, 2008).

Diagram: Three mode's of compulsory licensing



3.1.39 Another general compulsory licensing provision which is criticized for being inconsistent with TRIPS is the one with respect to granting of compulsory licence on the ground that the invention is not worked in the territory of India. However, it may be noted that this criticism is unfounded in that this provision is in tune with Article 5 A of the Paris convention, which is being incorporated in to the TRIPS agreement. Article 27.1 of the TRIPS agreement only states that "*patents shall be available and patent rights enjoyable* without discrimination as to the place of invention, the field of technology and *whether products are imported or locally produced*". The provision granting compulsory licenses on the ground of non-working of the patent in the territory of India is no way interfering with the right under Article 27.1 as it does not affect the availability of patent or enjoyment of patent rights. As Article 31 keeps it open the grounds under which authorization to use the subject matter of a patent by the governments and third parties without permission from the patent right holder, it cannot be said that the Indian provision allowing granting of compulsory license on the ground of not working it locally is violative of Article 31 as well.

3.1.40 It is to be noted that the pre-requisite for grant of compulsory licence is the ability of the applicant to work the invention in India. This presupposes that compulsory licence will make a difference only in sectors where India has existing industries with manufacturing capabilities. The provision can be used by the existing industries to negotiate for a reasonable voluntary licence from the owner of patent since this is also a pre-requisite for applying for compulsory licence. It also envisages a fair procedure for granting compulsory licence by the Controller of Patent. There are also guidelines regarding the fixing of the terms and conditions of the licence and these are in

conformity with Article 31 of the TRIPS. It is also stipulated that the decision on the application shall be taken ordinarily within one year.

3.1.41 The second category of compulsory licence relates to situations of national emergency. The provision states that where, in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, the govt. is satisfied that in respect of any patent it is necessary that compulsory licence should be granted at any time after the sealing of the patent, it may make a declaration to that effect by a notification in the official gazette. In such cases the licence can be granted without waiting for the lapse of three years after the sealing of patent. What is needed is a Government notification of the patents that fall under this circumstance. However, there is confusion when one attempts to interpret subsections 2 and 3. As per subsection 2, all the provisions under sections 87-90 are to be applicable while granting compulsory licences under this provision. But subsection 3, which is a *non obstante* clause, authorises the controller, if he is satisfied that it is necessary, to exempt the application from the procedural requirements contained under section 87, relating to notice to the patentee and giving the patentee a chance to be heard, in cases including public health crises relating to AIDS, HIV, tuberculosis, malaria or other epidemics. The confusion is relating to the reason for such differentiation in cases of emergency and the extent to which the differentiation is applicable and the reason for giving discretionary power to the Controller in determining whether it is a fit case to be exempted from the procedural requirements under section 87. Having in view the purpose behind incorporating such a special provision, the ideal situation is to exempt entire applications under this provision from the procedural requirement under section 87 so as to expedite the granting of compulsory licence. Taking into consideration the gravity of the situations which section 92 intends to cover, there is no justification for insisting for compliance with section 87 requirements. Moreover, there is also no justification for conferring any discretionary power on the Controller in determining whether a patent is to be exempted from the procedural requirements under section 87.

3.1.42 But a better option is to follow a different procedure in these cases. A statutory form of licence with safeguards to protect the interest of the owner of patent would have been better. The licence could be automatic so that the interested parties could use the patent immediately after notification to meet the urgency. There could be provisions for negotiations of the terms and conditions after the working of the patent if the parties have problem in reaching reasonable agreement. The possibility of the owner of patent seeking injunction from the Court in such cases also needs regulation. In the absence of these modifications it is easy for the owner of the patent to defeat the purpose of the notification. India is yet to see a notification based on this provision and only when it is put into practice one can clearly articulate the need for change in this section. The third type of compulsory licence is introduced in 2005 by inserting section 92A to facilitate manufacture and export of patented pharmaceutical products to countries having insufficient or no manufacturing capabilities. This provision is structured based on para 6 of the Doha Declaration. In line with the requirement under para 6 of the Doha Declaration the TRIPS General Council has decided on 30th August 2003 to waive the obligations of an exporting member under Article 31 (f) of the TRIPS Agreement for the purpose of production and export of a pharmaceutical product to an eligible importing member. Later on in 2005 the General Council again decided to adopt the protocol amending the TRIPS agreement to insert Article 31bis after Article 73.

3.1.43 Issue of compulsory licence from the importing country or a notification permitting import from India is mandatory before issue of compulsory licence by the Controller of Patent permitting manufacture and import of the patented pharmaceutical products from India. It is also clarified that “pharmaceutical product” would include not only patented products and processes but also ingredients necessary for their manufacture and the diagnostic kits required for their use. It may be noted that the agreement reached on Para 6 and the proposed Article 31bis mandate exporting countries also to take precautionary measures such as notification to the WTO, labelling standards etc., to ensure that the product is not going to enter into the normal market. There is no statutory provision regarding this in the Indian Act. The Controller is permitted to issue licence based on such terms and conditions specified and published by him. It is also clear that the Controller in this case is not mandated to follow

the normal procedures that are followed in issue of compulsory licence. There are not many instances of use of this provision and one need to wait and see how this is going to work in India considering her strength in manufacturing generic drugs. In a recent development Natco Pharma Ltd., a Hyderabad based cancer drug maker, announced withdrawal of its application under section 92 A to export cancer drugs to Nepal, as the company had not yet received an import requisition from the Nepal government for the drugs (Mint, September 2008). However, an interesting question came up for consideration in connection with this application. The Controller of Patents gave the holders of patent (Roche and Pfizer) an opportunity to be heard while making a decision on Natco's application and Natco's petition questioning the legality of the Controller hearing the patent holder, was dismissed by the patent office.

3.1.44 It must be noted that there is no time bound scheme guaranteed for a compulsory license. Any potential application would run into deep litigation and may take considerable time in disposal. Further the three year rule appears absurd in the light of measures to be taken in case of anticompetitive practices. A Compulsory license would not issue if there is an abuse of patent prior to the three year expiry. This creates complications since the Competition Act also does not have enough teeth to handle situations arising out of patents. Further it has to be noted that a compulsory licensing remedy is missing in the competition Act, 2002.

3.1.45 One of the most important but controversial provision which will be known to be notorious and possibly raising TRIPS compliance issue, concerns Section 66 of the patent Act. It provides for revocation of patent in public interest where the Central Government is of the opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to the effect in the official Gazette and thereupon the patent shall be deemed to be revoked. This provision is again very broadly worded and creates a lot of scope for interpretation. It leads one to conclude that the Government feels (based on certain reasons) that the patent is "mischievous" to the State- the scope of which remain undefined and "prejudicial to the public"- again very wide and ambiguous to include even over pricing and other effects of patent abuse- may be seen as within the scope of this provision. Much is yet to be desired on possible clarification from the Government. There is no provision for compensating the patent holder for revocation of the patent. Further this provision is also different from a situation under Section 3(b) where commercial exploitation may warrant serious public interest impact. Here generic production can assume since the patent is repudiated. But in 3(b) the commercial exploitation must be shown to affect *public order or morality,* in which case even a competitor cannot exploit the patented invention.

3.1.46 Claims interpretation is not part of any jurisprudential developments in the Indian legal space. Again, it would be important that the judiciary maintains restraint and watches closely over the developments in other jurisdictions about problems arising from the rise and fall of certain interpretational techniques. The above analysis reveals that subject to the interpretative province of the judiciary, if exercised with diligence and from a national policy based perspective, it is sure that India will go one step ahead in providing better access to medicines at cheaper prices and yet carry forward with its resolve to join the global markets.

3.2 The Protection and Utilisation of Public Funded Intellectual Property Bill, 2008

3.2.1 The introduction of the Protection and Utilization of Public Funded Intellectual Property Rights Bill, 2008 (**PUPFIP Bill**) in the Rajya Sabha in December 2008 has triggered debates among public interest organizations, science policy makers, academia, and other stake holders including some sections of the industry on issues of Intellectual Property (IP) protection of public funded research as envisaged in the Bill. The PUPFIP Bill proposes the mandatory creation of intellectual property on all public funded research. It further provides that the ownership of such intellectual property rights shall lie with the university/institution which has got government funding which can then license the IPR to private parties. These private parties can then commercialize the research and bring it to the market. These proposals have led to concerns that there are few safeguards in the Bill to ensure that the public interest is paramount in setting research priorities or that products of such public funded R&D are available and

affordable. In mandating the creation of IPR, the Bill also puts onerous obligations on universities and scientists that need to be examined.

3.2.2 There are accusations from the public interest organizations that the Ministry of Science &Technology, throughout the process of drafting the Bill, had maintained unnecessary secrecy on the one hand while giving free participatory access to industry organizations and other vested interest actors on the other hand. Presently, the Bill is under the consideration of the Parliamentary Standing Committee on Science and Technology and Environment and Forest. The denial to access and the speed with which the Bill is being pushed through the Parliament has made public interest organisations skeptical about the Bill. The lack of a common platform to raise concerns has weakened the space for informed criticism of the Bill by different stake holders. The Bill has implications for the manner in which R&D is conducted in India for access to the outcomes of the public funded research.[84]

3.2.3 The general legal schema of the Bill has a definite time mechanism and every duty cast upon different actors is time-bound. Broadly the presentation gave an overview of the legal modalities involved in the Bill, which covered the objectives of the Bill, duties of the Recipient (university or public funded institution), Intellectual Property Creator (inventor), Intellectual Property Management Committee and the Government (funding agency), Income and Royalty sharing arrangement, penalties and liabilities under the Bill, limited exceptions and other miscellaneous provisions in the Bill.

3.2.4 The Bill makes it normative that every outcome of public funded research having "commercial potential" must be compulsorily IPR protected- not just in India but in other countries as well. Although the term "utilization" by definition, in the Bill, tends towards commercialization of public funded research, it fails to inform how such commercialization would be mandatory on the assignee or licensee of the IPRs. Wider consumer welfare implications are not considered. Importantly, softer forms of incentive mechanisms like Creative Commons Licensing and Open Source models, including open source drug discoveries were not prioritized within the scope of the Bill. All universities are specifically included in the Bill without due consideration to nature and type of research activity conducted by them. The Bill mandates that the recipient should make "disclosure" of the "actual knowledge" created by public funded research to the government, in such form and manner as may be prescribed, within a period of sixty days. The terms "actual knowledge" "creation" and the type and degree of "disclosure" required are left undefined. The stipulated time period of sixty days can be questioned based on the time required to understand the credibility of the research outcome as an invention and its eligibility for IP protection. The financial liability of enforcing IP Protection falls on the recipient. Creator cannot publish, exhibit or publicly disclose the outcome of public funded research without ensuring that there is an application made for respective IP protection. This provision takes off certain flexibility of the Patent Act, 1970, given to the inventors in respect of prior publishing/exhibition before the making of a patent application. There is ambiguity in case of the outcome of the research projects undertaken by students (who may not be engaged as inventors) during the routine university functioning. However, the speaker also noted that the Bill to a large extent clarified issues of royalty sharing arrangements and issues of ownership.

3.2.5 Proper guidelines for the formation and membership of IP management committee are not laid down in the Bill. The Bill for the most part leaves certain important details for the Rules to decide. Important duties of IP management committee are to assess, document and protect public funded intellectual property with commercial potential. The definition of all these terms and more specifically of the word "commercial potential" has been left

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[84] Critique on Public Funded R&D Project Bill: Indian version of US Bayh Dole Act. *By Shailly Gupta, Centad (2008)*

undefined. The mode of assessment by IP management committee is ambiguous. In particular, is it possible at the very beginning point of an invention to determine the degree of "commercial potential" it has. The duties of the government agency include applying for IP protection if the recipient defaults; to grant licenses on protected IP, which includes exclusive and non-exclusive licenses while the premises for granting such forms of licenses remains unclear. The Bill has no provisions that deal with keeping the knowledge within public domain in certain cases or on granting a mandatory non-exclusive form of license as part of first principles of the legal mandate. The legal scheme of the Bill seems overly archaic and excessively ceremonial; while some aspects of the Bill were introduced even without appreciating the routine systemic and structural challenges posed by the universities and public funded research institutions in India.

3.2.6 Failure to fulfil the conditions laid down in the contract with the government or for non-compliance of duties cast under the Act invites harsh penalties for the recipient of public fund research grant and the intellectual property creator (inventor) in some cases. However, liabilities or penalties do not fall on the IP management committees. The presenter concluded by pointing out that the Bill was trying to fix a problem that does not exist. The present autonomy and divergence of approach in facilitating IPR protection and commercialization of public funded research among different institutions, he said, must be preserved and improved upon without resorting to a normative and archaic framework as envisioned in the current version of the Bill.

3.2.7 It must be noted that various studies have noted that the US experience in Bayh Dole has not proved to be effective. In fact, learned academicians from the US have warned that developing countries must not legislate the US styled bill.[85] Apart from this the bill will have huge ramifications for how publicly funded pharmaceutical R&D is carried out and disseminated.[86]

3.3 Drug Price Regulation in India: NPPA Price Controls and *Ex Ante* Price Competition[87]

3.3.1 In the 1970s, India put into place a series of policies aimed at moving the country towards self-sufficiency in medicines. For instance, measures such as Patents Act 1970, ceiling on the foreign equity participation with insistence on local manufacturing in a way helped the domestic players. The policies of liberalization that emerged in the 1980s and gained strength in the 1990s saw the focus of drug policies move further from a health perspective to an industry perspective. As a result of this change, the number of drugs under price control fell dramatically from 347 in 1979 to 74 in 1995. The Drug Policy of 1986 was a reversal of the Policy of 1978 and marked a move towards state decontrol. Further, both the Drug Policy, 1994 and the Pharmaceutical Policy, 2002 reasserted the broad economic policy of liberalization set in motion in the previous decade and augmented in the early 1990s. Public sector manufacturing units, emasculated by internal factors, were finished off by the Drug Policy, 1994.

3.3.2 A principal barrier to access continues to be the cost of medicines. According to WHO figures (2004), 65% of the population (approximately 640 million) lack access to essential medicines and the barrier are largely economic. The continuous liberalization and decontrol of drug prices have contributed to this in large measure.

3.3.3 Over the past 30 years the vision of incorporating health concerns while formulating drug policies has changed fundamentally. While policy making in the pharmaceuticals sector has always been flawed as it rarely had any role of the Ministry of Health, the 1978 Policy did show a certain direction in addressing public health concerns. However, subsequent policies have relied increasingly on market based pricing and have ignored the fact that the drug industry's principal role is to address health needs.

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[85] Antony Dso et al. Is Bayh Dole Good For Developing Countries: Lessons from The US Experience, Available at: http://biology.plosjournals.org/archive/1545-7885/6/10/pdf/10.1371_journal.pbio.0060262-L.pdf

[86] UAEM paper on India Bayh Dole (2009)

[87] This part is heavily drawn from the Study undertaken by Centad on Economic Constraints for Access to Medicines in India (2008), Centad

3.3.4 Successive drug polices in India since 1986 have argued about the merit of using market competition as a method of stabilising drug prices. It would be useful, hence, to examine in some detail the criteria and arguments used by these policies. Annual turnover requirement: This is based on the premise that annual turnover would help in identifying drugs of mass consumption. This leads to exclusion of those that may not be drugs of mass consumption but are nonetheless critical or life-saving. The Essential Drugs List identifies drugs using health as the criterion, whereas annual turnover identifies drugs of mass consumption using the market as the criterion. There has been no attempt to link price control with the Essential Drugs List. The criterion of lack of competition is based on the assumption that the presence of market forces will lead to competitive prices. This argument has also been constantly extended by the industry in favour of relaxation of price controls and this is based on the assumption that pharmaceutical products behave like other goods in the market. However, drug markets behave very differently for several reasons.

3.3.5 The pharmaceutical market is characterized by low cross-elasticities of demand. This implies that a product in one therapeutic submarket is of little use to consumers in another submarket. Standard economic theory assumes that the decisions to purchase, pay and consume are taken by the same person. The pharmaceutical industry differs from other industries in this respect. Demand decisions in pharmaceuticals involve: the doctor who chooses and prescribes the drug; the pharmacist, who may choose among branded or generic substitutes; the insurer, who may pay in full or for a portion of the drug; and the patient, who consumes the drug and may additionally influence the choice of drug and make partial or full payment. Prescription practices are prone to being influenced by marketing strategies of drug companies.

3.3.6 Demand elasticity varies with the form of payment. The larger the proportion of out-of-pocket expenses, the larger the elasticity. In the case of medicines, elasticity of demand would vary with the urgency of the situation. In all circumstances, the demand for medicines will be less elastic than that for many other consumer products. Pharmaceutical markets of high-income countries differ widely from those of developing countries in this respect. Not only is per capita spending on health and medicines many times higher in high-income countries, but a much greater share of the cost of medicines is also publicly subsidized. In low-income countries, spending on medicines comes largely from household resources. Therefore, the demand for pharmaceuticals is stronger and less elastic in developed countries in comparison with developing countries. This points to the need to control drug prices with greater rigour in developing countries such as India. However, drug prices are actually regulated much more purposively in developed countries (Centad, 2008).

3.3.7 For example: Price control used only for reimbursable pharmaceuticals: Austria, Finland, France, Ireland, Italy, Latvia, Lithuania, Poland, Slovenia, Spain; Price control used for all products: Belgium, Cyprus, Hungary, Greece, Slovakia; Price control used for all products (except OTC): Norway, Portugal, Romania; No (direct) product price regulation: Denmark, Germany, The Netherlands, Malta, Sweden, UK

3.3.8 There are several broad issues that compromise the effectiveness of price controls, as exercised in India. As pointed out earlier, a system of price control where only a small percentage of drugs are kept under price control is fraught with a fatal flaw. Experience in India has repeatedly shown that companies shift production away from price controlled drugs. This would not have been a problem if market mechanisms were to actually work in stabilising prices in decontrolled categories. As we see above, this seldom does happen and as a result manufacture and sales shift from affordable low medicines to higher priced medicines. Such shift is also accompanied by strong initiatives to promote high priced drugs, which also affect the prescription patterns and patterns of drug consumption. Thus, it not only increases economic barriers to access but also promotes irrational practices in prescribing and drug consumption.

3.3.9 In the year 1970, the Drug Prices Control Order issued under the Essential Commodities Act, 1955. Subsequently DPCO was revised in 1979, 1987 and 1995. Not all drugs available in the country are under price control. Only 74 out of about 500 commonly used bulk drugs are kept under statutory price control. All formulations containing

these bulk drugs either in a single or combination form fall under price controlled category. However, the prices of other drugs can be regulated, if warranted in public interest.[88] Rest of the drugs are under the category of essential and life saving drugs, and as directed by the Hon'ble Supreme Court in the *K.S. Gopinath case* (2003), the government is duty bound to ensure that "… essential and life-saving drugs do not fall out of price control". However, the dwindling numbers from the list of scheduled drugs under price control conveys a different story. The bulk drugs are regulated under the DPCO.

3.3.10 As per par 3 of DPCO, 1995 prices of scheduled bulk drugs are fixed by the NPPA to make them available at a fair price from different manufacturers. These prices are fixed from time to time by notification in official gazette. The bulk Drugs are identified on the basis of:[89]

- Whose validity period is due to expire
- Request from the concerned manufacturer/company.
- Drug produced in the country for which no price has been notified under DPCO, 1995.

3.3.11 Then, data is collected by issuing questionnaire/Form I of DPCO, 1995/cost-audit report etc. and verification by plant visits, if required. Actual cost for the year for which data is submitted is prepared based on data submitted / collected & verified during plant visit. Technical parameters are prepared based on data submitted, collected and verified during plant visits. Plant capacity is assessed considering 330 working days for normal operation of plant leaving 35 days for scheduled maintenance of plant. The achievable production level is considered at 90% utilisation of assessed capacity allowing 10% production loss on account of unforeseen break down and non-scheduled maintenance. The estimated cost for the pricing period are then prepared based on actual cost & the technical parameters. While projecting the future cost, an increment is recognised at 5% per annum in respect of salaries & wages. Wage agreement, if any, which has been finalised and signed is also recognised while preparing the estimates. In respect of other overheads of fixed/semi variable nature, increase at 2.5% per annum is made to cover the normal incremental effects. The customs duty and other taxes as per the current budget are considered.

3.3.12 Fair price is calculated by providing returns as specified in sub para (2), para 3 of DPCO, 1995. While fixing the maximum sale price of the bulk drug, a post tax return of 14% on net-worth or a return of 22% of capital employed or in respect of a new plant an internal rate of return of 12% based on long term marginal costing is considered depending upon the option exercised by the manufacturer of the bulk drug. In case, the production is from basic stage, additional 4% return is considered on net worth/capital employed.

3.3.13 When the number of manufacturers of the said drug is more than one, the maximum sale price is fixed at 2/3rd cut off level or weighted average price, depending upon the situation. It may be noted that the fair price may be further revised, if asked for by the manufacturers, based on escalation formula for change in major raw materials and utilities rates.

Under the current DPCO 1995, the prices for formulations are fixed as follows:

= (MC+CC+PM+PC) x (1+MAPE/100) + excise duty

(MC = material cost including cost of bulk drugs/excipients: CC = conversion cost; PM

= cost of packing material; PC = packaging charge; MAPE = Maximum Allowable Post-manufacturing Expenses)

Under DPCO 1995 - a uniform MAPE of 100% is granted.

[88] See Economic constraints for access to medicines in India, WHO publication available at: www.centad.org
[89] See http://nppaindia.nic.in/may-2002/procedure-bd.html

3.3.14 The manufacturer of non-scheduled drugs (drugs not under direct price control) is not required to take price approvals from NPPA for such drugs. However, NPPA is required to monitor the prices of such drugs and take corrective measures wherever warranted and includes the power to fix and regulate such prices.

3.3.15 There have been recent attempt to bring out a formula for price negotiations of patented drugs. While there is committee constituted under the department of pharmaceuticals, no relevant background papers are available in the public domain. As per interviews and informal sources at the Department of pharmaceuticals, the price negotiations of patented drugs will be based on lowest market price available. There are three categories envisaged for this purpose.

- First category: Patented drugs where drugs are of significant therapeutic efficacy and substitutes are not available.
- Second Category: Patented drugs where drugs are of significant therapeutic efficacy but substitutes are available
- Third category: Patented drugs without significant therapeutic efficacy

3.3.16 Under price negotiations for patented drugs, only the first category will be considered. If the prices marked by companies is lowest in the world (market price as reference price), than further negotiations will not ensue. However, if not, then negotiations will be made to bring it down to lowest world market price. It may be noted that lowest free market price in the world is a contradiction in itself. Except countries like United States, many country resort to one or other form of direct or indirect control of prices. Hence free market reference price may be a miscalculation. Further 40-70% reduction is envisaged for prescriptions generating out of public facilities. Price negotiations as opposed to price control may not bring down the costs so as to make it accessible to the public at large. It may also undermine the use and willingness to utilize safeguards available viz., compulsory licensing under the Patents Act, 1970.[90]

3.3.17 There are no quantitative or qualitative studies done on influence of negotiations with third party payers on the price of medicines in India. It is also because insurance coverage for drugs is abysmally low neither are they any general schemes for reimbursement by the government except in case of health schemes for government employees. However, studies in jurisdictions that have strong insurance mechanisms or reimbursement schemes have shown that price setting by market players are substantially influenced.[91] Table 3.1 provides for an overview of wide variations in drug Prices: Jan Aushadhi Vs Price Leader Brand.

Table 3.1

Name of Salt	Dosage	Pack	Prices in Rs. (Feb 2009)		Price Gap (Market price/Jan Aushadhi price X 100)
			Jan Aushadhi	Market	
Tab. Ciprofloxacin (antibiotic)	250mg	10	11.1	55	495.4%
Tab. Ciprofloxacin (antibiotic)	500mg	10	21.5	98	455.8%
Tab. Diclofenac (anti-inflammatory)	100mg	10	3.5	36.7	1048.6%
Tab. Cetrizine (anti-allergic)	10mg	10	2.75	20	727.3%
Tab. Paracetamol (anti-pyretic)	500mg	10	2.45	10	408.2%
Tab. Nimesulide (anti-pyretic and analgesic)	100mg	10	2.7	25	925.9%
Cough Syrup	110ml	Liquid	13.3	33	248.1%

Source: Santhosh M R. Centad (2009)

[90] See Centad discussion meeting report on proposed price negotiations. available at: www.centad.org

[91] See EU pharmaceutical sector inquiry final report (June 2009) available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

3.3.18 There has been no attempt to develop a comprehensive national database on pharmaceuticals. Instead, a commercial database has been relied upon. This is open to manipulation and can be reflective of commercial interests. Currently drug price control mechanism is based on the data provided by the ORG-MARG. It is a private MNC in the business of collecting data for the past several years. A number of criticisms have been raised against the use of ORG data as the base for monitoring the drug prices. The Report (Seventh) of the Standing Committee on Chemicals and Fertilizers on Availability and Price Management of Drugs and Pharmaceuticals (2005) observes that ORG takes about 1 percent sample of the sales of the retail outlets. In May 2005, out of total 237318 chemists, it collected data from 2236 chemists. It is an extrapolation from 280 companies of about Rs 19000 crore annual sales to retailers. A significant number of regional companies are not covered. The report of the Drug Price Control Review Committee also pointed out other lacunae in the ORG data and concluded that the committee did not consider their assessment as reliable". Pharmaceutical companies have used caveats in the process of drug registration and licensing to circumvent price control. India probably has one of the largest numbers of irrational combinations in the world. Where leader prices have not been announced, companies attempt to manufacture a combination or a drug delivery system for which there is no precedence. By the time pricing authorities compute the price, the drug has often been in the market for many years. Even if the company withdraws the drug from the market it has already made profits. The DPCO 1995 control the price of imported medicines on the basis of declared landed cost. However, there is no mechanism to verify whether the declared cost is true. This limitation allows companies to resort to import and continue charging high prices. One study revealed that MNCs are more interested in importing to India rather than producing in India because the transfer pricing loophole would give them an incentive to produce drugs elsewhere and then import them into India.

3.3.19 While controlling the price of a drug, the DPCO does not control the price of close substitutes of the price controlled drug. This has prompted many firms to produce related substitutes and continue charging higher prices. An example of such a practice is the substitution of Psuedoephedrine with Phenylpropanolamine (PPA). Actifed, an international brand of Glaxo for cough and cold, contains psuedoephedrine. However, in India it contains PPA. In high doses, PPA has been found to enhance the risk of cerebrovascular accidents. Glaxo preferred to use PPA in India because while psuedoephedrine is under price control, PPA is not. The Report (Seventh) of the Standing Committee on Chemicals and Fertilizers on Availability and Price Management of Drugs and Pharmaceuticals 2005 observes "in some cases, it has been noticed that whenever Government/ NPPA fixes/revises ceiling or non-ceiling price of medicines/formulations some drug companies change the composition of the medicines/ formulations and obtain new licenses from respective State Drug Controller/ Licensing Authority. The State Drug Controller/Licensing Authority should not allow change in composition without any valid ground and without consulting DCG(I) and NPPA" (para 2.9). This practice can be effectively checked by "a penalty such as cancellation of drug license is considered. For this purpose, DPCO, 1995 should have some power as provided in Drugs and Cosmetics Act 1940" (para 2.15.iv).

3.3.20 State Drug Controllers who are in charge of enforcing the DPCO provisions have to resort to prosecution and arrest in cases of violation under the provisions of Essential Commodities Act. There is no provision of compounding of offences. The lengthy procedure of prosecution sometimes deters the state officials to take action. Moreover, for such action the number of agencies involved viz. State Drug Administrations, police authorities and judiciary etc. are numerous and the effect of enforcement of DPCO is sometimes not achieved on the desired lines. Hence, the Interim Report of the Committee to Examine the Span of Price Control for Medicines (Dept. Chemicals and Petrochemicals 2004) had recommended that it would be appropriate to examine if provision can be made in Essential Commodities Act/DPCO for compounding of offences and for levy of fine and penalty for violation of provisions of DPCO. The Drug Price Control Review Committee (1999) had also recommended in favour of providing more powers to the Drugs Control Authorities to dispose off small & petty offences/ contraventions by compounding provision for such offences in the DPCO. This would obviate the necessity of launching prosecutions in minor cases.

3.3.21 The Report (Seventh) of the Standing Committee on Chemicals and Fertilizers on Availability and Price Management of Drugs and Pharmaceuticals (2005) observed that "…the stringent action of prosecution under the Essential Commodities Act sometimes does not lead to desired results. Since there are no provisions for compounding of offences and no provisions of fine or penalties for the violation of the DPCO in accordance with the Essential Commodities Act and the only provisions available are for prosecution and recovery of the overcharged amount, the State Governments find the process cumbersome for initiating any action". The Pronob Sen Committee has recommended that the Drug Prices Control Order, which is presently an order under the Essential Commodities Act 1955, should be converted into a legislative enactment – The Drugs and Therapeutic (Regulation) Act. It has recommended a readily monitorable, market-based benchmark to determine the "reasonableness" of the ceiling price for each of the essential medicines whose prices were to be regulated. Rightly catching the issue on its nerve, the Pranob Sen Committee has also recommended for compulsory de-branding of selected prescription drug when there is evidence of clear market dominance. However, the Committee's prescription for healthy pricing has not found favour within the Government and hence has not been implemented

3.3.22 The DPCO has a provision that manufacturers would apply for price fixation/revision as and when there is a change in the price of a bulk drug within a period of 30 days. However, in the case of downward revision in bulk drug prices, manufacturers seldom apply for price revision. The Report (Seventh) of the Standing Committee on Chemicals and Fertilizers on Availability and Price Management of Drugs and Pharmaceuticals (2005) observes that "drug companies fail to furnish information as prescribed under DPCO '95, but no specific provision for punitive actions are there in DPCO'95 to take action against errant companies/units".

3.3.23 The Drug Policy 1994 envisaged setting up of an independent body of experts to be called the National Pharmaceutical Pricing Authority (NPPA) to do the work of price fixation and monitoring of prices of decontrolled drugs and formulations and to oversee the implementation of the provisions of DPCO. The governments constituted the NPPA vide its resolution dated the 29th August 1997 as an attached office of the Department of Chemicals and Petrochemicals. The Authority is entrusted with the task of price fixation, revision and other related issues as per the provisions of para 3 of the Drugs (Prices Control) Order 1995. The authority also has power to regulate its own procedure for performing the functions entrusted to it and it is free to call for notes, memoranda, results of studies, data and other material relevant to its work from official and non-official bodies and hold discussion with them. NPPA fixes/revises the prices of the scheduled bulk drugs and formulations in accordance with the provisions of DPCO 1995. The State Drugs Controllers help NPPA in monitoring the prices and enforcing the provisions of DPCO. NPPA is empowered to regulate the price of not only the scheduled bulk drugs and formulations but also non-scheduled bulk drugs and formulations if required to protect the public interest. Para 10 (b&c) of DPCO 1995 states "the Government may, if it considers necessary so to do in public interest, after calling for such information by order fix or revise the retail price of any formulation including a non-Scheduled formulation.

3.3.24 The Government may, if it considers necessary so to do in public interest, by order include any bulk drug in the First Schedule and fix or revise the prices of such a bulk drug and formulations containing such a bulk drug in accordance with the provisions of paragraphs 3, 7, 8 and 9, as the case may be". There are some internal guidelines approved by NPPA for monitoring the prices of non-scheduled formulations. These guidelines are suitably modified from time to time based on experience. The latest guidelines for monitoring the prices of non-scheduled formulations are issued on 16th March 2007. According to these guidelines, companies will be short listed and will have to provide reasonable explanation if the prices of its nonscheduled formulation increased by more than 10% (earlier the limit was 20%) during a period of 12 months and the annual turnover of the formulation pack exceeded Rs.1 crore. Further, NPPA will initiate action against non-compliance of internal guidelines/directions and direct the manufacturers to reduce prices and then maintain the price-levels in absence of any reasonable explanation regarding the price hike. The monitoring of prices of non-scheduled formulations is

done on the basis of regular data from ORG-IMS. It has been decided by NPPA that the price fixation meetings will be held in every alternate month.

3.3.25 The need to strengthen the NPPA has been pointed out in many reports. The Interim Report of the Committee to Examine the Span of Price Control for Medicines (Dept. of Chemicals and Petrochemicals, 2004) points out that there is lack of coordination between NPPA and State Drug Controllers. The Committee was informed by the State Drug Controllers that sometimes the notifications, fixing or revising the prices do not reach them on time. However, NPPA officials clarified that copies of notifications relating to fixation or revision of prices by NPPA are regularly sent to all State Drug Controllers. Moreover, the notifications are also available in the NPPA website. The other major limitation of the Authority is the limited strength of officers. In 2004, it had only 21 officers. With greater emphasis on the monitoring of prices of drugs and increase in the workload manifold, this strength seems inadequate.

3.3.26 With a view to strengthen the NPPA by monitoring the prices of drugs effectively at the State level, the Chemicals Department is in the process of creating DPCO cells in all the States, after the finalization of the national pharmaceutical policy. The cells will ensure implementation of prices fixed or revised by NPPA from time to time, detect cases of overcharging and forward the same to NPPA for further action, and follow up the overcharging cases for recovery of overcharged amount. They would also ensure availability of data from manufacturing units, where units fail to provide data/information to NPPA, according to the sources in the Chemicals Ministry. The recent report of the Parliamentary Standing Committee on Chemicals and Fertilisers also endorsed the need for such cells and wanted the Centre to expedite the moves in a time-bound manner in this regard for proper monitoring of drug prices.

3.3.27 The idea of creation of a DPCO cell in each state has also been supported by the Task Force under the Chairmanship of Dr Pronob Sen. The issue of creation of DPCO cell in all States have been included as part of the draft National Pharmaceutical Policy, 2006. NPPA has recently initiated another move to check strategies of pharma companies to evade price controls. It has asked the government to have a second look at the freedom enjoyed by pharma companies to choose the introduction price of a brand. It is concerned about the abuse of this flexibility. The companies can use the route to circumvent checks on abnormal price hikes of control-free brands. At present, NPPA can intervene if the annual price rise is more than 10%. With all brands that breach the ceiling coming under price control, the tendency to inflate the price initially to avoid getting caught later may be high. NPPA has suggested that the government amend the drug law to address the issue of entry-level price.

3.4 Drug Regulation and Competition

3.4.1 Drug regulation can play a significant role in enhancing or reducing ex ante competition in the pharmaceutical market, including the early entry of generic drugs. The Drugs and Cosmetics Act, 1940 is one of the major regulatory norms based framework which actively decides on entry of pharmaceutical products into the market. The purpose of the Drugs and Cosmetics Act is to regulate the sale, manufacture, distribution and sale of drugs in the country. The main objective is to prevent substandard drugs for maintaining high standards of medical treatment and to eradicate the dilution of the necessary concomitants of medical or surgical treatment (*Chimanlal Jagjiwandas Seth v. State of Maharashtra,* AIR 1963 SC 665). The Act clearly mentions that its provisions have to be implemented in addition to other laws existing in relation to drugs. The Drugs Technical Advisory Board is to be constituted by the Central Government. The main function of the Board would be to advise the Central and State Government on all technical matters that come up in relation to this Act. The Central Government shall also constitute a Central Drugs Laboratory.

3.4.2 The term 'drug' is defined under section 3(b) to include all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, such substances intended to affect the structure or any function of

the human body, all substances intended for use as components of a drug or such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals as may be specified by the Central Government. In *Chimanlal Jagjiwandas case* it was pointed out by the court that the term drug would not only include medicines but also substances other than medicines which are used for treatment of diseases in human beings or animals.

3.4.3 The Act defines misbranded drugs (sec 9 and 17) as those that are coated, coloured or polished so that the damage prescribed manner or if anything accompanying the drug makes a false claim for the drug. Adulterated drugs (sec 9A and 17A) are those that contain any filth, putrid or decomposed substance, those that have been prepared or stored under insanitary conditions, if the container is made of any poisonous substance, if it bears a colour other than what is prescribed, if it contains any harmful or toxic substance or if any substance has been mixed with it to reduce its quality and strength. Spurious drugs (sections 9B and 17B**)** are those that are manufactured under the name of another drug, or if it is an imitation or substitute of another drug, if the label or container bears the name of a manufacturer that is fictitious, if it has been substituted wholly or in part by another drug or if it claims to the product of a particular manufacturer when it is not. The section relating to spurious drugs is closely related to section 8 of the Trade Marks Act which states that no trade mark or part of any trade mark shall be registered which consists of, or contains, any scandalous design or any matter the use of which would by reason of its being 'likely to deceive or cause confusion'.

3.4.4 This issue was further discussed in the case *Cadilla Health Care v. Cadilla Pharmaceuticals* (AIR 2001 SC 1952). This case involved two companies had taken over the Cadila group. Both companies were allowed to use the name. The appellant was selling a tablet named falcigo and the respondent came out with its own tablet called falcitab. Falcigo was manufactured for the treatment of cerebral malaria called falcipharum and the appellant got it registered with the Trade Marks Registry and got permission from the Drugs Controller of India by Oct 1996. The respondent got permission from the Drugs Controller to manufacture a drug containing mefloquine hydrochloride in April 1997. This drug was also used for the treatment of falcipharum. The appellant sought an injunction from the court against the respondent's medicine as it claimed that the same would be passed off as their drug as there was a confusing similarity and the drugs were medicines of last resort. The respondents claimed that the term 'falci' was derived from the disease which the medicine was intended to cure and also these medicines were sold to hospitals and clinics and could not be sold over the counter. Hence the chance of confusion and deception was very remote.

3.4.5 The court pointed out that due to the lack of knowledge of the English language in India and therefore a stricter approach should be adopted while applying the test to judge the possibility of confusion of one medicinal product for another by the consumer. The court also stated that measures should be more stringent when it comes to medicines of last resort. The court pointed out Drugs and Cosmetics Act, section 17B where an imitation or resemblance of another drug in a manner likely to deceive is regarded as a spurious drug. Section 8 of Trade Marks Act states that no trade mark or part of any trade mark shall be registered which consists of, or contains, any scandalous design or any matter the use of which would by reason of its being 'likely to deceive or cause confusion'. This creates direct implications for competition where usurpation of part of therapeutic names by competitors. Moreover, it is relevant in this context that prescription drugs may not create consumer confusion since the doctor is knowledgeable enough than the average consumer. The Court stated that authorities before granting permission to manufacture a drug under a trade must be satisfied that there is no confusion or deception in the market. The court laid certain factors to be considered while deciding a question on deceptive similarity: the nature of marks- word, label or composite**;** degree of resemblance, phonetic similarity, similarity in idea**;** nature of goods; Similarity in nature, performance and character of goods**;** class of purchasers (intelligence, education, degree of care); mode of purchasing goods**;** other surrounding circumstances**.** The court sent the case back to the trial court to decide upon keeping these factors in mind.

3.4.6 This Act under Section 10 and 18 prohibits any person from importing, manufacturing for sale, selling, offering for sale, stocking or exhibiting any drug which is not of a standard quality, any misbranded, adulterated or spurious drug or cosmetic. If a licence has been prescribed then a drug cannot be imported otherwise. In case of patented or proprietary drugs, a list of active ingredients along with quantities needs to be specified on the cover. The Act also prohibits the import, manufacture, sale, offer for sale, stock or exhibit of any drug that claims to cure a disease or ailment that has been prescribed, any cosmetic which contains any harmful ingredient. Small quantities of any drug can be imported for testing, examination, analysis or personal use. The Government can also in certain cases allow the import of drugs that are not of standard quality. The Central Government can also prohibit the import and regulate, restrict or prohibit manufacture, sale etc of certain drugs if it feels that there is a risk to human beings or animals, there is no therapeutic value to the drug or if there is no therapeutic justification for the quantity of active ingredient in the drug. The Customs Collector or any other Officer authorized by the Central Government in this behalf can detain any package containing drugs or cosmetics that are banned from import. He shall report to the Drugs Controller of India and can also forward the package or a sample of the drug. The Central Government has the authority to make further rules to ensure the implementation of the law relating to import, sale, manufacture etc of drugs and cosmetics. These rules can specify drugs for which a licence is required, the conditions of such licences, the authority empowered to issue the same etc. It can also specify the methods of test or analysis of standard quality, methods of standardization, specify diseases that an imported drug cannot purport to claim, regulate the mode of labelling drugs, provide for exemptions from any of the provisions etc.

3.4.7 The penalties for offences under this Act were increased by the Drugs and Cosmetics (Amendment) Act 2008. The escalation of penalties was preceded by various estimates being made about the extent of spurious drugs in India. Some studies claimed that 35% of fake drugs in the world were from India. However, no systematic study has been undertaken to generate any credible data. The Indian Government's own estimates for the extent of spurious drugs vary between 0.24 to 0.47 per cent and for substandard drugs from 8.19 to 10.64 per cent.[92]

3.4.8 A drug will not be considered misbranded or adulterated or spurious because a substance has been added to make it fit for carriage or consumption and not to increase weight, measure or bulk of product or if in the preparation of the drug some substance has unavoidably mixed with it and the drug was sold or distributed before the distributor became aware of such intermixture. A person other than the manufacturer cannot be held for manufacture and sale of prohibited drugs if he can show that he acquired the drug from a duly licensed manufacturer or distributer, if he did not know and could not have ascertained that the drug or cosmetic in any way went against the requirements of the Act and if the drug while it was in his possession was stored properly and was in the same state as when he acquired it. The Central and State Governments can appoint Government Analysts or Inspectors. The inspector has powers, within his local area to search premises where any drug is being manufactured, sold etc, take samples of any drug, search any vehicle , person or place where it is suspected that a prohibited drug is present. The inspector also has the power to inspect any document or require a person to produce any document for inspection. When the Inspector takes a sample of a drug for test he shall inform of his purpose and pay the price for it. If he is seizing the drug then he should give a receipt for it. The Government Analyst on receipt of a sample shall test the same and deliver three copies of a signed report to the inspector. The report of the analyst will be held to be conclusive evidence unless the person from whom a sample has been taken notifies the Inspector or court that he wants to bring forward evidence to prove the report wrong. The Court in such cases can send the sample to the Laboratory for testing and the report produced on the basis of that shall be held to be conclusive evidence.

3.4.9 The Union ministry of health has proposed a whistle blower scheme for all those informants who volunteer with information on spurious or counterfeit drugs. According to the policy a maximum of 20% of the total cost of

[92] A report of the Expert Committee on "A Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs", Ministry of Health, Government of India, November 2003.

consignments will be payable to the informant provided that the total compensation does not breach a ceiling of Rs. 25 lakhs. Even government officials can claim rewards under this new policy.

3.4.10 Good manufacturing practices are in the form of drug safety standards. GMP standards are laid down by the WHO. Schedule M, which implements the GMP deals with requirements for plant, equipment and premises for pharmaceutical products. The National Human Rights Commission in 1999 made certain recommendations regarding manufacture, distribution and storage of drugs and the need to upgrade good manufacturing practises under schedule M. WHO had also prescribed guidelines. The Parliamentary Standing Committee on Health and Welfare in their 12th report on Drugs and Cosmetics (Amendment) Bill, 2005 had recommended stringent measures against manufacturing spurious and sub standard medicines and drugs. Following such practises, it felt, was necessary for sustaining export of drugs. This called for an amendment of Schedule M. Amendment of Schedule M was done at the Bureaucratic Level, as only the Drugs Act Amendments need Parliament approval. But its implications are immense. The pretext of amendment was improvement of quality but SSIs claim that there are unreasonable clauses of the Amendment which are not acceptable because they are brought in by Multinationals to eliminate SSI. To achieve that end SSIs believe that Multinationals or their Indian Counterparts started to create a paranoia in public about quality by planting disinformation in media with regard to number of Fake and Spurious Drugs in the country (SPIC-SSI briefing, Centad, 2009) The amendments were notified in December 2001 and it stressed on – adequate documentation at every stage, validation of process and equipments, efficient standard operative procedures (SOPs) at every stage of manufacture and quality control operations, adequate and periodic training to the technical personnel in the industry. There arose a huge debate with respect to these amendments and the Najma Heptullah Committee was constituted to study the impact of implementation of the revised schedule M on the small scale pharma units in the country.

3.4.11 The Committee put forth certain questions to the Ministry of Health with regard to new amendments. The Ministry was of the opinion that the amendments would not be detrimental to small scale units as most of them had already upgraded their facilities and others were in the process of doing so. The Ministry claimed that all sectors of the pharmaceutical industry were consulted regarding the amendments and in specific stated that the IDMA which also consisted of the small scale units had been consulted. The Ministry felt that small scale industries did not require much investment in equipment, area, documentation etc as most of the provisions required proper application of norms and manufacturing practises and only a minor portion required a change in infrastructural facilities. In order to apply these GMPs the government had convened workshops in various parts of the country. NIPER (National Institute for Pharmaceutical Education and Research) had also conducted programs for the training of the staff of SSIs. With respect to the licensing authority having discretionary powers, the Ministry was of the opinion that licensing authorities had discretionary powers even under the earlier version of the Schedule M and such discretionary power was only in relation to chemical and pharmaceutical aids, bandages, medical gases, empty gelatine capsules etc for which there are no specific requirements relating to space and equipment in Schedule M. The Ministry pointed out that various demands of SSIs had been taken into consideration such as use of alternative material instead of aluminium, removal of ancillary area, usage of non- linting cleaning material etc.

3.4.12 The SME Pharma Industries Confederation (SPIC) submitted a letter to the Department of Pharmaceuticals pointing out the factual mistakes in the Ministry's reply to the Committee. They disagreed with the claim that most SSIs had already complied with the new provisions. They stated that in fact many SSIs had closed down. If most SSIs had complied with the new provisions, why then, they questioned, was the Pharma Technological Upgradation Fund (PTUF) being set up four years after implementation and why was NIPER setting up a sample SSI unit to guide SSIs? In response to the Ministry's statement that 80 per cent did not require investment, the SPIC pointed out that 80 per cent could be implemented only after 20 per cent of investment is complied. Upgradation of each section would cost upto Rs 1 crore and equipments would cost more than 50 lakhs which an SSI could not afford An example would be bio- burden free water supply to the unit which is mandated by Schedule M, which would cost about Rs 10,00,000. Also to comply with documentation requirements alone, atleast

3 B Pharm graduates would be required, which is cost prohibitive. The SSIs had submitted that they objected to certain provisions as it increased the area of minimum requirement. Since most SSIs were situated at metropolitan areas, an increase in area would prove to be too expensive. The Ministry accepted that expansion of old existing areas were not possible and that SSIs might have to relocate to new premises which would involve tremendous expenditure. The Ministry of Micro, Small and Medium Industries also pointed that even though the time period given for abiding by the rules had been extended, the SSIs were still unable to comply with the timeline and also the issue of cancellation or non- renewal of licenses on account of non compliance with the new provisions needed to be addressed.

3.4.13 In certain areas large numbers of SSIs had closed down and Ministry stated that they were still in the process of collecting information. They however maintained that most SSIs had already adopted the revised norms. The MSME had a Credit Linked Capital Subsidy Scheme for the modernisation and technology upgradation in the small scale sector and the Department of Chemical had proposed a scheme where 5% interest subsidy had to be provided on an amount upto one crore. The MSME Development Act had also created enabling provisions whereby investment limit in plant and machinery had been increased to 5 crores for small scale units and 5- 10 crores for medium scale units. The Act also had other provisions that mandated the government and its units to procure goods of micro and small units.

3.4.14 The Najma Heptullah Committee was of the opinion that the proposed amendments to schedule M in relation to good manufacturing practices and plant, premises and equipment requirements would help in making the country an international hub in manufacturing drugs and that these standards were desirable to protect interests of consumers. It noted that the Ministry of health and family had allowed stakeholders a 45 day period to submit views and extended compliance date till 30th june 2005. It however acknowledged that SSIs would have difficulty in meeting deadline and would require additional investment. For this purpose the Government was to support SSIs through the transitory phase through schemes such as Credit Linked Capital Subsidy Scheme (CLCSS) and Credit Guarantee Fund Scheme. The Committee also proposed that the Certification Reimbursement Scheme should be extended to all expenditure related to documentation incurred by SSIs. It recommended that a Special Package for infrastructure facilities should be made under Micro and Small Enterprise and Cluster Development Program and along with the proposal to provide 5% interest subsidy by the Department of Chemical, the CLCSS should also be linked to provide upfront relief in capital investment. The Committee acknowledged that there was possibility of misinterpretation of provisions, therefore the MMSME, NIPER and SSIs should conduct workshops under its Entrepreneurship and Business Development Programmes for field level enforcement agencies of the government and the technical staff of SSIs. It also stated that the Government should without further delay finalise rules for setting up funds to support SSIs under MSM Enterprises Act 2006 and the Purchase Preference Policy under Section 11 MSM Enterprises Act 2006 have to be finalized. The committee also pointed out that the MMSME and MHFW had different views on the impact of the amended Act on SSIs. Since the presence of SSIs are essential in annual medicine production and to prevent monopoly, it is important they are preserved. Hence the MMSME along with the Drugs Technical Advisory Board has been instructed to conduct a survey to examine the extent of closure of SSIs due to non compliance since the amended provisions have come into effect from 2005. The Committee noted that the prices of medicines have increased since the MRP based excise regime. It has also denied small scale manufacturers a level playing field. The government must do something to restore level playing field.

3.4.15 Schedule Y contains requirements and guidelines on clinical trials for import and manufacture of a new drug. Marketing approval of a new drug would depend on the status of the drug in other countries. If the drug has been marketed in other countries, then phase III trials are required. If the drug has not been marketed in other countries, then trials are initiated at one phase earlier to the phase of trials in other countries. Phase I trials are generally not permitted in India for drugs discovered in other countries unless data from phase I trials done in other countries are available or if the drug in question is relevant to a health problem in India. For new drug substances discovered in India, clinical trials have to be carried out right from phase I. Approval is given for each phase and it is dependent

on the data emerging from the previous phase. Permission to conduct trials must be sought by applying for a test licence to import or manufacture the drug. The application must be submitted along with data for each phase of the clinical trial, protocol for proposed trials, case report forms to be used, names of investigators and institutions. The institution's ethical committee is supposed to approve the protocols for the trials. In case the institution does not have such an ethical committee, then the approval of the protocol of the ethical committee of one institution can be used for the protocol of the institution that does not have an ethical committee. If no institution has an ethical committee, then the investigator and the Drugs Controller have to give approval. Permission for clinical trials in the paediatric age group is given only after phase III trials in adults are completed but if the drug is of value primarily in a disease of children then permission for earlier trials in the paediatric age group may be given. Sponsors are required to submit an annual status report of each trial that is ongoing, completed or terminated. In case of termination, reasons should be specified and any unusual or serious adverse drug reaction (ADR) must be notified to the licensing authority. An informal written consent signed by the volunteer and the investigator is required.

3.4.16 **Approval of biological drugs:** There are no special guidelines for approval of biosimlars in India. The regulations that are in force are the Drugs and Cosmetics Act, 1940 and rules therein (Schedule-M), WHO current Good Manufacturing Practices (cGMP) requirements, Indian Council of Medical Research's (ICMR) Good Clinical Practices (GCP) guidelines, and the Indian Pharmacopoeia. "All regulations fall under the Schedule M of the Drugs and Cosmetics act and the relevant ICH guidelines on manufacturing of drug substances. Currently, there are no separate guidelines in India for biotechnology products. Though, there are certain relevant US Food and Drug Administration (US FDA) and European Medicines Agency (EMEA) guidelines that cover these products.

3.4.17 The regulation of biologicals in India is controlled by the Drug Controller General of India (DCGI) and Central and State Drugs Control departments like Central Drugs Standard Control Organisation (CDSCO) and Drug Regulatory Authorities (DRAs). However, in certain cases for example, where the product is developed or manufactured using recombinant-DNA (r-DNA) technology, the approval of various other agencies/committees is essential. These include Genetic Engineering Approval Council (GEAC), recombinant DNA advisory Committee (RDAC), Review Committee on Genetic Manipulation (RCGM), Institutional Biosafety Committee (IBSC) and many more such committees, at the state and district levels. This needs to be regulated through a single window clearance channel. This may at time require clearance from the department of biotechnology.

3.4.18 The official standards and specifications setting body is the Indian Pharmacopoeia Commission (IPC). For biologicals including recombinant DNA products the IPC works in collaboration with National Institute of Biologicals (NIB). IPC publishes periodically the Official Pharmacopeia, the latest being in 2007 and also publishes its supplements (latest in 2008) which contain specifications (monographs) of biologicals approved by the DCGI.

3.4.19 The MNC groups have requested to consider establishing Regulatory criteria for the approval and consideration for comparability to the innovator product. This would be on the basis of 'prescribability' and 'switchability'. Prescribability essentially means a clinical setting, where a clinician prescribes the product for the first time based on its characterization during clinical trials. Interchangeability (or switchability) refers to a clinical setting when a clinician transfers a patient from one product to another based on its bioequivalence data.

3.4.20 It may be noted that EU has established a procedure for supervising and authorizing the regulatory approval of generic biological products. In 2006, EMEA (European Medicines Agency) released final guidelines containing details of clinical, non-clinical and quality expectations for biosimilar protein therapeutics. These guidelines were themselves an expansion of the general guideline released in September 2005 and of two earlier documents, a note for guidance containing non-clinical and clinical issues (December 2003) and a quality guideline (also December 2003). The EMEA's work in developing regulatory and scientific guidance documents has enabled the EU to be the first major governmental body to authorise a biosimilar product. However, across the Atlantic in the US, the innovator industry filed several court petitions challenging the use of Section 505(b)(2) to approve FOPs. The Biotechnology Industry Organisation (BIO) filed a citizen petition in April 2003 objecting to the use of this

section to approve a biologic without a "full complement" of non-clinical and clinical data. However, till date no legislation is in place for approval of such products. Nevertheless in May 2006, the US FDA approved a recombinant human growth hormone (rhGH) after a legal battle. The US FTC is also striving its way forward for implementing a regulatory regime for approval of biologics so as to ensure adequate competition while not compromising safety.[93]

3.4.21 **Data Protection:** Clinical Trials and the data generated by them have come to be of special significance when read with Article 39.3 of the TRIPS agreement. Article 39.3 of the TRIPS Agreement states:

> "Members when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use".

3.4.22 The terms in Article 39.3 provide flexibility to countries, allowing them to interpret the provision in the manner that would them best. Some countries have introduced a trade secret form of protection where the regulatory authority can rely on this information to grant marketing approval to subsequent applicants for similar products without disclosing the confidential information to them. Another method that is adopted by countries is data exclusivity as a form of protection. As per 'data exclusivity', the regulatory authority cannot rely on data submitted by the originator for approving the second and subsequent applications for the same product. The approach to be taken under this provision in India gave rise to a huge debate. A few argued that it was important to facilitate early entry of new drugs in the country and this would be determined by the protection that Indian law was able to provide. Others were of the opinion that Article 39.3 was a TRIPS- plus provision and therefore India was under no obligation to provide for data exclusivity. Data exclusivity would also affect the generic pharmaceutical industries in the country and also lead to an increase in prices in the country.

3.4.23 The Satwant Reddy Committee was set up to address this issue and to recommend appropriate measures in this regard. They were to identify steps to be taken in the context of Article 39.3 of the TRIPS Agreement and to gauge whether data protection can be undertaken under the existing legal provisions. The committee came out with its report on 31st May 2007. With respect to pharmaceuticals, it noted that the Drugs and Cosmetics Act had in place an established system of marketing approval and evaluation of test data generated for drugs in India. They noted that within this legal system changes need to be made to explicitly provide for the minimum requirements of data protection. However, they recommended that any higher standards of data protection need to be done after a detailed study of its impact on the domestic sector and the general public.

3.4.24 An examination of the trend of drug approvals showed that most of the new drugs have first been launched in other countries and thereafter launched in India as generics. The committee was of the opinion that this likely to continue and therefore any immediate strict application of data exclusivity would have an adverse effect on the industry as well as the people. The committee therefore recommended that the minimum requirements under Article 39.3 which would be non- disclosure of test data and non- acceptance of fraudulently obtained data should be implemented after making the necessary legal changes. They recommended a transition period during which modifications such as a critical upgradation of the Office of the Drug Regulator in terms of physical infrastructure and technical skills, constitution of a Central Drug Authority under the Ministry of Health and Family Welfare etc. It opined that in the long run, it may be in the country's interests to move towards higher standards of data protection but during the transition period only the minimum requirements should be implemented. The duration of the transition period was not specified.

[93] US FTC Study on Entry of Biological Drugs (June 2009)

3.4.25 In a recent development, pharma major Bayer sought to restrain generic competitors from getting their patent infringing version from marketing approval[94]. This was an attempt to bring in patent linkage within the Indian drug regulatory framework. However, a HC decision stayed the order of a single judge who had passed a favourable order for Bayer against Cipla. The single judge order had made a reference in its order that the DCGI is expected not to violate any other law of the land. On appeal, Bayer argued that the drug "Soranib" for which license was sought was a "spurious drug" under Section 17B of the Drugs and Cosmetics Act. Bayer relied on Section 2 of the Drugs Act to contend that the legislative intent is to read the provisions of the Drugs Act in conformity with Section 48 of the Patents Act. It was argued that section 48 of the patents act 1970 would be violated by virtue of granting marketing approval to a potentially infringing product. Bayer argued that "generic drugs can only be legally produced for drugs which are free of patent protection". But this concept is not factually correct. Patent infringing drugs cannot be called as spurious under any wild understanding of the drug regulatory procedures.

3.4.26 Bayer emphasized that the interpretation of Section 2 by pointing out that under Section 156 requires that a patent granted under the Act has the same effect on the government as on others. And since the Drug Authority is a functionary of the Central Government, it should be equally bound by and respect the patent granted to Bayer. The defendant (CIPLA) argued that the grant of a regulatory approval by the Drug Controller does not amount to infringement of the patent and that infringement needs to be established in a court of law in accordance with the provisions of the Patent Act. Cipla also argued that it cannot be assumed on the basis of statements of the patentee or decided by the Drug Authority which is institutionally incapable of delaying with complex issues relating to scope of the patent, its validity and infringement. It is a settled principle that Drug regulation is different from intellectual property protection. Conflating the two institutions could allow usurpation of authority and delay/ cause impediment to generic entry.

3.4.27 Cipla pointed out that Section 107A of the Patents Act clearly exempts from patent infringement any of acts of making, using or even selling a patented invention, in so far as such acts are necessary to obtain information for the filing of a drug regulatory application before the Authority. It is not surprising to note that the 'Bolar provision' or Section 107(a) would be rendered redundant if the approval by the Drug Authority amounts to infringement. Cipla also contended that Soranib cannot be a 'spurious drug' as Cipla was not trying to pass of its drug as that of Bayer's. Reference was made to the different schemes of the Patent Act (and the existence of an exhaustive opposition and infringement proceedings) and the Drugs Act and the lack of a specific legislative provision providing for an overlap; essentially amounting to attempting backdoor entry of 'patent linkage'.

3.4.28 The Court noted that accepting Bayer's position would confer jurisdiction on one set of agencies denuding the powers, jurisdiction and meaningful role conferred lawfully on another set of specialized statutory authorities, under the Patents Act. The Court emphasized on the point that the absence of specific legislative enactments in favour of patent linkage portrays the legislative intent to exclude it. If the Drugs Authority can decide on patent infringement, the provisions of the Patent Act would be reduced to "useless lumber". It is intriguing to note that the Court made a reference to the European Union Competition Authority's preliminary report on the pharmaceutical sector inquiry.

3.5 **Consumer Drug Information in India[95]**

3.5.1 Consumer drug information includes all information directed to patients and consumers regarding drugs and treatments used by them with a view to enabling them to take informed decisions. The need for such information emanates from the basic right to the health of individuals. People must have knowledge about what medications they are being advised to consume in the interest of their own health. It is a basic right to know what one is consuming. The Alma Ata Declaration states: "People have the right and duty to participate individually and collectively in the planning and implementation of their health care". Moreover, the issue of right to essential

[94] See Bayer v. Cipla, WP(C) No.7833/2008

[95] This section is largely based on a study carried out by Centad on Consumer Drug Information in India (2007)

medicines, right to safe medicines is closely tied with the right to health, right to livelihood with dignity and right to life.

3.5.2 Generally speaking, the information about drugs should be accurate, reliable, understandable, relevant to people in different contexts, accessible, and comparative (where possible). Drug information is also the basis for the development of tools essential for rational prescribing and use such as formularies and standard treatment guidelines. There is a range of actors involved in the dissemination of different types of information to consumers relating to drugs. Organisations that are considered as the actors providing consumer drug information are considered as such because of their mandates, which are relevant, even indirectly, to issues of consumer drug information. These include governmental and quasigovernmental authorities, civil society and nongovernmental organisations, patients' associations, pharmaceutical associations, drug manufacturers' associations, and societies involved in promoting rational drug use.

3.5.3 The objective of the Centad study on this issue involved the following:

- To determine the type of information referred to when discussing 'consumer drug information'. To determine the nature of information currently being disseminated to consumers.
- To identify which actors are involved in dispensing such information and the type of information that each provides.
- To identify models and guidelines for what kind of information should ideally be provided, how this should be done, and how this can further the cause of helping consumers make informed choices.
- To examine the law and policy regimes applicable to drug information disseminated to consumers.
- This paper seeks to address the above objectives through a study of a sample of relevant drug information materials for consumers. The first step of the project involved the identification of contacts to approach for information. This was done through searching for organisations and individuals on websites, posting requests on online mailing groups dealing with issues on drugs, as well as approaching individuals for providing relevant contacts.

3.5.4 There are some interesting conclusions that can be drawn from a situational analysis of the provision of consumer drug information in India. The availability of consumer drug information in India is very low in terms of quantity. Information is not provided in a user-friendly manner in most cases. It is provided mostly on allopathic drugs, and there is only limited information on traditional medicines, medical technologies and equipment, and on diagnostics. There is a particular lack of information relating to drug prices, and there is no single, dedicated actor concentrating only on consumer drug information. There is no coordination among different actors providing consumer drug information, and there is no level of consistency with respect to the information supplied. Information directed at consumers is largely aimed at awareness creation on preventive strategies and is not very technical in terms of providing medical details pertaining to the drugs or in terms of providing practical information regarding the usage and consumption of the drug. Most technical information with respect to drugs is directed to medical professionals and not consumers. Information to consumers in not made available in a simple manner, since this is usually done through the publication of books, booklets or CDs or other formats that would not normally be accessed by common consumers. Information is sometimes being provided in both English and local languages though for some sources of information such as labels on medicines or those in the internet, information is primarily in English. The current law and policy regime does not deal comprehensively with issues of consumer drug information. There is no comprehensive, single database of information, which contains technical information on drugs that has been approved by government. The Ministry of Consumer Affairs does not provide exclusive information on drugs. Government websites, such as that of the Ministry of Chemicals and Fertilizers, do provide information on prices in the form of relevant government orders, notifications and news dealing with the drugs under price control, lists of essential drugs, and so on.

3.6 A Brief Survey of laws Governing Various Actors in Pharmaceutical Supply Chain

3.6.1 **The Pharmacy Act, 1948:** The Pharmacy Act was passed with the objective of regulating pharmacy education in the country and to regulate the profession and practise of pharmacy. A central council was to be constituted under section 3 of the Act by the Central Government called the Pharmacy Council of India which was to operate as a corporate body. From the Central council an executive committee was formed, consisting of the President, Vice President, ex officio and five other members, elected by the Central Council from among its members. The central council in addition was to form from its members, other committees for such general or special purposes as that Council may deem necessary.

3.6.2 The Central Council has to make educational regulations that prescribe the minimum standard of education required for qualification as a pharmacist. Any authority which conducts a course on pharmacy or an exam on the subject has to get the approval of the central council. The Central Council has to ensure that a register containing the names of all the persons for the time being entered in the register of the State is maintained called the central register. The central council with the permission of the central government may make regulations regarding the management of the property of the central council, manner in which elections are to be held, summoning and holding of meeting of the central council, functions of the executive committee, powers and duties of president and vice- president, qualifications, term of office etc.

3.6.3 Except in cases of a joint state council, the state shall constitute a state council. Two or more states can enter into an agreement to constitute a joint state council, to provide that the state council for one shall serve the needs of the other, to provide for the apportionment of expenditure between the states, provide for consultation between states etc. The state council shall also constitute an executive committee on the similar lines of the executive committee of the centre.

3.6.4 The state government has to prepare a register of pharmacists in the State. The register shall include the full name, address, qualifications etc. The first register shall be prepared and then published in the manner as directed by the State government. A registration tribunal shall be constituted for this purpose. Any person above the age of eighteen years after paying the requisite fee can have his name entered in the first register if he resides or carries on the business of pharmacy in the state and holds a degree or diploma in pharmacy or pharmaceutical science or a chemist and druggist diploma approved by the Government, or if he holds any degree and he has been involved in the compounding of drugs in a hospital or dispensary, if he has passed an examination recognized as adequate or if he has passed any examination that is considered as adequate by the Government or if he has been involved in the compounding of drugs for at least five years. Displaced people, who have been carrying on the business of pharmacy as their principle means of livelihood from a date prior to 4th March 1948, can also be eligible for entry of names into the register if they satisfy the conditions as laid out above. Citizens of India who have been carrying out the business of pharmacy outside India and satisfy the above mentioned conditions etc are also eligible for entry into the register. Sections 32 A and 32B also discuss other special provisions for registration of persons in the register. Applications for registration along with the requisite fee shall be sent to the registrar of the state council and on his approval, an entry shall be made in the register. On rejection by the registrar, the applicant within three months may appeal to the state council. The decision of the state council in this regard shall be held to be final. On payment of a prescribed fee, registered pharmacists can enter in the register any additional qualifications and degrees in pharmacy that he may have obtained.

3.6.5 A person's name can be removed from the register where his name has been entered by error, on misrepresentation or suppression of facts, if he has been guilty of any offence in a professional aspect or a person employed by him has committed the above which would make him liable. This can be done permanently or for a

stipulated time. Any party aggrieved by this action can appeal to the State Government. No order refusing to enter a name or removing a name can be called in question in any court.[96]

3.6.6 If any person whose name is not entered in the register falsely pretends or suggests that it is so, then he shall be held to be liable. This would include usage of terms such as 'pharmacist', 'chemist', 'druggist', 'pharmaceutist', 'dispenser', 'dispensing chemist' etc. The person who claims to be registered has the onus of proving it. Whether or not any person was deceived by such use is of no consequence. No person other than a registered pharmacist can compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner. But this does not apply to a medical practitioner dispensing medicines to his own patients, or with the permission of the government dispensing medicines for the patients of another medical practitioner. If a person whose name has been removed from the register fails to surrender his certificate of registration, then he shall be liable to a fine. If the central government feels that the central council is not complying with the provisions of this Act then it can set up a commission of enquiry consisting of three persons. Two persons shall be appointed by the central government out which one shall be a judge of the high court and the remaining one shall be appointed by the council. The commission shall make enquiries and submit a report along with recommendations. Once the report is accepted, the central government can ask the council to comply with the recommendations given and if not complied with, the central government can take such action as necessary to ensure compliance with the recommendation.

3.6.7 The state government also has the powers to make rules in relation to the management of the property of the state council, the manner in which elections are to be held, the summoning and holding of meetings of the state council, the qualifications, term of office, powers and duties of the registrar, president, vice president and other officers, form of certificates of registration, fees payable, the conduct of pharmacists and their duties in relation to medical practitioners, the public and the profession of pharmacy etc.

3.6.8 **The Drugs And Magic Remedies (Objectionable Advertisements) Act, 1954:** The purpose of the Act is to control advertisements of drugs in certain cases and to prohibit advertisements of remedies that claim to possess magic qualities. According to this Act, advertisement includes any notice, circular, label, wrapper or other document and any announcement made orally or by means of producing or transmitting light, sound or smoke. The term drug would include medicines for internal or external use of human beings, substances used in diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals, any article that would influence the structure or organic function of the body of human beings or animals other than food and any article used as a component of any medicine substance. Magic remedy would include any talisman, mantra, kavacha and any other charm which claims to possess miraculous powers in relation to the diagnosis, cure, mitigation, treatment or prevention of any disease or influencing structure or organic function of the body.

3.6.9 Section 3 of the Act states that no person can advertise any drug aiming at miscarriage in women or prevention of misconception, maintaining and improving sexual pleasure, correction of menstrual disorders in women or any drug mentioned in the schedule or the rules made under this Act. Section 5 of this Act extends the above provisions to persons claiming to administer magic remedies and Section 6 extends it to persons importing and exporting drugs. The schedule under the Act specifies a list of ailments for which no advertising is permitted. The list contains 54 ailments including Cancer, Venereal Diseases, Tuberculosis, and Diabetes to name a few. Apart from this, there is no specific law which prohibits advertising of prescription drugs although industry practice is not to advertise prescription- only drugs.[97]

3.6.10 No person can advertise anything that directly or indirectly gives a false impression of the drug, makes a false claim or is false and misleading in any material particular. This issue was addressed by Court in the case *Colgate-*

[96] Section 38

[97] Vijay Bhangale, International Marketing Conference on Marketing and Society, April 2007, IIM Kolkata

Palmolive (India) ltd v. Anchor Health and Beauty Care Private ltd.[98] The case was filed by Colgate against Anchor for telecasting advertisements that disparage or slander Colgate toothpastes. Colgate raises its objection on two main issues, namely, that Anchor claims that it is the 'only' toothpaste containing triclosan, fluoride and calcium. Also it claims that it is the 'first' toothpaste to provide all round protection

3.6.11 Colgate objected to the words 'only' and 'first' pointing out that they also had the three ingredients in their toothpaste and they had been in the market for much longer and hence the two claims of Anchor were false statements. Anchor claimed that 'only' is used with reference to a range of their own products and 'first' is not with reference to the product but with reference to the slogan 'all round protection'.

3.6.12 The Court in this case held that since even Anchor had admitted that the words 'only' and 'first' is not intended to convey the meaning it does, Colgate has a prima facie case. The court pointed out that it is in public interest not to allow Anchor to make such a misleading claim and that the balance of convenience went against Anchor. As per section 8 an officer authorized by the state government can enter and search any place where he feels that an offence has been committed under this Act, seize an advertisement that is in contravention to this Act or examine any record or document and seize if it is evidence of the commission of a crime. If the offence is carried out by a company, then the person in charge of the company and the company itself will be held liable. But if the person in charge can prove that the crime was committed without his knowledge or that he exercised due diligence to prevent the crime, then he will not be held liable. If the offence has been committed with the consent or due to the neglect of any officer of the company, then he shall be held liable. If a person is convicted of an offence, then the offending document, article or thing along with its contents shall be seized. A person shall not have a suit or proceeding instituted under him for an act done in good faith. Section 13 states that the provisions of this Act are in addition to the provisions of any other law.

3.6.13 Section 14 points out instances where the Act will not apply such as a sign board displayed by a medical practitioner on his premises indicating treatment of diseases mentioned in section 3, the schedule or the rules, any book etc dealing with matters under section3 from a scientific or social point of view, any advertisement of any drug sent confidentially to a medical practitioner, any advertisement of any drug that is printed or published by the government or if the sanction of the government has been attained prior to this Act. If the government feels that it is in public interest to advertise a particular drug even though it would fall under the restricted categories, it can pass a notification to that effect. The government can make further rules relating to diseases to which section 3 would apply, prescribe the manner in which advertisements may be sent confidentially etc.

[98] (2008) 7MLJ 1119

CHAPTER IV

THE APPLICATION OF COMPETITION LAW IN THE PHARMACEUTICAL SECTOR: PRINCIPLES AND EXECUTION- A VIEW FROM COMPARATIVE JURISDICTIONS

4.1 Introduction

4.1.1 In this section, the study examines the conceptual, policy and practical foundations for the application of competition law in the pharmaceutical industry and markets. Here, a review of the positions in comparative jurisdictions (primarily United States of America (US) and European Union (EU) - with timely reference to the position in other common law jurisdictions -whenever necessary) is undertaken. Positions in comparative jurisdictions are examined by referring to respective legislative provisions and through the developments in case law jurisprudence.

4.1.2 The *Treaty Establishing the European Communities (as amended by the treaty of Amsterdam)* (TEC), primarily governs the EU Competition law:

- Cartels or control of collusion and other anticompetitive which has an effect on the EU. This is covered under **Articles 81** of the TEC
- Monopolies or preventing the abuse of firms' dominant market positions. This is governed by **Article 82** TEC. This article also gives rise to the Commission's authority under the next area;
- Mergers, control of proposed mergers, acquisitions and joint ventures involving companies which have a certain, defined amount of turnover in the EU/EEA. This is governed by the **Council Regulation 139/2004** EC (the Merger Regulation).
- There are number of block exemptions available under the EU competition law by way of directives and regulations, which equally govern the EC space.

4.1.3 The US Antitrust law is governed by the *Sherman Act, 1980, Clayton Act, 1914 and the FTC Act, (1914), Title 15 U.S.C. §§ 41-51and the Robinson-Patman Act of 1936* (as amended up-to date). The Sherman and the Clayton Acts provides for regulation of trusts, combinations and abuse of dominant position.

4.1.4 § 1. of the Sherman Act deals with "Trusts, etc., in restraint of trade illegal; penalty". It states: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal…"Section 2 deals with end results that are anticompetitive in nature. Sections 1 and 2 supplements each other in an effort to outlaw all types of anticompetitive conduct. US Congress designed the supplementary relationship to prevent businesses from violating the spirit of the Act, while technically remaining within the letter of the law.

4.1.5 Because the courts found certain activities to fall outside the scope of the Sherman Act, the Congress passed the Clayton Act to further widen its scope. For example, the Clayton Act of 1914 added the following practices to the list of impermissible activities: price discrimination between different purchasers, if such discrimination tends to create a monopoly; exclusive dealing agreements; tying arrangements; and mergers and acquisitions that substantially reduce market competition. The Robinson-Patman Act of 1936 amended the Clayton Act. The amendment aimed to outlaw certain practices in which manufacturers discriminated in price between equally-situated distributers to decrease competition.

4.1.6 Violations under the Sherman Act take one of two forms - either as a per se violation or as a violation of the rule of reason. Section 1 of the Sherman Act characterizes certain business practices as a per se violation. A per se violation requires no further inquiry into the practice's actual effect on the market or the intentions of those individuals who engaged in the practice. Some business practices, however, at times constitute anticompetitive behavior and at other times encourage competition within the market. For these cases the court applies a totality of the circumstances test and asks whether the challenged practice promotes or suppresses market competition.

Courts have often found intent and motive relevant in predicting future consequences during a rule of reason analysis. A presumption exists in favor of the rule of reason for ambiguous cases. The FTC Act established the FTC, a bipartisan body of five members appointed by the US President.[99]

4.1.7 As we shall review positions under both US and EU law as under, it would, however, be important to have a firm understanding of the classification system used in defining relevant product markets in the pharmaceutical sector. From both the demand and the supply side perspective, any drug that is marketed for human use should have some therapeutic effect. A therapeutic effect is a consequence to a medical treatment on any type or degree, the results of which are judged to be desirable or beneficial. This is irrespective of the intended benefits of the drug in question and its actual working, and includes side effect or undesirable effects also (toxicity). It is not necessary that both the US and the EU follow similar therapeutic classification- for e.g. the European Commission follows the European Pharmaceutical Market Research Association (EPhMRA) classification system, which is structurally similar to the standardized Anatomical Therapeutic Chemical Classification System administered by the WHO. The US has not officially subscribed to the WHO or EPhMRA classification. But it would be important to understand such classification in greater detail for the purposes of this study.

4.1.8 While there is no inherent difference between therapeutic and undesired side effects, both responses are behavioural and physiological changes which occur as a reaction to the treatment strategy or agent. However, those changes which are viewed as desirable, given the situation are called therapeutic; those undesirable for the situation are viewed as unfavorable. The scope of therapeutic effect is wide and varies in degree and includes all methods of healing. It is not specific to allopathic treatment. In common parlance, there is an understanding that therapeutic and undesired side effects only apply to medicines, drugs or supplements. However, therapeutic treatment can encompass any form of treatment leading to a particular effect on the target living organism.

4.1.9 The therapeutic effect is understood by studying the pharmacology of a particular drug. Pharmacology refers to the study of drug in action. Specifically, it is the study of the interactions that occur between a living organism and exogenous chemicals that alter normal biochemical function. If substances have medicinal properties, they are considered as 'pharmaceuticals'. The field encompasses drug composition and properties, interactions, toxicology, therapy, and medical applications and anti-pathogenic capabilities.

4.2 The classification of therapeutics:

4.2.1 The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses (ATC/DDD) system classifies therapeutic drugs. The purpose of the ATC/DDD system is to serve as a tool for drug utilization research in order to improve quality of drug use (WHO, 2009). As per the World Health Organisation, which maintains this classification, drugs in the ATC classification systems are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties (WHO, 2009).

4.2.2 The ATC classification evolved by modifying and extending the European Pharmaceutical Market Research Association (EPhMRA) classification system. As per the WHO, it is important to have both a classification system and a unit of measurement in order to measure drug use so as to deal with the objections against traditional units of measurement; a technical unit of measurement called the Defined Daily Dose (DDD) to be used in drug utilisation studies. Further, as per the WHO, the purpose of the ATC/DDD system is "to serve as a tool for drug utilization research in order to improve quality of drug use. One component of this is the presentation and comparison of drug consumption statistics at international and other levels".[100] However, the WHO specifically provides for a broad caveat which states that: "the classification of a substance in the ATC/DDD system is not a recommendation for use, nor does it imply any judgments about efficacy or relative efficacy of drugs and groups of drugs". Hence the ATC system is non-binding on the WHO member countries.

[99] The Commission is authorized to issue cease and desist orders to violators of federal antitrust law to curb unfair trade practices. This Act also gave more flexibility to the US congress for judicial matters. Section 5 of the FTC Act gives it broad powers in this matter.

[100] WHO, 2009

4.2.3 The Anatomical Therapeutic Chemical (ATC) classification system divides the drugs into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

4.2.4 The first level of the code indicates the anatomical main group and consists of one letter. There are 14 main groups. They are as under :

Box: 6- Classification of ATC 1

Code	Contents
A	Alimentary tract and metabolism
B	Blood and blood forming organs
C	Cardiovascular system
D	Dermatologicals
G	Genito-urinary system and sex hormones
H	Systemic hormonal preparations, excluding sex hormones and insulins
J	Antiinfectives for systemic use
L	Antineoplastic and immunomodulating agents
M	Musculo-skeletal system
N	Nervous system
P	Antiparasitic products, insecticides and repellents
R	Respiratory system
S	Sensory organs
V	Various

Source: WHO, 2009 and Wikipedia [online]

4.2.5 The second level of the code indicates the therapeutic main group and consists of two digits: Example: ***C03*** *Diuretics*. The third level of the code indicates the therapeutic/pharmacological subgroup and consists of one letter. Example: C03**C** High-ceiling diuretics. The fourth level of the code indicates the chemical/therapeutic/pharmacological subgroup and consists of one letter. Example: C03C**A** *Sulfonamides*. The fifth level of the code indicates the chemical substance and consists of two digits. Example: C03CA**01** Furosemide

4.2.6 As per the WHO, the nomenclature used include: International non-proprietary names (INN) are preferred. If INN names are not assigned, USAN (United States Adopted Name) or BAN (British Approved Name) names are usually chosen. WHO list of drug terms is used when naming the different ATC levels. The WHO Collaborating Centre in Oslo establishes new entries in the ATC classification on requests from the users of the system. These include manufacturers, regulatory agencies and researchers. The coverage of the system is not comprehensive. A major reason why a substance is not included is that no request has been received. The WHO Centre gives priority to preparations containing well-defined substances which have an INN name and which are:

- New chemical entities and biologicals proposed for licensing in a range of countries.
- Existing well-defined substances used in a variety of countries.
- Other medicines are considered on a case by case basis.

4.2.7 A new medicinal substance is normally not included in the ATC system before an application for marketing authorisation is submitted in at least one country. Complementary and traditional medicinal products are in general not included in the ATC system (WHO 2009).

4.2.8 However, as per the WHO, the ATC system is *not strictly a therapeutic classification system*. At all ATC levels, ATC codes can be assigned according to the pharmacology of the product. Subdivision on the mechanism of action will, however, often be rather broad, since a too detailed classification according to mode of action often will result in having one substance per subgroup which as far as possible is avoided. Some ATC groups are subdivided in both chemical and pharmacological groups. If a new substance fits in both a chemical and pharmacological 4th level, the pharmacological group should normally be chosen (WHO, 2009). Substances classified in the same ATC 4th level cannot be considered pharmaco-therapeutically equivalent since their mode of action, therapeutic effect, drug interactions and adverse drug reaction profile may differ.

Box: 7- The Structure of ATC Classification

The Anatomical Therapeutic Chemical (ATC) classification system of the World Health Organisation divides the drugs into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups. An example from the WHO could illustrate the point further: The complete classification of *Metformin* (a chemical substance used in treating alimentary tract and metabolism) illustrates the structure of the code:

A	Alimentary tract and metabolism (1st level, anatomical main group)
A10	Drugs used in diabetes (2nd level, therapeutic subgroup)
A10B	Blood glucose lowering drugs, excl. insulins (3rd level, pharmacological subgroup)
A10BA	Biguanides (4th level, chemical subgroup)
A10BA02	Metformin (5th level, chemical substance)

Thus the ATC system can be used to classify therapeutics at various levels and at an increasing level of sophistication. The WHO website has a free ATC classification available online [WHO, 2009]

4.3 **Identification of "relevant markets" and assessment of "market power" in the pharmaceutical sector:**

4.3.1 Any competition law inquiry involving assessment of market power starts with identification of the relevant market. Defining relevant market is *sine qua non* in assessing the market power/share of the violator in question. The concept of relevant market is inherently fluid. Without identification of the correct market definition, the market power of the enterprise allegedly violating the law cannot be assessed. The application of competition law is primarily concerned with problems that occur where one firm possess, or will possess after a combination, such market power that has a possibility of limiting output, raising prices and depriving consumers of choice, which are clearly detrimental to consumer welfare (Landes and Posner, 1981). Two basic prongs have been identified by courts and legislatures in comparative jurisdictions to evaluate competition law concerns. There are strong conceptual and pragmatic reasons for why assessing market power is relevant in the context of competition law. Both the EU Competition law and the US Antitrust law requires the assessment of market power for various purposes, including but not limited to understanding what type of combinations can lead to foreclosure of competition or may lead to a dominant position or concentration, agreements can have adverse impact on competition- and to evaluate the *'de minimis'* exception where parties lack market power, to evaluate whether or not block exemption is available to parties to agreement, and to evaluate the abuse of dominant position (Whish, 2008), (Hovenkamp, 2005). Such concerns are clearly reflective of abuse or potential abuse of market power. Thus market power of the party allegedly violating competition law has to be contextualized to a relevant market in question. Relevant markets can be "relevant product market" and "relevant geographic market".

4.3.2 Thus the key question would be to define the relevant market in question and identification of the market power in the particular market. Defining the concept and practice of 'relevant market' is essentially an economic one. However, competition law and case law developments in comparative jurisdictions do provide the necessary framework essential for legal certainty and for defining the thresholds. It thus brings in more transparency and legitimacy in decision making in the area of competition law and policy.

4.3.3 The guidance (although not a legislative instrument) on the starting point for defining relevant markets within the EU context can be the European Commission's '*Notice on the Definition of Relevant Markets for the Purposes of Community Competition Law'* (Commission's Notice, 1998). Paragraph 2 of the Commissions notice succinctly emphasis on the importance of the definition of relevant markets for the purposes of competition law. It states:

> *"Market definition is a tool to identify and define the boundaries of competition between firms. It serves to establish the framework within which competition policy is applied by the Commission. The main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face. The objective of defining a market in both its product and geographic dimension is to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure".*

The Commission's notice in its further paragraphs state that "the definition of the relevant market in both its product and its geographic dimensions often has a decisive influence on the assessment of a competition case".

'Relevant product markets' are defined as follows:

> *"A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use".*

'Relevant geographic markets' are defined as follows:

> *"The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently*

homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those area".

Further, paragraph 9 states: *"The relevant market within which to assess a given competition issue is therefore established by the combination of the product and geographic markets".*

The notice also prescribes evidence relied on to define relevant markets, calculation of market shares and additional considerations (Commission's Notice, 1998)

4.3.4 Relevant product market: *Europpemballage Corpn and Continental Can Co Inc v Commsission* [Case 6/71 (1973) ECR 215], popularly known as the *Continental Can case* is the seminal decision in which it was held that when identifying a dominant position the delimitation of the relevant product market was of crucial importance. The judgment of the ECJ shows that the definition of the market is essentially a matter of interchangeability, to mean that where goods and services can be regarded as interchangeable, they are within the same product market. The ECJ in this case stated that: *"those characteristics of the products in question by virtue of which they are particularly apt to satisfy an inelastic need and are only to a limited extent interchangeable with other products"*

4.3.5 In *United Brands v. Commission* [Case 27/76 (1978) ECR 207], in evaluating the relevant market for the fruit 'Banana', the ECJ held that: *"singled out by such special features distinguishing it from other fruits that it is only to a limited extent interchangeable with them and is only exposed to their competition in a way that is hardly perceptible"*

4.3.6 The commission's notice suggests that firms are subject to three main competitive constraints: demand side substitutability, supply side substitutability and potential competition (Whish 2008, p. 29). Demand side substitutability essentially involves the determination of the range of products which are viewed as substitutes by the consumer. This is equivalent to the US FTC- DOJ's approach in defining markets in the merger context, where they use the **S**mall but **S**ignificant **N**on-transitory **I**ncrease in **P**rice [popularly called as the **SSNIP** test]. This hypothetical monopolist test is also defined in paragraph 17 of the Commission's notice:

"The question to be answered is whether the parties' customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5 % to 10 %) but permanent relative price increase in the products and areas being considered. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market. This would be done until the set of products and geographical areas is such that small, permanent increases in relative prices would be profitable".

4.3.7 However, in *United States v. El du Pont de Nemour and Co* [351 US 377(1956)], it was held the SSNIP test may at times not be useful in determining the relevant market mostly in abuse of dominant cases. It is so because a monopolist may already be charging a monopoly price: if it were to raise its price further, its customers may cease to buy from it at all. Thus the possibility of consumers switching to other products is high, which may unduly exaggerate the degree of substitutability essential in evaluating the interchangeability of the product. This is popularly called as the *'Cellophane Fallacy'*.

4.3.8 The *Continental Can case* also laid foundations for the supply-side substitutability. Here substitutability in production from a manufacturer's point of view is taken into consideration to evaluate substitutability. The Commission's notice in its *para* 20 to 23 emphasis on this important aspect.

4.3.9 The evidence relied in defining relevant markets are through the use of economic and econometric analysis. The commission's notice provides the necessary guidance. However, there is no-hierarchy as such. The examples evidence that may be used in defining relevant product markets is well narrated by commentators (Whish, 2008, pp. 33-34). It includes, evidence of substitution in the recent past, quantitative tests, views of customers and competitors, marketing studies and consumer surveys, barriers and costs associated with switching demand to potential substitutes, different categories of customers and price discrimination.

4.3.10 Further considerations in the context of relevant markets concern the issue of after sales market where supplier of primary goods would essentially hold the a dominant position in supply of secondary one [*Hugin v. Commission* Case 22/78 (1979) ECR1869]. In the US the courts have followed the US FTC-DOJ *Antitrust Guidelines on Licensing Intellectual Property* (1995) and have considered a "market for innovation", separate from products already on the market. Even the EU in some of its cases (*Shell/Montecatini* OJ (1994) L 332/48) has suggested that it may consider a market for innovation. But some courts have applied the 'potential competition' test to deal with such situations.

4.3.11 In short, the existence of firms- or lack there-of (number of players in the market from the supply side) and existence or non-existence of different/substitutable products determines the scope of relevant product market. This can be explained with a simple diagram as under:

Source: Pindyck Robert (2006), p. 2.

4.3.12 There is perhaps no industry that has been as constant a source of competition law concerns in recent years as the pharmaceutical industry. Commentators have argued that relevant product markets in case of pharmaceuticals are the difficult to define (Pindyck Robert, 2006). Indeed, the US FTC-DOJ and the European Competition Commission has devoted such extensive resources to pharmaceutical matters that it maintains a regularly updated and hyperlinked websites. Both the jurisdictions have elaborate reports on issues governing the pharmaceutical industry and its interaction with health care concerns.

4.3.13 Experience in comparative jurisdictions suggests that in non-merger cases, the FTC/ Commission and private plaintiffs generally argue for narrow markets, limited to a single drug and its generic equivalent in some cases and to generic drugs excluding the bioequivalent 'brand-name' (all drugs under valid patents are called brand name drugs in the US) drug in other cases. In its merger challenges, on the other hand, the FTC has alleged markets ranging from those based upon a particular chemical compound, to broader markets based upon various drugs' manner of interaction or dosage form, to still broader markets of all drugs used to treat a disease or condition. In numerous pharmaceutical merger challenges, the competition authorities have included in the market not only currently marketed drugs but also other drugs under development, by considering "innovation market". As market definition issues are extremely factual and often resolved in appeals, there are only few pertinent court decisions providing guidance about how to define markets in the pharmaceutical industry.

4.3.14 Certain relevant product markets identified in the US context involving combinations have included: drugs for the treatment of a particular disease or condition; drugs; that have the same mechanism of action, and (iii) specific compounds. For e.g. in an acquisition case *Pfizer Inc. & Pharmacia Corp., FTC Docket No. C-4075 (May 27, 2003),* the FTC evolved the broadest definition of the relevant product market to include all drugs for a disease or condition. Pfizer's $60 billion acquisition of Pharmacia Corporation, held that market of "research and development, and the manufacture and sale of prescription drugs for the treatment of ED" or erectile dysfunction. Pfizer's Viagra was alleged to have a 95 percent share in that market while Pharmacia had two drugs in early clinical development stage. As per the consent order, Pfizer had to agree to divesture.

4.3.15 In *Glaxo-Wellcome plc & SmithKline Beecham plc.* FTC Docket No. C-3990 (Jan. 26, 2001) the FTC stated that markets of "drugs for the treatment of irritable bowel syndrome" and "prophylactic herpes vaccines" could be foreclosed. In each of these cases, the merging parties were two of few firms marketing any drugs in the broad

category, or one was marketing and the other was developing such a drug. Hence, the FTC classified them under the same category of therapeutic substitutes. The FTC also defined certain markets by *mechanism of action*. There, as per the FTC: (1) "prescription pharmaceuticals of the topoisomerase 1 inhibitor class . . . for the treatment of cancer," (2) "drugs of the triptan chemical class . . . for the treatment of migraine headaches," and (3) "any 5HT-3 receptor antagonist prescription pharmaceutical compound indicated for the prevention and treatment of nausea and vomiting associated with medical treatment."

4.3.16 *Baxter Int'l, Inc. & Wyeth*, FTC Docket No. C-4068 (Feb. 3, 2003) the focus was on specific chemical compounds, the FTC alleged that the acquisition would reduce competition in five distinct markets. One market was defined as the manufacture and sale of Propofol, a specific general anesthetic commonly used during surgery and as a sedative for patients on mechanical ventilators. It emphasized the product's unique characteristics and uses, compared to other anesthetics, noting its "many benefits" including "the ability to quickly adjust the amount of sedation and its superior safety profile," and the fact that it is "the preferred anesthetic agent for out-patient surgery." Three other markets, for two specific neuromuscular block agents used to freeze muscles during surgery and for patients mechanically ventilated, and a specific antiemetic used to prevent and treat nausea and vomiting in patients undergoing certain types of chemotherapy and for post-operative treatment, were similarly defined to include branded and generic equivalents of specific chemical compounds.

4.3.17 In *Schering Plough Corporation, et. al.*, (136 F.T.C. 956 (2003)), the FTC rev'd 402 F.3d 1056 (11th Cir. 2005), the relevant market considered was the market of a single drug and bioequivalent generics for the purposes of anticompetitive agreements. The complaint asserted a market of 20 milliequivalent extended-release potassium chloride tablets and capsules, used to treat patients with depleted potassium levels. The FTC stated that such patients have "no practical substitute for potassium chloride supplements" and "[f]or clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride." The complaint asserted further that "[t]he existence of other potassium chloride products has not significantly constrained Schering's pricing of K-Dur 20." According to the complaint, Schering's K-Dur 20 had 100 percent of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules. When in appeal, the ALJ found that the there are many "therapeutically equivalent" products, and concluded that the relevant product market must be all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. The ALJ noted that advertisements urged doctors to substitute two 10 mEq pills for a 20 mEq pill and emphasized that the FTC did not systematically study relative prices or rebates and rejected the FTC approach. In 2003, the Commission reversed the ALJ's decision. In March 2005, the Eleventh Circuit set aside the Commission decision, and vacated the cease and desist order. The Eleventh Circuit held the Commission did not establish that the challenged agreements restricted competition beyond the exclusionary effects of Schering's patent. On May 31, 2005, the Eleventh Circuit denied the Commission's petition for rehearing *en banc*. The Commission filed a petition for certiorari in August, 2005. The Supreme Court denied the certiorari petition on 2006.

Box: 8- Tests Adopted to Identify Relevant Product Market Definition by the US FTC-DOJ and US Courts

Various commentators have emphasized that the FTC-DOJ decisions on defining pharmaceutical markets lack consistency (Morse 2003); (Green 2008). A brief summary of review of FTC Cases by commentators would suggest that there can be a variety of variables that the FTC-DOJ may consider for defining relevant product markets in pharmaceuticals, including but not limited to (Morse 2003):

- Whether drugs have the same dosage and delivery forms such as injectable, liquid, capsule, tablets, or topical;
- whether drugs have the same frequency of dosage, such as once -a- day or extended release;
- whether drugs have the same strength of dosage, distinguishing, for example, 10mg and 30mg tablets;
- whether drugs are branded or generic; whether drugs require a prescription or are sold over-the counter;
- whether drugs are currently marketed or are in development;
- whether drugs treat the same disease, condition, or indication;
- whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same "mechanism of action");
- whether drugs have the same specific chemical compounds

Thus it may be noted that the tests adopted have at times considered some or few of these above mentioned considerations in defining relevant product markets. It points to the flexible nature of tests that have emerged in the US context. Thus fundamentally, the tests to determine relevant product market in case of pharmaceuticals are not static. Relevant policy consideration may go into determining the exact nature and scope of the definition for defining relevant markets for all legal purposes. But it is desired that there must be legal certainty an consistency in interpreting or considering/selecting among the available variables.

4.3.18 The principle that markets are composed of products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered- have been taken in to consideration in a few appellate courts where such definition was disputed and the courts have had an opportunity to interpret the same. (*SmithKline Corp.v. Eli Lilly & Co* (575 F.2d 1056, 1062–63 (3d Cir. 1978)). As per some commentators this means that the tests must not change in case of pharmaceuticals (Morse, 2003). But as seen above, the courts have interpreted various standards and have adopted a flexible approach in defining relevant markets.

4.3.19 On the other side of the Atlantic, few other cases have tried to define what should constitute relevant product markets within the context of EU Competition Law. Competition Law enforcement in the EU pharmaceutical industry has traditionally focused on prohibiting agreements that restrict parallel trade either through the imposition of a Supply Quota System ("SQS") or by means of dual pricing. The Commission is now focusing more on attempts by companies to delay or hamper the introduction of generic medicines or of new, innovative drugs that may compete with their products already on the market. The EU Pharmaceutical Sector Inquiry is the step in this direction.

4.3.20 In *AstraZenaca* (2005) [T-321/05- Appeal pending], the Commission adopted a decision fining AstraZeneca AB and AstraZeneca plc (AZ) EUR 60 million for having infringed Article 82 EC and Article 54 EEA by misusing public procedures and regulations in a number of EEA states with a view to excluding generic firms and parallel traders from competing against AZ's anti-ulcer product Losec. The relevant market comprises national markets for so called proton pump inhibitors (PPIs) sold on prescription which are used for gastrointestinal acid related diseases (such as ulcers). AZ's Losec was the first PPI. Interstingly, challenge of the Commission's Decision involves a question if the EU mistakenly defined the relevant market as being only that of proton pump inhibitors, used for the treatment of gastrointestinal acid related diseases, and excluded histamine receptor antagonists from the relevant market. Thus the Commission has intensified the monitoring of competition in the sector of generic medicines and

the sector inquiry currently ongoing suggests that competition in the market for human medicines may not be working well in Europe.

4.3.21 In *Bayer/Schering* case No Comp/M.4198 (2006), one of the high profile merger cases, although allowing the merger, the Commission in its opinion relying on past cases and practices the commission applied the ATC classification devised by EphMRA and has stated that the *third level of the ATC classification* allows medicines to be grouped in terms of their therapeutic indications and can therefore be used as an operational starting point for market definition. However, in certain cases it may be necessary to analyze pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC 3 classes on the basis of demand-related criteria. The Commission also defined separate markets for OTC (as opposed to prescription) pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories. Therefore, and as the market investigation confirmed this view, the Commission will assess OTC medicines and prescribed medicines as two separate product markets. Again relying on past practices, the Commission demonstrated that originator drugs were exposed to generic competition. Therefore the Commission has never made a distinction between generics and originator drugs. The parties have shared this approach and the market investigation has confirmed that drugs are exposed to generic competition. As per the commission's opinion, the concentration will give rise to five horizontally affected markets which relate to five ATC 3 classes: G1B (gynaecological antifungals), C5A (topical anti-haemorrhoidals), D1A (antifungals, dermatological), D7B (topical corticosteroids combinations), N5B (hypnotics/sedatives).

4.3.22 In an opinion of the Advocate General (Jacobs) Case C-53/03 (2004) in *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. Glaxosmithkline AEVE,* the Competition Commission wished to know, *interalia*, whether a dominant pharmaceutical undertaking must always be regarded as abusing its dominant position within the meaning of Article 82 EC simply because it fails to meet in full all the orders placed with it with a view to limiting its customers' export activity. Secondly, and if not, the Competition Commission enquires which factors will go to determine whether or not an undertaking is liable for such conduct. The opinion without dealing with the very issue of relevant product market proceeded to declare that a pharmaceutical undertaking holding a dominant position *does not* necessarily abuse that position by refusing to meet in full the orders sent to it by pharmaceutical wholesalers only by reason of the fact that it aims thereby to limit parallel trade. In November 2006 the Athens Appeal Court asked the European Court of Justice to clarify whether supply quotas could constitute an abuse of dominant position under Article 82and to what extent State intervention that fixes prices for pharmaceuticals must be taken into account to assess the infringement (see cases C-468/06, C-469/06, C-477/06 and C-478/06)

4.3.23 In *GlaxoSmithKline Services Unlimited v. Commission of the European Communities* Case T-168/01 (CFI 2006) suggests that the CFI endorsed the Commmission's approach to apply ATC Level 3 classification of the EphMRA but stated that peculiar conditions of sale in national markets should be considered for evaluating relevant product markets. In this case involving parallel trade in Spanish markets, it was noted that the Commission has undertaken to define the relevant product market principally by reference to demand substitutability and supply substitutability. The CFI noted that: "It does not appear to be manifestly incorrect to consider that the buyer, that is to say, the Spanish wholesaler who might engage in parallel trade, is less interested, for that purpose, in the therapeutic indication and the pharmacological products of each of the medicines which he buys from GW than in the fact that all of those medicines are reimbursed by the Spanish sickness insurance scheme and that their price is therefore set by the Spanish authorities. Likewise, it does not appear to be manifestly incorrect to consider that the buyer is less interested in the price of each of the medicines as such than in the fact that there is a sufficient price differential to render parallel trade lucrative, for all of those medicines, between Spain and the Member State of destination. In those circumstances, it is not manifestly incorrect to accept that all the medicines reimbursed by the Spanish sickness insurance scheme which are capable of being sold at a profit owing to the price differential between Spain and the Member State of destination constitute a product market". It further noted that the "existence of the Spanish rules appears, from the point of view of both buyers and GSK, to be more a factor which confers unity on the relevant product market than an element which ought to serve to distinguish a market for the distribution of medicines intended for domestic consumption, which would be regulated, from a market for the

distribution of medicines intended for export, which would be free. In reality, the distinction suggested by GSK relates rather to the evidently territorial nature of the Spanish rules and the national dimension of the relevant geographic market…" In this connection, the court stated that it is necessary "to examine the actual or potential effects of the agreement on competition. That examination entails a comparison of the competitive situation resulting from the agreement and the situation that would exist in its absence".

4.3.24 A review of case laws defining relevant product markets in pharmaceuticals essentially warrants us to ask if pharmaceutical markets are fundamentally different from other markets. Who is the customer- since doctor chooses and the patient pays? Does price matter at all- since costliest drug is the top selling? Should a single drug define the market in-itself? Should generic drugs be in the same market as pioneer drugs or a distinct product market? Further there is little guidance from comparative jurisdictions whether the "*Cellophane* trap" applies in case of pharmaceutical product. Defining pharmaceutical product markets requires a thorough understanding of the role of government regulation, technological innovation, and competition in the industry (Morse, 2003).

4.3.25 The essential question to be asked after the review of case laws in comparative jurisdictions is whether pharmaceutical markets are different is some ways and hence it has implications in defining relevant product markets. The case law offers conflicting answers. Some cases start from the premise that they are different. While the traditional tests laid down by appellate courts in these jurisdictions suggest that the markets which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration, but the tests shall always remain constant. But this does not address the unique nature of pharmaceutical markets where the demand and supply factors often do not work based on market forces. In pharmaceutical markets, the costliest brand is the most sold even in the presence of a good substitute.

4.3.26 Further, who is the customer in case of pharmaceutical prescription markets? Is the patient the consumer? Or, is the doctor the consumer? If the patient is consumer, in a prescription drug situation, he cannot switch to any other equivalent even in the presence of it. Some district courts in the US have held that patient-consumer's option must be considered for defining relevant markets. [*In re Cardizem CD Antitrust Litigation* 105 F. Supp. 2d 618 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003); *Schering-Plough Corp., Upsher-Smith Labs. & Am. Home Prods. Corp.,* FTC Docket No. 9297 (Oct. 21, 2002)].However, some other courts have held that since the doctor diagnoses and is knowledgeable about what drugs are available to meet the patient's needs. It is also because the place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor. A consumer may lack specialized information about the range of therapeutics available as substitutes. For example, the US CAFC (3rd) held in *Barr Laboratories, Inc. v. Abbott Laboratories*, 978 F.2d 98 (3d Cir. 1992) that "[i]n the case of prescription drugs . . . the person who selects the particular product in the first instance is the prescribing physician." In some other cases, the insurance provider may also be influential in the ways the consumer prescribes the drug (Morse 2003). If the insurance companies have an exhaustive list of medicines available for the insurer, there is no question of any further choice or selection by the consumer or the physician.

4.3.27 However, are consumers price sensitive? In evaluating the market definition one of the main indicia is the extent to which customers shift their purchases in response to changes in price. This examination can become problematic in prescription markets since it involves a complex interaction among various actors in the distribution and consumption network. It may be noted that they are the least price sensitive consumer as they only prescribe and not pay for the consumers. The physician who prescribes hardly does an actual cost-benefit analysis. However, may be in the long run due to excessively prohibitive costs, the doctor may want to look into to cheaper substitutes. Thus cross-elasticity of demand is often, of course, a critical factor in defining markets (Morse, 2003). Thus it would be difficult to determine, given the unique consumer habits (physician habits), whether any increase in price could lead to a switch over. In most cases, it may not. Thus in defining market physician-consumer practices may be relevant in case of prescription drugs. However, in case of OTC drugs, such a distinction may not be important since ultimate consumer is the chooser. However, in the OTC situation, the pharmacist may have a little influence in determining who the consumer is and if such consumers are price sensitive. So it may be concluded that even in

case of substitutes available, the physician consumer may not be price sensitive and hence existence of other products in prescription drugs context may not lead the consumer to switch over to other products.

4.3.28 It may be noted that courts in the US and EU have decided that two products or services are reasonably interchangeable where there is sufficient cross- elasticity of demand can constitute competing products in a relevant market. However, in case of pharmaceutical, it is difficult to see such interchangeability since one product may be therapeutically more advanced than the other. Further, a pertinent question is if unique conditions of a patient demand a particular therapy that is unique to a particular drug. Some commentators have remarked that "preferences by some customers for a particular product are the beginning and not the end of the analysis. Absent an ability to discriminate against the customers with the preference, one must consider whether other customers more willing to switch will protect such infra-marginal customers" (Morse, 2003). Further, in *SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063 (3d Cir. 1978)* it was held that "[D]efining a relevant product market is a process of describing those groups of producers which, because of the similarity of their products, have the ability—actual or potential—to take significant amounts of business away from each other. The court concluded that while there was some overlap in therapeutic capability, there were "sufficiently unique features," including "significant differences" in effectiveness and toxicity or undesirable side effects between cephalosporins and other antibiotics, to warrant the characterization of cephalosporins as a discrete market. It was noted that cephalosporins were generally used to treat specialized (penicillin-allergic) patients (Morse, 2003). This is may be emphasized that unique patient needs of a particular class of customers and the properties of a particular drug may lead to a particular drug being non-substitutable even in the presence of equivalent substitutes for the same disease but different patient conditions.

4.3.29 It is true that the foundations of US and EU law consider that it cannot be presumed that there is a possible monopolistic competition in every non-standardized commodity with each manufacturer having power over price and production of the said product. It is so because such power is not the power that can be regarded as illegal as it derives from the products uniqueness and quality. However, in *Eastman Kodak Co. v. Image Technical Services, Inc [*504 U.S. at 482] the US Supreme Court has held that sometimes reliance upon to support single-firm markets. In many ways this would mean that in some instances one brand of a product can constitute a separate market. In this context, it would be important to know if this logic applies in the pharmaceutical markets. In *United States v. Ciba Geigy Corp.*, 508 F. Supp. 1118 (D.N.J. 1976) the court concluded otherwise. It rejected a narrow hydrochlorothiazide market and instead found a market of all products indicated for the treatment of hypertension. It was noted that "different patients react in their own idiosyncratic ways to different drugs or to different combinations of drugs" and patients typically were given various dosages and combinations to obtain optimum control of the disease. The court concluded that the various medicines were, "from a medical point of view, reasonably interchangeable" and that interchangeability "translated into commercial competition." This medical point of view needs some consideration. It connotes a specialist view of a drug. Even if a doctor knows about substantial interchangeability, he may be influenced by other factors including patient condition and improvement of suitability of a drug to his patient. This means in most cases the drug may become not-substitutable. It is interesting to note that the FTC uses the narrower version and may in most cases conclude that one product may itself constitute relevant market. It is noted by some commentators that the FTC "in determining a relevant market, the Commission usually will start with a presumption that the market is limited to a specific therapeutic compound and then broaden the market as evidence is available that physicians and hospitals use other compounds as substitutes. If sufficient substitution occurs, the market may be expanded to a whole class of drugs used to treat a particular condition or illness" (Balto & Mongoven, 1999).

4.3.30 It is interesting to note the consequences of the application of *Cellophane Fallacy* in determining the scope of relevant product market in case of pharmaceuticals. *Cellophane fallacy* is inapplicable when there are excellent substitutes. In most cases, it is difficult to envision a situation where doctors would prescribe alternate medicines to cure a disease. Interchangeability is highly impossible given that patient needs can be addressed only through particular drugs. In a prescription market situation, it is evident that there does not exist a high cross-elasticity of demand. At a high enough price, interchangeability with poor substitutes may not be warranted by the doctors who

prescribe the medicine. Thus the *Cellophane fallacy* does not apply in case of pharmaceuticals. However despite of the *Cellophane fallacy* questioning the legal and economic foundations of the SSNIP test, some have argued that the existence of the cellophane fallacy does not imply the need for a new framework for defining relevant markets. It is suggested that the following points must be duly considered in a relevant product market inquiry to minimize the damage done by *Cellophane Fallacy.*[101] *They are:*

- all hypothesised market definitions are at least consistent with the principles of demand and supply-side substitution that underpin the SSNIP test;
- all products claimed to be part of the same market as the products of the firm under investigation are at least substitutable at current prices;
- any assessment of the product characteristics of the products is rigorously undertaken and that only the most relevant characteristics are considered; and
- whenever possible, empirical evidence that is not tainted by the cellophane fallacy is used to shed light on the relevant market definition.

4.3.31 In conclusion, it must be emphasized that there is no one standard benchmark for assessing relevant market in pharmaceuticals. The problem of who is the consumer and about consumer choice is at the heart of controversy in identifying relevant markets in the ethical drug industry. It is expected that the Commission and courts will base their decisions on a variety of variables and influences that alters the demand and supply factors in the pharmaceutical industry.

4.3.32 Relevant Geographic Market: It is vital to the assessment of relevant market to know the geographical boundaries where the market power is alleged to have been exercised in an anticompetitive manner. The definition of relevant markets has had impact on the outcome of many cases. For example; in *Volvo/Scania* decision in defining the relevant geographic market regard was had to national market and not to pan European markets, which led to the rejection of the merger. There may be legal, technical or practical reasons as to how one market may differ from the other [Whish, 2008]. Identifying the relevant markets does help in knowing if there are any other competitors constraining the market power of the alleged firm conducting in an anticompetitive manner.

4.3.33 Thus in *United Brands* case [Case 27/76 (1978) ECR] it was held that:

> *"[t]**he opportunities for competition under article 86 of the treaty must be considered having regard to the particular features of the product in question and with reference to a clearly defined geographic area in which it is marketed and where the conditions of competition are sufficiently homogeneous for the effect of the economic power of the undertaking concerned to be able to be evaluated" .***

4.3.34 **Even the commission notice on market definition in its paragraph 28 clears the approach to be adopted in determining the geographic dimension of relevant market definition. It states:**

> **T***he Commission's approach to geographic market definition might be summarized as follows: it will take a preliminary view of the scope of the geographic market on the basis of broad indications as to the distribution of market shares between the parties and their competitors, as well as a preliminary analysis of pricing and price differences at national and Community or EEA level. This initial view is used basically as a working hypothesis to focus the Commission's enquiries for the purposes of arriving at a precise geographic market definition.*

4.3.35 **The possible evidence that can be used in defining geographic market can take into consideration, past evidence of diversion of orders to other areas; basic demand characteristics; views of the customers and competitors; current geographic pattern of**

[101] Office of Fair Trading, "The role of market definition in monopoly and dominance inquiries", Economic Discussion Paper 2, A report prepared for the Office of Fair Trading by National Economic Research Associates OFT342 (July 2001)

purchases; tradeflows and patterns of shipment; barriers and switching costs associated with the diversion of orders to companies located in other areas etc… [Whish, 2008]

4.3.36 *GlaxoSmithKline Services Unlimited v. Commission of the European Communities* as regards to the relevant geographic market, the the CFI endorsed that Commission's view that for defining relevant geographic market it must be considered to be the national market, owing, in particular, to the existence in the Member States of the Community of different price and reimbursement regulations, different brand and packing strategies, different distribution systems and different prescribing habits.

4.3.37 Thus in defining the relevant geographic markets in the pharmaceutical context, regard can be had to disease burden (effective demand), conditions of sale (licensing and other legal or technical constraints); effectiveness and substitution by a drug procurement system; availability of other cheaper avenues for medication; etc…

4.3.38 Evaluating Market Power: Assessment of market power is one of the important issues to be resolved in any competition investigation. Though relevant market definition can provide guidance about the nature of market power, the inquiry does not end there. Market power is commonly defined as the ability to profitably charge prices above the competitive level for a significant period of time. In Europe, this concept is called as "significant market power" (SMP), which a firm is deemed to possess "if, either individually or jointly with others, it enjoys a position equivalent to dominance, that is to say a position of economic strength affording it the power to behave to an appreciable extent independently of competitors, customers and ultimately consumers." [Commission Regulation, Guidelines on Market Analysis and the Assessment of Significant Market Power, 2002 O.J. (C 165) 6]. Evaluation of the presence or absence of market power is a key element of most antitrust and competition analysis and many Competition commissions have issued guidelines on the evaluation of market power in the merger context and other areas. These guidelines typically follow the framework of market definition followed by calculation of market shares along with a summary measure of market concentration—typically the Herfindahl- Hirschman Index (HHI), which sums the squared market shares of firms in the relevant market. In performing market power analysis, other structural features of the market are also considered. However, use of structural factors need not lead to correct conclusions- an approach evident in other jurisdictions.

4.3.39 HHI approach to evaluating market power is necessarily an economic one. It is a widely and commonly accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in a market, and then summing the resulting numbers. The HHI number can range from close to zero to 10,000. The HHI is expressed as: HHI = s1^2 + s2^2 + s3^2 + ... + sn^2 (where sn is the market share of the ith firm). The closer a market is to being a monopoly, the higher the market's concentration (and the lower its competition). If, for example, there were only one firm in an industry, that firm would have 100% market share, and the HHI would equal 10,000 (100^2), indicating a monopoly. Or, if there were thousands of firms competing, each would have nearly 0% market share, and the HHI would be close to zero, indicating nearly perfect competition. Many competition authorities across the world use this method for evaluating market power.

4.3.40 While market shares can provide good guidance about the state of existing competition, it does not provide any clue of barriers to expansion and entry. They can be in the form of legal barriers, capacity constraints, economics of scale and scope, absolute cost advantages, privileged access to supply, a highly developed distribution and sales network, established position of the incumbent, and other strategic barriers [Whish, 2008]. It is also possible that buyer power may constrain behaviour of suppliers. In many cases, monopsony can be substantially challenged through monopoly.

4.4 Anticompetitive Agreements

4.4.1 Business undertakings get into routine agreements for carrying on economic activities. While not all agreements can be termed as anticompetitive, certain agreements between competing firms or among firms in the supply chain may constitute a violation of competition law. Agreements can either be horizontal or vertical. Mergers are a form of horizontal agreement but they raise distinctive competitive concerns. The concept of restriction on competition is an economic one. Thus generally economic analysis is needed to determine whether an agreement could have an

anticompetitive effect. A small class of agreements may be considered to have as their object restriction of competition. Article 81 of the EC Treaty deals with the treatment of anticompetitive Agreements.[102] The US law on anticompetitive agreements is contained in section 1 of the Sherman Act.[103]

4.4.2 Article 81 is applicable both to horizontal and vertical agreements. Horizontal agreements are those between undertakings at the same level of market, while vertical agreements are between undertakings at different levels of market. The policy of Article 81 is to prohibit cooperation between independent undertakings which prevents, restricts or distorts competition. More specifically, it is concerned with the eradication of cartels and 'hardcore' restrictions of competition. However, it is not just that legally enforceable agreements are within the scope. Article 81 also applies to cooperation achieved through the decisions of trade associations and to more informal undertakings, known concerted practices. Under Section 1 of the Sherman Act is read as a general standard that 'Every agreement whose anticompetitive effects on trade outweigh its precompetitive effects is illegal'. However,

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[102] **Article 81 reads as follows**:

1. The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:

   (a) directly or indirectly fix purchase or selling prices or any other trading conditions;

   (b) limit or control production, markets, technical development, or investment;

   (c) share markets or sources of supply;

   (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

   (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.
3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:

   - any agreement or category of agreements between undertakings;

   - any decision or category of decisions by associations of undertakings;

   - any concerted practice or category of concerted practices,

   which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

   (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;

   (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

[103] **15 USC Section 1 of the Sherman Act (1890) reads as follows.**
15 U.S.C. §1: Trusts, etc., in restraint of trade illegal; penalty : Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court

even though the above being the general standard the US Courts have held that there can be certain agreements which are so likely to be anticompetitive and so unlikely to have precompetitive effects that they are condemned '*per se*'- which is to mean that no inquiry on case by case basis is conducted since the nest effect is anticompetitive [Elhauge and Geradin, 2007, p. 56]. Thus if the *per se* rule does not apply, then the general rule of reason will apply.

4.4.3 Within the EU, a broad interpretation has been given to each of the terms 'agreement', 'decision' and 'concerted practice' [Whish, 2008, p. 97-113]. It is important to note that undertakings cannot take a defence that they were forced into anticompetitive agreements because of the conduct of the other traders.[104] However, this may be significant in the way competition authorities may mitigate a fine, or to exempt parties from any proceedings [Whish 2008]. In the context of pharmaceuticals- where actions of trade associations in the supply chain lead to a host of anticompetitive practices- it is very important to note that actions of trade associations to enter into anticompetitive agreements are well within the scope of Article 81(1). Recommendations made by associations have been held to amount to a decision and violative of Article 81- even while the decision may not be binding upon members.[105] Decisions taken by associations formed through a statutory mode are also not immune to action under Article 81.

4.4.4 Further, apart from 'agreements' and 'decisions', the inclusion of 'concerted practices' within the meaning of Article 81 means that conduct which does not fall into the two categories will also fall into the domain of Article 81(1) as amounting to a 'concerted practice'. The EU approach to a legal test of what constitutes a concerted practice for the purpose of Article 81 is that there must be a mental consensus whereby practical cooperation is *knowingly* substituted for competition- however, such consensus need not be achieved verbally, an can come about by direct or indirect contact between the parties.[106] The ECJ has held that a concerted practice is caught by article 81(1) even in the absence of anticompetitive effects on the market.[107]

4.4.5 It must be noted that there can be a situation where agreements are combined with unilateral conduct. Under Article 81, the conduct must be between two or more undertakings which are consensual in nature. Thus Article 82 applies in case of unilateral action by a dominant firm. Thus unilateral conduct by a firm that is not dominant is not culpable at all [Whish, 2008, p. 107]. Thus in number of vertical agreement cases where the Commission has held that cases that first appeared to be unilateral fell within Article 81(1) as an agreement or a concerted practice. But in some other cases the findings of the commission that there were agreements between supplier and its distributors were annulled on appeal.[108]

4.4.6 In *AEG-Telefunken v Commission* and *Ford v Commission*, the commission has succeed to apply Article 81(1) to apparently unilateral conduct.[109] In In *Sandoz* case, it was held that where there was no written record of agreements between a producer and its distributors, unilateral measures, including placing the words "export prohibited" on all invoices, were attributable to the continuing commercial relationship between the parties and were within the scope of Article 81(1).[110] In *Bayer AG/Adalat* the commission adopted a decision that Bayer and its wholesalers were parties to an agreement to restrict parallel trade in a pharmaceutical product, Adalat, from France and Spain to the UK. Here, the CFI annulled the decision since in its view the commission has failed to prove the existence of an agreement. An appeal by the commission and a parallel importer to the ECJ to reverse

[104] *Modena* v *High Authority [1962] ECR 289.*
[105] In such cases the EU Commission has noted if such compliance of recommendations was made by the members of the association in the past, and whether such compliance would have a significant influence on competition within the relevant market. See, Whish, 2008, p. 103.
[106] *ICI* v. *Commission 1972 CMLR 557 and Suiker Unie v. Commission 1976 CMLR 313.*
[107] *Huls AG v Commission [1999] ECR-4287.*
[108] *Bayer AG/Adalat (*1996) 5 CMLR 416.
[109] (1984) 3 CMLR 325; (1985)3 CMLR 528
[110] This decision has been upheld on appeal by the ECJ. See *Sandoz Produtti Farmaceutici SpA V Commission (1990) ECR 1-45*

the CFI Judgment also failed. Noting that the Commission's analysis risked confusing the respective roles of Article 81 and 82, the ECJ held that:

"*The mere fact that the unilateral policy of quotas implemented by Bayer, combined with the national requirements on the wholesalers to offer a full product range, produces the same effect as an export ban does not mean either that the manufacturer imposed such a ban or that there was an agreement prohibited by Article 81(1) of the Treaty."*[111]

4.4.7 However, as noted by commentators, it would be dangerous for suppliers wishing to suppress exports or to maintain resale prices, to suppose that this case law means that this is something that can be achieved without risk [Whish, 2008, p. 113]. Thus inasmuch as they can achieve their intended purpose on a purely unilateral basis, *Bayers* decision shows that Article 81 can be avoided.

4.4.8 Article 81(1) prohibits agreements 'which have as their *object* or *effect* the prevention, restriction or distortion or competition'. Thus either of the conditions is necessary for the application of article 81 (1). Thus it is important to classify agreements that have anticompetitive object vis-à-vis agreements where the effect is anticompetitive [Whish, 2008]. This is also similar to section 1 of the Sherman Act in the US where agreements are characterized based on *per se* rule or *rule of reason* analysis. It is important to note that in case of agreements where the object is anticompetitive, it is not necessary to prove that anticompetitive effects would follow. Thus under Article 81(1) the EC evaluates agreements relating to price fixing, exchange of current or future price information, sharing or allocating markets, limiting outputs, collective exclusive dealing as forming part of horizontal agreements where the object in itself is anticompetitive. Among vertical agreements, the EC evaluates fixing of minimum resale prices and imposing of export bans. In case of agreements which have possible adverse effect on competition, the evaluation of such agreements shall depend upon extensive analysis of the agreement in its market context is required to be done. There is also a need to establish the counterfactual in such cases so as to show what the position would have been in the absence of the agreement, of that the agreement could have ffects on competition. [Whish, 2008, p. 124].

4.4.9 Furthermore, not all agreements (horizontal or vertical) have actual effects on markets. This is due to their weak position in the market concerned. This is called as the *deminimus* doctrine. Because of their diminutive impact, they may not be prosecuted against. The EC Commission has provided guidance on the *de minimus* doctrine through a series of notices, which provide a good framework for understanding agreements are within the *deminimus* category.[112] While the *EC* does not discriminate between horizontal and vertical agreements for the purpose of *qualifying* as *deminimus,* there can be a distinction made, as noted in some case, in the approach adopted for 'hard-core' restrictions [Whish, 2008, p. 140.]. Furthermore, in some instances, the EC commission has categorized certain agreements as *deminimus* even while they exceeded the thresholds established in the notice [Whish, 2008, p. 138].

4.4.10 A general exemption from the application of Article 81(1) is contained in the legal exception created by Article 81 (3). Article 81 (3) of the EC treaty is satisfied when an agreement contributed to improving the production or distribution of goods or to promoting technical development or economic progress; or while allowing consumers a fair share of the resulting benefits. Such agreements to qualify Article 81 (3) must not impose on the undertakings concerned restriction which are not indispensable to the attainment of these objectives, nor, afford such undertakings the possibility of eliminating competition in a substantial part of the product in question [Whish, 2008, p. 148]. Article 81(3) can also be satisfied if the agreement in question falls into one of the block exemptions issued by the EC or by the Commission.

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[111] C-3/01

[112] See, *Notice on Agreements of Minor Importance [OJ 2001] C 368/13.*

4.4.11 There is a worldwide consensus against hard core cartels. Horizontal agreements between undertakings to fix prices, divide markets, to restrict output and to fix the outcome of competitive bidding are the most contentious among the variety of targets of competition authorities in comparative jurisdictions. The OECD has a consistently through its report and recommendations called upon member countries to "effectively halt and deter hard-core cartels". The nature and seriousness of penalty including the benefit of leniency programmes have helped competition authorities in dealing with such cartels. Even apart from developed competition law jurisdiction, new and emerging jurisdictions have also cracked down horizontal agreements which are in the nature of cartels. However, cartels are most difficult to detect, they are more so in pharmaceutical sector due to the very nature and structure of the industry and market. Cartel investigations are most difficult ones amongst the variety of practices prohibited by Competition law. The OECD's *Best Practices for the Formal Exchange of Information between Competition Authorities in Hard Core Cartel Investigations*¸ can provide a ready reference for increasing cooperation among competition authorities world over for investigating cartels.

4.4.12 It is clear from the decisions of the commission that price fixing in any form is caught, including the obvious blatant price fixing. Thus there is a body of decisions that have condemned agreements which might directly or indirectly facilitate level price fixing [Whish, 2008 pp. 507-511]. Price fixing may also occur in conjunction with other type of anticompetitive practices. For example in the *Polypropylene* case, the commission found price fixing and market sharing. Furthermore, the commission will also examine and consider after careful scrutiny markets in which price competition is already limited by extraneous factors, in order to ensure that the parties do not further impede competition in those markets. This can have special relevance in pharmaceutical markets where price competition for patented products is limited due to a variety of factors. Buyer's cartels are also subject to investigations under Article 81 (1) of the EC treaty. In the Commission's view and agreement on purchasing eliminates the autonomy of strategic decision-making and competitive conduct, preventing the undertakings concerned from competing on the merits and enhancing their position vis-à-vis less efficient firms [Whish, 2008, p. 511].

4.4.13 The *Vitamins case* (2003) is one of the most severe cartels that occupied considerable attention of competition authorities' world over. The EC Competition Commission fined eight undertakings totaling to Euro 855.23 million (reduced to Euro 790.50 million) for running the vitamins cartel. Foreign MNCs like Roche, BASF, Aventis were found to be involved in cartels. However, Aventis paid substantially less as it turned out to be the whistle blower. It must be noted that price fixing in any form is caught. Article 81 (1) and its application in any cases have led to the emergence of a set of jurisprudence that it is not just blatant price fixing that is caught, but also any agreement that might directly or indirectly suppress price competition. Cases also suggest that it is not a defence that a participant in a cartel sometimes does not respect the agreed price increases. However, the most important aspect of the cartel is that the leniency programme helped a great deal in ascertaining the cartel. The prosecution in the vitamins case is the cornerstone of treatment of complexity presented by cartels. Hence it would be important to discuss it as a comprehensive case study since it is one of the most comprehensively documented cartel prosecutions undertaken in various jurisdictions. The box below profiles the Vitamins case in terms of the nature of complaint, investigation, prosecution, evidence and outcomes.

Box: 9- In re Vitamins Antitrust Litigation (A study of many related cases)[113]

The vitamins cartel lasted from 1990 to 1999- one of the widely recognized world-wide cartel, largely involving pharmaceutical companies. The litigation also returned the victims an unprecedented total amount for any related series of competition law inquiries; however, as argued by some commentators the total of damages and penalties worldwide were still less than the excessive profits gained through the act of cartelization.[114] The first suit in the case was filed in Alabama state court in 1997, on behalf of a class of indirect purchases with a named plaintiff who had purchased vitamin products for

[113] Stratis G Camatsos and Albert Foer, *Cartel Investigations in the USA,* American Antitrust Institute, Jan 13, 2007
[114] Connor, John M, "The global Vitamins Conspiracy: Sanctions and Deterrence," Draft 2/14/06.

use in his farming operations.[115] The complaint alleged a conspiracy among the three major vitamins manufacturers, Hoffman La Roche, Rhone—Poulenc S. A, and BASF AG. Apart from the allegation that the defendants were fixing the prices, it was also alleged that the defendants participated in the meetings and discussions on prices, to have exchanged completely significant information, and to have monitored compliance. A high-profile attorney specializing in antitrust class action litigation in the year 1997 was told about some secret price-fixing meetings in the vitamins industry. After private investigation by his law firm, it was found that there was a possible price-fixing among vitamins manufacturers. As more evidence was gathered by the law firm, decided they had gathered enough to file suit in the year 1997. It may be noted that the price-fixing was discovered by a private entity without any particular type of government involvement. However, it might not be a general rule that private entities would have an incentive to investigate cartels in the industry. Further, the same period also saw that the US Justice Department was working on an investigation of price fixing among the vitamins manufacturers.[116] As more and more evidence of illegal activity began to appear in 1997, after the initial investigations, the private law firm started hearing many complaints from Roche customers. It was unilateral refusal to supply to customers who purchased from Roche would not be able to get price quotes from BASF or other suppliers. Such buyers of vitamin C were threatened with unspecified retaliation should they try to resell purchased products. In fact, Roche had already heard about such price fixing and its company's possible involvement which made a top official to issue a direction to stop all price-fixing conspiracies. This was later produced as evidence by the private law firm Boies & Schiller when it filed a civil price-fixing suit in 1998.

Subsequently, in 1999 after the choline chloride cartel was revealed, the DOJ negotiated with Roche-Poulenc, a French pharmaceutical manufacturer to admit them into the leniency-program. This explains the importance of leniency programme. The Roche-Poulenc managers agreed to attend the conspiracy meeting and record it. The government noted that these companies cooperated with the investigation which directly led to the evidence to frame charges. Possibly, there was a lot of incriminating evidence which led to heavy fines to be paid by both.[117] It is noted that during the duration of the vitamin cartels, vitamin prices increased by 60 % to 100 %.[118] In terms of direct over charges on buyers, the total amount worldwide was about $ 7 billion. The vitamin cartel has impact on buyers in North America, the European Union, and Asia incurred, which approximately 90% of the global cartel overcharges.

It is interesting to note that by and large all of the private vitamins cases were settled. Choline chloride cartel was the only vitamins case that went to where the jury decided that the cartel had overcharged purchasers because the defendants conspired to fix the price of choline chloride.[119] Six of the main vitamins companies agreed to a settlement in the private class action litigation brought in federal court in 1999 on behalf of direct purchasers of vitamins and vitamin premix.[120] Another interesting lesson to note is that the justice department announced guilty plea agreements from two Swiss nationals and two German nationals, three of whom were high officers in BASF's fine chemicals division and one of whom was in similar position to Roche in the year 2000. Further, two more German Pharmaceutical manufacturers were added to the list, Merck and Degussa-Huels Ag, along with two US firms, Nepera, Inc and Reilly Industries. These guilty pleas involved the vitamin C and vitamin B3. In total, fourteen chemical companies were convicted by the US for price fixing in the vitamins market.[121] Criminal prosecutions against sixteen senior executives of the vitamin manufacturers show that comparative

[115] *Robertson v. F. Hoffman-LaRoche, Ltd*., Complaint 7, CV-97-200a (Cir. Ct., Cullman City., Ala Filed Dec. 5, 1997)

[116] Connor, John M, "The Great Global Vitamins Conspiracy: Sanctions and Deterrence," at 25-26.

[117] Hoffmann-La Roche agreed to pay $ 500 million in fines, almost five time the previous record antitrust fine. BASF paid $ 225 million.

[118] Connor, John M, "The Great Global Vitamin Conspiracy: Sanctions and Deterrence," at 4.

[119] *In Re: Vitamins Antitrust Litigation, Misc No. 99-197 (TFH) MDL No. 1285, (Animal Science Products, Inc., et al v Chinook Group, Ltd et al)*

[120] The settlement was for $1.5 billion, the largest private antitrust price-fixing settlement in history. Details can be found in Barboza, David, "$ 1.1 Billion to settle suit on Vitamins, N. Y Times Nov 4. 1999 at CI

[121] US fines for these fourteen companies and fiteen of the officers were $ 915 million. Two Firms received amnesties from the DOJ under the leniency programme.

jurisdictions have stricter criminal measures in dealing with cartels effectively since fifteen of them received personal sentences. [122]

4.4.14 Competition may also be impeded when two independent undertakings in way other than direct price fixing enter into agreements that apportion particular markets between themselves. While is it argued sometimes that market sharing agreements have a pro-competitive element since it reduces distribution costs and benefits consumers by lower prices. But it is not necessary that such effect on the market comes out through the agreement. Even in the absence of an agreement, based on cost benefit analysis parties would chose to distribute in particular geographic markets.

4.4.15 Quota restrictions may also take form of cartels. If output is limited or reduced, price will rise- and hence output restrictions have the same effect as price cartels. It must be noted that there can be differences between naked restrictions on production which limit output without producing any compensating benefits and agreements involving restrictions of production which may be ancillary to some legitimate objectives [as discussed later].

4.4.16 In *Danish Association of Pharmaceutical Producers and the Danish Ministry for Health*, the commission investigated quota sharing arrangements aimed at controlling public spending on price subsidies of pharmaceuticals. Through a consent order the Commission asked the parties not to renew that quota scheme when it was terminated in 2001. The parties readily agreed to do so since the threat of action under Article 81(1) loomed large.[123]

4.4.17 Collusive tendering agreements also form part of horizontal agreements that pose significant anticompetitive effects on the market. However, it is not necessary that such collusive tendering agreements do affect the markets in reality. Such agreements are condemned *per se*. Collusive tendering is "a practice whereby firms agree amongst themselves to collaborate over their response to invitations to tender". [Whish, 2008, p. 519]. Actions concerning collusive bidding activities have concentrated in engineering and construction industries where there are large bidding contracts. [Whish, 2008, p. 520-521]. Hence, a review of collusive bidding cases in the EU does not show action taken against pharmaceutical companies. There may be many forms of collusive bidding. The firms may agree to quote identical prices, or parties may rotate the bid, form complementary bidding, subcontracting etc... Collusive bidding agreements may also take form of agreement not to bid each other, agreements on common norms to calculate prices or terms of bids, agreements to squeeze out outside bidders, agreements designating bid winners in advance on a rotational basis, or agreements which allocate geographic markets or customers. Some of such agreements may permit compensation to unsuccessful bidders by dividing a certain percentage of profits of successful bidders. The EU Commission has delivered two important decision pertaining to collusive bidding activities in the recent past. They are: *Gas Insulated Switchgear; Elevators and Escalators.*[124]

4.4.18 The position in UK derived out of CAT's decision is *Apex Asphalt and Paving Co Ltd* is of particular relevance for collusive tendering practices [Whish, 2008 p, 542]. The CAT viewed that:

- A tendering process is designed to produce competition in a very structured way
- Bidders are sometimes required to certify that they have not had contact with competitors in the preparation of their bids

[122] Id. at 48-49 (these cases were in different courts, for example, United States v Bronnimann, No 399-CR -316 (N.D. Tex Filed Aug 3, 1999). In real (2005) dollars US fines were $ 677 million. Two firms received amnesties that might otherwise have added $ 550 million in fines and seven firms went unpunished. Because of discounts on fines, the vitamins conspirators paid only 19% of the maximum possible fines of $ 4.8 Billion. In addition, 16 senior executives of the vitamins manufacturers were criminally indicted of which 15 received personal sentences that averaged $ 110,000 in fines and 8 months in prison.

[123] Commission Press Release IP/99/633 (1999)

[124] Commission Press Release of 24th January 2007Commission Press Release 21 Febraruary 2007 and

- Where tendering is selective rather than open to all potential bidders, the loss of independence through knowledge of the intentions of the other selected bidders is particularly likely to distort competition.[125]

4.4.19 Information exchanges may at times result in action under Article 81 of the EC treaty. It is important to note that this issue has been given thoughtful consideration over many years since 1968 in its *Notice on Cooperation Agreements*[126] and in other case decisions the ECJ has led down some guidance on the treatment on agreements relating to information exchanges.[127] The relevant test the ECJ jurisprudence lays down in identifying what type of information sharing should be exempted from the application of Article 81 (1) is mentioned in the *Thyssen Stahl AG v Commission case:*

"While it is true that this right of independence does not deprive traders of the rights to adapt themselves to the existing or anticipated conduct of their competitors, it does, however, strictly preclude any direct or indirect contact between such traders, the object or effect of which is to create conditions of competition which do not correspond to the normal condition of the market in question, regard being held to the nature of product or services offered, the size and number of the undertakings and the volume of the said market".[128]

4.4.20 Thus in case of information agreements a full market analysis may be warranted since such an agreement is not condemned by object but by effects on the market. This position is clearly laid down by the ECJ in *Asnef-Equifax* case.[129]

4.4.21 At times, competition concerns may arise due to the behavior of firms in an oligopolistic market structure, even in the absence of any agreement. They are in the nature of 'tacit collusion' conscious parallelism' 'tacit coordination'. While there have been broad criticisms of this theory,[130] such practices do exist in reality. Hence commentators agree that there can be structural, behavioral and regulatory ways of dealing with oligopolistic interdependence {Whish, 2008, p. 55-552]. The most relevant decision delivered by the ECJ in this regard is the *Dyestuffs case*, where the court said:

By its very nature, then, the concerted practice does not have all elements of a contract but may interalia arise out of coordination which becomes apparent from the behavior of the participants. Although parallel behavior may not itself be identified with a concerted practice, it may however, amount to strong evidence of such a practice if it leads to conditions of competition which do not respond to the normal conditions of the market, having regard to the nature of the products, the size and number of the undertakings, and the volume of the said market. Such is the case especially where the parallel behavior is such as to permit the parties to seek price equilibrium at a different level from that which would have resulted from competition, and to crystallize the status quo to the determinant of effective freedom of movement of the products in the common market and free choice by consumers of their suppliers[131]

4.4.22 Since competition law cannot prohibit all horizontal agreements outright because of efficiency gains that may follow from cooperation that are sufficient to outweigh any restriction on competition that might ensue, the Commission adopted *Guidelines on Horizontal Cooperation Agreements* in the year 2000. The guidelines state that horizontal cooperation agreements may lead to substantive economic benefits, in particular given the dynamic nature of markets, globalization and the speed of technological progress. In particular, of much importance to pharmaceutical sector is the treatment of R&D agreements under the Commission's guidelines. Such agreements are evaluated on the basis of their effects, rather than objects, since the object of such agreements are not among

[125] 2005 CompAR 507
[126] OJ [1968] C 75/3
[127] See, *John Deree v Commission; Thyssen Stahl AG v Commission*
[128] Case C-194/99 (2003) ECR I- 10821
[129] Case C – 238/05 [2006]ECR I-11125, [2007].
[130] See, Bork, *The Antitrust Paradox* (Free Press, 1993), ch. 8.
[131] Case 48/69 [1972] ECR 619.

the hard core restrictions on competition. The Commission shall evaluate agreements based on their nature. The starting point in the Commission's approach to evaluating R&D agreements is to see whether an agreement could have the effect of restricting competition by analyzing the position of parties in the market. This would essentially require the evaluation of relevant markets as evolved by the Commission through its guidelines and practices. Thus market shares that accrue out of horizontal agreements can be classified based on the certain percentage of shares in the relevant market. [Whish, 2008, p. 580].

4.4.23 Chapter II of the Guidelines on horizontal agreements contains agreements that have their centre of gravity R&D, other than combinations falling within the Merger Regulations. Thus where the agreement concerns the improvements to the existing products, they and their close substitutes will form the relevant market. Thus the concept of relevant market will vary based on the nature and object sought to be achieved by the R&D agreement in question. The position with reference to R&D agreements is relatively complex where the object is to come out with totally new products. Here the Commission will consider if by the agreement sufficient R&D poles are left even after two competing undertakings enter into R&D agreements. However, no further clarification is provided by the guidelines in ascertaining sufficiency of R&D poles. Thus the commission considers that R&D agreements would normally fall outside the scope of Article 81(1). But those R&D agreements which have in them elements that can effect or restrict competition may well fall within the scope of Article 81(1). Thus Regulation 2659/2000 provides for a block exemption on R&D agreements. Three types of R&D agreements are covered within the scope of Article 1. They relate to:

- Joint R&D of products or processes and joint exploitation of the results of the R&D
- Joint exploitation of the results of R&D of products and processes jointly carried out pursuant to a prior agreement between the same parties; or
- Joint R&D of products or processes excluding joint exploitation of the results.

Article 3 furthers defines the terms and conditions for the exemption. Article 4 defines the market thresholds and duration of exemption. It provides that at the end of seven year period, the exemption can continue as long as the parties' combined market share does not exceed 25%. Article 5 of the exemption deals with agreements not covered. There are about 10 such type of clauses which have as their object the limitations viz., freedom of parties to carry out R&D in a field unconnected; prohibition for challenging IPRs; price fixing when selling the products; market allocation; licensing restraints on third parties; restraints on resellers

4.4.24 Horizontal agreements between unrelated rivals not to business with another firm/s are also considered *per se* illegal boycotts under EU and US antitrust law. While there are no case laws from comparative jurisdictions on group boycotts in pharmaceuticals, some guidance can be deduced from cases in other products.[132] It is noted by commentators that boycotts are often aimed at harming particular competitor and not competition in general. They thus question if group boycotts are subject matter of competition law inquiry if the aim of competition law is to protect competition and not competitors [Elhauge and Geradin, 2007, p. 126]. But there seems no other plausible argument for a group boycotts other than to injure competition, or for unfair enrichment by collectively harming a market player through group boycott. However, in case of group boycotts, there may be non-economic reasons in the nature of providing punishment to bad actors in the market [Elhauge and Geradin, 2007, p. 127]. But this may at times represent overstepping of private power and exercising governmental functions if private actors were to take charge of curing the so called bad actors from the market as it is only in their self interest and totally lacking objectivity.

[132] See, *Brooke Group Ltd v. Brown & Williamson Tobbacco Corp.* 509 US 209 , 224 (1993); *Copperweld Corp* v *Independent Tube Corp, 467 US 752*.

4.4.25 **Vertical Restraints:** Producers of goods will distribute their products into the market either directly to consumers or through a supply chain in the market. At the same time there can be consumers who purchase goods for their own use or for further selling. Contracts are the basis for such transaction and the legal tradition has been responsive for valuing such contracts (Hovenkamp, 2005, p. 181).[133] When distribution is relatively cheaper the firm may do it for itself, then the firm tens to be vertically integrated and relatively larger. When distribution becomes cheaper due to firm's contracting with others firms, then the firm tends to be relatively smaller and leaves distribution to others (Hovemkamp, 2005, p. 181). Thus self-distribution and contract based distribution are common to any economy. Thus there may arise concerns that can have appreciable adverse effect on competition. Not all vertical agreements can be categorized as restraints, but certain agreements surely will. Since such contractual agreements cannot be avoided as a matter of practice, they need to be evaluated based on their impact in the market. However, there can be *per se* invalidation of certain type of vertical agreements. In fact, until very recently, the US followed an approach to condemn resale price maintenance on *per se* basis until it was overruled by the *Leegin* decision in 2007. Thus it would be pertinent to evaluate each of such possible agreements from a comparative jurisdictional point of view.

4.4.26 The oft cited pro-competitive benefits of vertical agreements in promoting a healthier distribution system are well known. Among them the most commonly cited it the "free-rider" problem (Hovemkamp, 2005, p. 184; Whish 2008, p. 616). Since dealers are required to perform certain functions at the point of sale, without territorial restraints a price cutting dealer might free ride on such efforts. Thus prevention of discounting is possible by using resale price maintenance which forces each dealer to compete by providing cost justified point of sale functions (Hovenkamp, 2005, p. 184). However, it follows that EC competition law does not apply to vertically integrated firms within a corporate group (Viz., parent-subsidiary firms).[134] There can be both price related and non-price related restraints. In the US, most vertical agreements, except resale price maintenance is governed by the Robinson Patman Act.

4.4.27 *Resale Price Maintenance:* In *Dr. Miles Medical Co.* v *John D Park & sons*[135], one of the seminal decisions of the US Supreme Court where the validity of resale price maintenance was questioned, RPM were held to be unlawful per se. In this case retail druggists were fixing prices and using manufacturers as their "enforcer". Here the US Supreme Court implicitly noted in the decision that the enforcement of prices through examination of the record led to facilitating cartels, which was the main function of imposing RPMs. However, the decision did not address situations where RPM may not have been used to facilitate collusion or where economic understanding of the effects of RPMs was that they produced pro-competitive benefits. Thus in *Leegin Creative Leather Products, Inc v. PSKS Inc.,*[136] overruling *Dr Miles* decision for five to fours votes, the US Supreme Court said that *per se rules* are among the disfavored category and are reserved for types of conduct that have manifestly anticompetitive effects-conducts that would almost always restrict competition by reducing output or increasing prices. They held that RPMs do not fall into such a category because it encourages retailers to invest in services and promotion by eliminating free-riders, who would let other resellers provide the service and promotion and then undercut their price. It held that RPM facilitate consumers by providing more options among dealers. The decision also emphasized that RPM could promote market entry of new firms who would otherwise not be wanting to invest. However, this decision has been criticized by scholars and commentators for overly stating the "free-rider" justification and for its conservative economics approach.[137]

4.4.28 In the EU, the Block exemptions provided by regulation 2790/99 OJ [1999] L 336/21 provides useful guidance on the type of practices exempted under the category of vertical restraints. These exemptions typically provide 'safe

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134 *Viho v Commission* Case C-73/95 p [1996] ECR I -5457

135 220 US 373 (1911)

136 127 S.Ct. 2705 (2007).

137 Fox E. (2008)… Explanation for positions taken by majority opinion in various apex court cases that harp upon the efficiency paradox in antitrust.

havens' for considering the scope of application of Article 81(1). Further, the *Guidelines on Vertical Restraints*[138] are to be read in conjunction with the block exemptions. There are both pro-competitive and anticompetitive of such form of agreements. The combined effect of the *deminimus* doctrine and the block exemption is that most vertical agreements where the market share of each of the parties is below 15% will fall outside the scope of article 81 (1) [Whish, 2008, p. 619]. Further, most vertical agreement that might violate Article 81(1) will be block exempted under the above mentioned regulation provided that the supplier's market share is less than 30% and that the said agreement does not contain any hardcore back listed provisions mentioned in the block exemption [Whish, 2008, p. 619]. The block exemptions also provide that the exemption shall be apply to vertical agreements "containing provisions which relate to the assignment to the buyer or use by the buyer of IPRs, provided that those provisions do not constitute the primary object of such agreements and are directly related to the use. Sale or resale of goods or services by the buyer or its customers". However, the application of such a rule is fraught with difficulties [Whish, 2008, p. 646]

4.4.29 The *Guidelines* suggest that there are generally four steps in evaluating a vertical agreement under Article 81. First, identification of relevant market for determining the supplier's or the buyer's market share; second, if market share is less than 30% it will usually avail the block exemption provided that there are no hardcore restrictions; third, if market shares exceeds 30% it will be seen whether the agreement falls under Article 81(1); lastly, where Article 81(1) is infringed, to see further if it is exempted by Article 81 (3). Further, the guidelines also suggest relevant factors for the assessment under Article 81(1) and (3).

4.4.30 Direct and indirect export bans are violative of Article 81(1) and will not get exempted under Article 81 (3). However, in *GlaxoSmithKline Services v Commission*[139] it was held the contractual restrictions designed to prevent parallel trade did not have as their *object* the restriction of competition, although it concluded that such measures restricted competition by *effect*. The CFI placed reliance on the unique nature of pharmaceutical sector in this regard. The judgment is in appeal to the ECJ.

4.4.31 The following are the list of hardcore restrictions which lead to the exclusion of the entire vertical agreement (and not simply the provision in question) from the application of block exemption-

- *Resale Price maintenance:* the block exemption shall not be applicable where the object of the agreement is "(a) restriction of the buyer's ability to determine its sale price, without prejudice to the possibility of the supplier's imposing a maximum sale price or recommending a sale price, provide that they do not amount to a fixed or minimum sale price as a result of pressure from, or incentives offered by, any of the parties". The obvious example of an agreement which fixes minimum retail price is directly in conflict with the exemption. The guidelines further provide some clue on the indirect means of entering in to a RPM agreement. It states "fixing the distribution margin, fixing maximum level of discount the distributor can grant from a prescribed price level, making the grant of rebates or reimbursement of promotional costs by the supplier subject to the observance of a given price level, linking the prescribed retail price to the resale prices of competitors, threats, intimidation, warnings, penalties, delay to suspension of deliveries or contract terminations in relation to the observance of a certain price level".

- *Territorial and customer restrictions*: The block exemption shall not be available where the object of the agreement is "the restriction of the territory into which, or the customers to whom, the buyer may sell the contract goods or services". The guidelines explain that two restrictions on buyers that would not be regarded as hard core. They are: a prohibition on resale except to certain end users based on certain objective justification, especially in health related cases[140] and an obligation on the reseller to display

[138] OJ [2000] C 291/1, [2000] 5 CMLR 1074

[139]

[140] See *Kathon/Biocide* OJ [1984] C 59/6

supplier's brand name. However, there are four more exceptions to the above general rule [Whish, 2008, p. 655-656].

- *Restriction of active or passive sales to end users by members of a selective distribution system operating at the retail level of trade*
- *Restrictions on cross supply within a selective distributive system*
- *Restrictions on the supplier's ability to supply components to third parties*

4.4.32 There are certain obligations in vertical agreements that are not exempt by the block regulations which are provided in order to ensure 'access to or to prevent collusion on the relevant market'. They are in the nature of non-compete obligations which extend to infinity or which exceed five years in term; post-term non-compete clauses and competing products in a selective distribution system.[141]

4.4.33 The most common form of vertical restraints are single branding agreements, exclusive distribution agreements, exclusive customer allocation agreements, selective distribution agreements, franchising agreements, exclusive supply agreements, tying agreements, recommended and maximum resale price agreements. The four factor test is applicable in evaluating whether such agreements have pro-competitive effects on the market.

4.5 **Abuse of Dominance:**

4.5.1 Abuse of dominance basically concerns itself to the unilateral acts of dominant firms as it might infringe competition laws. Article 82 of the EC Treaty prohibits abuses of a dominant position.[142] As per the case-law developments, it is not in itself illegal for an undertaking to be in a dominant position and such a dominant undertaking is entitled to "compete" on the merits. However, the undertaking concerned has a special responsibility not to allow its conduct to "impair genuine undistorted competition" on the common market. In the US, section 2 of the Sherman Act makes it unlawful for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations . . . ."

4.5.2 The first step in the application of Article 82 requires the assessment of whether an undertaking is in a dominant position and of the degree of market power it holds. Developments in case-law emphasize that holding a dominant position confers a special responsibility on the firm concerned, the scope of which must be considered in the light of the specific circumstances of each case.[143] Dominance has been defined under EC law as a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on a relevant market, by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers.[144] The Commission may consider a combination of several factors to ascertain the dominant position derives from a combination of several factors which, taken separately, are not necessarily determinative. It may also consider that effective competitive constraints are absent even if some actual or potential competition remains.

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[141] See *Vertical Guidelines (2000)*

[142] Article 82 reads as follows:

[143] Case T-228/97 *Irish Sugar* v *Commission* [1999] ECR II-2969; Case T-203/01 *Michelin* v *Commission (Michelin II*) [2003] ECR II-4071; Case 322/81 *Nederlandsche Banden Industrie Michelin (Michelin I*) v *Commission* [1983] ECR 3461; Case T-83/91 *Tetra Pak* v *Commission (Tetra Pak II)* [1993] ECR II-755; Case T-111/96 *ITT Promedia* v *Commission* [1998] ECR II-2937.

[144] Case 27/76 *United Brands Company and United Brands Continentaal* v *Commission* [1978] ECR 207; Case 85/76 *Hoffmann-La Roche & Co.* v *Commission* [1979] ECR 461.

4.5.3 The Market shares provide a useful guidance for the Commission for assessing the market structure and of the relative importance of the various undertakings active on the market.[145] However, the Commission interprets the market shares in the light of the relevant market conditions, and in particular of the dynamics of the market and of the extent to which products are differentiated.

4.5.4 In the US, market power and monopoly power are related but not the same. The US Supreme Court has defined market power as "the ability to raise prices above those that would be charged in a competitive market,"[146] and monopoly power as "the power to control prices or exclude competition."[147] Thus where market power becomes so immense as to comprise what the law deems to be monopoly power is largely a matter of degree rather than one of kind. Furthermore, the US Antitrust agencies before subjecting a firm to possible challenge under antitrust law for monopolization or attempted monopolization, consider that the power in question is generally required to be much more than merely fleeting; that is, it must also be durable.

4.5.5 The US courts have defined that the relevant product market "is composed of products that have reasonable interchangeability for the purposes for which they are produced- price, use and qualities considered."[148] Thus, the market is defined with regard to demand substitution, which focuses on buyers' views of which products are acceptable substitutes or alternatives.[149] Thus the US courts typically determine whether a firm possesses monopoly power by first ascertaining the relevant market and then examining market shares, entry conditions, and other factors with respect to that market. However, there can be other means of identifying monopoly power by demonstrating monopoly power solely through direct evidence—for example, proof of high profits. While no court in the US has relied solely on direct evidence to establish monopoly power, one court found direct evidence sufficient to survive summary judgment despite plaintiff's failure "to define the relevant market with precision."[150] However, experts and commentators have found excessive problems with such an approach (Baker, 2007). By focusing on anticompetitive effects, such as the reduction of output, may be more useful than focusing on profits, price-cost margins, or demand elasticity. The most important concern here is that effects evidence is considered to be generally imperfect, and sometimes subject to differing interpretations.

4.5.6 On the other hand, the EU Competition Commission considers that low market shares are generally a good proxy for the absence of substantial market power. The view is that dominance is not likely if the undertaking's market share is below 40% in the relevant market. However, in certain specific cases, market shares below this threshold where competitors are not in a position to constrain effectively the conduct of a dominant undertaking have caught attention of the commission. The Commission also view that an intervention is likely or justifiable, depending on case by case basis, when with higher market share and longer period of time over which it is held, it more likely it is that it constitutes an important preliminary indication of the existence of a dominant position and, in certain circumstances, of possible serious effects of abusive conduct.[151] Further, the commission will also consider other barriers to entry, including legal and regulatory barriers. The EU also considers that competitive constraints may be exerted not only by actual or potential competitors but also by customers. This refers to the countervailing buying

[145] Case 85/76 *Hoffmann-La Roche & Co.* v *Commission* [1979] ECR 461
[146] *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 109 n.38 (1984)
[147] *United States v. E. I. du Pont de Nemours & Co.* (*Cellophane*), 351 U.S. 377, 391 (1956).
[148] United States v. E. I. du Pont de Nemours & Co. (*Cellophane*), 351 U.S. 377, 404 (1956); *see also Microsoft*, 253 F.3d at 51–52
[149] Jonathan B. Baker, *Market Definition: An Analytical Overview*, 74 ANTITRUST L.J. 129, 132 (2007)
[150] Re/Max Int'l, Inc. v. Realty One, Inc., 173 F.3d 995, 1016 (6th Cir. 1999) ("[A]lthough the plaintiffs failed to define the relevant market with precision and therefore failed to establish the defendants' monopoly power through circumstantial evidence, there does exist a genuine issue of material fact as to whether the plaintiffs' evidence shows direct evidence of a monopoly, that is, actual control over prices or actual exclusion of competitors.").
[151] Case T-228/97 *Irish Sugar* v *Commission* [1999] ECR II-2969

power.[152] However, the buyer power may not be considered a sufficiently effective constraint if it only ensures that a particular or limited segment of customers is shielded from the market power of the dominant enterprise.

4.5.7 The EU Commission primarily seeks that enforcement activity in relation to exclusionary conduct is to ensure that dominant undertakings do not impair effective competition by foreclosing their rivals in an anticompetitive way. This would naturally be having an adverse impact on consumer welfare, whether in the form of higher price levels than would have otherwise prevailed or in some other form such as limiting quality or reducing consumer choice. Thus the Commission will usually intervene under Article 82 where, on the basis of economic evidence, the allegedly abusive conduct is likely to lead to "anticompetitive foreclosure". The EU Commission considers the following factors to be generally relevant for assessing anticompetitive foreclosure: the position of the dominant undertaking; the conditions on the relevant market. the position of the dominant undertaking's competitors; the position of the customers or input suppliers; the extent of the allegedly abusive conduct; possible evidence of actual foreclosure; direct evidence of any exclusionary strategy.[153]

4.5.8 *Price-based exclusionary conduct:* In case of price base exclusionary conduct leading to anticompetitive foreclosure, the approach of the EU Commission is to intervene only where the conduct concerned has already been or is capable of hampering competition from competitors which are considered to be as efficient as the dominant undertaking.[154] Thus to determine whether even a hypothetical competitor as efficient as the dominant undertaking would likely be foreclosed by the conduct in question, the EU Commission will examine economic data relating to cost and sales prices, and in particular whether the dominant undertaking is engaging in below-cost pricing, on the condition that sufficiently reliable data are available.

4.5.9 The cost benchmarks that the Commission is likely to use are average avoidable cost (AAC) and long-run average incremental cost (LRAIC).[155] If the data suggest that the price charged by the dominant undertaking has the potential to foreclose as efficient competitors, then the Commission will integrate this in the general assessment of anticompetitive foreclosure also by taking into account other relevant quantitative and/or qualitative evidence.

4.5.10 Further, the EU Commission in the enforcement of Article 82, considers efficiency claims put forth by dominant firms will form part of the examination.[156] This the dominant undertaking may do so either by demonstrating that its conduct is objectively necessary or by demonstrating that its conduct produces substantial efficiencies which outweigh any anticompetitive effects on consumers. In this context, the Commission will assess whether the conduct in question is indispensable and proportionate to the goal allegedly pursued by the dominant undertaking.

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[152] *Id.* Case T-228/97 *Irish Sugar* v *Commission* [1999] ECR II-2969, in which the CFI considered whether the alleged lack of independence of the firm *vis-à-vis* its customers should be seen as an exceptional circumstance preventing the finding of a dominant position in spite of the fact that the firm was responsible for a very large part of the sales recorded on the industrial sugar market in Ireland.

[153] See Commission's Guidance on Article 82.

[154] See, Case 62/86 *AKZO Chemie* v *Commission* [1991] ECR I-3359, where in relation to pricing below average total cost (ATC) the ECJ expressed: "Such prices can drive from the market undertakings which are perhaps as efficient as the dominant undertaking but which, because of their smaller financial resources, are incapable of withstanding the competition waged against them".

[155] The EU Commission's Guidance on Article 82 states that "Average avoidable cost is the average of the costs that could have been avoided if the company had not produced a discrete amount of (extra) output, in this case the amount allegedly the subject of abusive conduct. In most cases, AAC and the average variable cost (AVC) will be the same, as it is often only variable costs that can be avoided. Long-run average incremental cost is the average of all the (variable and fixed) costs that a company incurs to produce a particular product. LRAIC and average total cost (ATC) are good proxies for each other, and are the same in the case of single product undertakings. If multi-product undertakings have economies of scope, LRAIC would be below ATC for each individual product, as true common costs are not taken into account in LRAIC. In the case of multiple products, any costs that could have been avoided by not producing a particular product or range are not considered to be common costs. In situations where common costs are significant, they may have to be taken into account when assessing the ability to foreclose as efficient competitors".

[156] Few landmark cases have led to the commission's view to evaluate efficiencies: See, Case 27/76 *United Brands* v *Commission* [1978] ECR 207; Case T-30/89 *Hilti* v *Commission* [1991] ECR II-1439, paragraphs 102-119; Case T 83/91 *Tetra Pak International* v *Commission (Tetra Pak II)* [1994] ECR II-755; Case C-95/04 P *British Airways* v *Commission* [2007] ECR I-2331.

The question of whether conduct is objectively necessary and proportionate must be determined on the basis of factors external to the dominant undertaking.

4.5.11 The EU Commission also considers that a dominant undertaking may also justify conduct leading to foreclosure of competitors on the ground of efficiencies that are sufficient to guarantee that no net harm to consumers is likely to arise. Factors for efficiencies[157] that are taken into consideration include efficiencies that have been, or are likely to be, realised as a result of the conduct- they may, for example, include technical improvements in the quality of goods, or a reduction in the cost of production or distribution; the conduct is indispensable to the realisation of these efficiencies: there must be no less anti-competitive alternatives to the conduct that are capable of producing the same efficiencies; the likely efficiencies brought about by the conduct concerned outweigh any likely negative effects on competition and consumer welfare in the affected markets; the conduct does not eliminate effective competition, by removing all or most existing sources of actual or potential competition.

4.5.12 There are certain specific forms of abuse that need special consideration. A lot of jurisprudence has evolved since the implementation of the EC treaty and interpretation given by the Commission, CFI and the ECJ. Such practices are in the nature of: Price related abuse of dominance and non-price related abuse of dominance. In price related abuse of dominance exploitative pricing practices, predatory pricing, rebates that have similar effects to single branding agreements , margin squeezing, price discrimination are the major forms of conduct that form part of abuse of dominance under Article 82. In non-price related practices, tying and bundling, exclusive dealing, refusal to supply are considered as the type of conduct demanding the application of Article 82.

4.5.13 Exploitative pricing by a dominant firm raises important questions for competition law. While it may seem necessary that Competition authorities may take steps to control or deter exploitative pricing, there have not been many cases where direct control of pricing practices has been held to violate principles of competition law. There are certain economic arguments presented against direct control of prices under competition law. Whish (2008) has articulated five major problems as to why direct control of exploitative pricing is not a feasible proposition under competition law.[158] First, working of normal market forces entails that new entry will solve the problem of exploitative pricing. Second, there is no scientific standard to evaluate what type of hypothetical competitive price is correct. Further, it is asserted that to identify reasonable price would entail identifying costs in production and distribution. Third, an argument that monopolist should be permitted to charge a monopoly price so that it will be able to earn sufficient large profits to be able to carry out expensive and risky R&D- this is based on the US supreme Court's jurisprudence in *Trinko.*[159] A view also that monopolistic pricing represents shift of wealth or wealth transfers from consumer to producers- so from one part of economy to other and hence not minimizing total welfare. However, the counterfactual is also that there is welfare loss where output is restricted by a firm with market power and improper allocation of resources. Fourth, the difficulty in translating this into realistic legal tests so that it ensures legal certainty to firms for marking reasonable prices on *ex ante* basis. Fifth, the problem of remedial action where the authorities may not be aware of total market conditions. Remedial actions may require continues surveillance and hence crafting precompetitive remedies is excessively complex. This was a specific problem in a case decided by the UK court of appeals in *Attherace*s.[160] Thus Whish has concluded that competition authorities have often stayed away from being price regulators and have only concentrated on abuses that keep out competitors from the market. However, on various occasions the EU Commission has dealt with matters on pricing by introducing legislations and not by direct intervention.

4.5.14 Article 82 however takes into consideration excessive pricing as abuse wherein it states that "directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions". Thus in the case of *General Motors,*

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158 Whish, 2008, pp. 709-710

159 590 US 398 (2004)

160 UKLR 309 CA.

the ECJ concluded that there was enough evidence to support allegations of excessive pricing. In *United Brands* the ECJ negated the Commission's decision on excessive pricing as the commission did not make a clear case, but it said that "charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied… is an abuse".[161] In concluding the same, the ECJ held that the commission would require the defendants to produce particulars of all the constituent elements of its production costs. Placing the burden on the commission, the ECJ remarked that the test for finding out excessive pricing should be "whether the difference between the costs actually incurred and the price actually charged is excessive, and if the answer to the question is in the affirmative, to consider whether a price has been charged which is either unfair or when compared to other competing products."[162] In *Deutsche Post AG- Interception of Cross-Border mail,*[163] the commission noted that it could not make a detailed cost examination, but concluded that it would use an alternative to compare Deutsche posts prices with domestic tarrif and concluded that there was an abuse.

4.5.15 Again, excessive prices can be detrimental to more than a single market when the owner of an essential facility charges an excessively higher price for granting access to such facility and this could be regarded as constructive refusal to supply consequently leading to the abuse of dominant position. The best example for this is the Commission's finding that Microsoft had charged unreasonably for accessing interoperability information.[164]

4.5.16 While it is difficult to assess costs, it is not totally impossible as explained by some reports of the UK OFT.[165] For example, in *Napp Pharmaceutical Holdings Ltd v. director General of Fair Trading* [166] the OFT concluded that Napp had abused its dominant position by charging excessive prices and for operating discriminatory discount policy, by predatory pricing. Napp had supplied morphine by offering very large discounts to hospitals and at the same time charging excessive prices to patients to community patients. The prices for community were more than 10 times to that in the hospitals. The OFT found abuse of dominance by comparing profit margins. The CAT also upheld commission's finding but held that prevailing uncertainty in the law would entail Napp certain mitigating factors and hence reduced the fine decided by the OFT.[167] Again, in *SSL International plc: contraceptive sheaths*[168] the OFT concluded that although it was possible that SSL's male condoms were highly priced, a substantial amount to time and expense would be needed to reach view of abuse of dominance. Thus the OFT closed the investigation, also noting that there was likely entry and hence emerging competition. Further it also noted that any action of SSL by imposing a price cap may also deter such an entry.

4.5.17 However, the South African Competition Commission has showed that there can be abuse of dominance through excessive pricing of patented pharmaceutical products. It was under pressure from South African Competition Commission that GSK, which was the world's largest producer of AIDS medicine holding a 50 percent stake of the $5 billion market, was forced to issue licenses on two major antiretroviral (ARV) drugs- known as AZT and Lamivudine- to four generic producers. In another similar case, Boehringer-Ingelheim (BI) was forced to license nevarapine – a major ARV to prevent mother to child transmission of HIV infection- to three producers. This led to forced but voluntary licenses being issued by drug companies to other producers at a low royalty rate of 5%. This case has turned out to be a trend-setter for developing country jurisdictions to follow a nuanced policy on addressing unfair and exploitative pricing policies adopted by drug companies in case of patented drugs.

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[161] 1 CMLR 429.
[162] 1 CMLR 429.
[163] OJ [2001] L 331/40, (2002)
[164] Commission's guidance on Article 82
[165] OFT Economic Discussion Paper 6, OFT 657, *Assessing Profitability in Competition Policy Analysis (NERA, July 2003)*.
[166] [2001] UKLR 597
[167] Case No 1000/1/1/01
[168] OFT Case closure 11th May 2005

x: 10- South African Competition Commission Threatens Compulsory Licenses for Generic Production of ARV Drugs

In November 2003, the South African (SA) government announced its policy to implement universal access treatment under its national programme for people living with HIV AIDS. This was to treat around 1.4 million people in treatment within five years. The Treatment Action Campaign (TAC) and others complained to the South African Competition Commission that GSK and BI in September 2002 challenging the monopoly pricing practices of the two pharmaceutical companies. Consequently, drug companies chose to voluntarily negotiate and bring down the prices and as it would be difficult for them to justify their pricing policies in open courts. The new licenses from GSK were to permit four generic producers in SA to produce ARV for sale in SA and Sub-Saharan Africa for both public and private sector markets as long as medicines were produced actually in South Africa. BI also agreed to license on voluntary basis to three generic companies on similar terms. These licenses were to permit generic producers to manufacture Fixed Dose Combinations (FDC). It should be noted the FDC would not have been possible but for the generic manufacturers since such companies are not able to cross license each other's patents for the fear of diluting each other's rights. Post license the combinational therapies were to be available at $ 140 per year, four times cheaper than discount prices from brand name companies sin the public sector and fifteen times cheaper than the price in the private sector.

In October 2003, the SA Competition Commission issued findings upholding a complaint by TAC holding that GSK and BI had charged excessive prices for their patent protected ARV drugs. The Competition Commission based its finding on three theories:

- That drug companies charged monopoly prices, even when partially discounted , and this can impede access to medicines
- That the refusal of drug companies to issue voluntary license to generic producers can abusively impede competition
- That the refusal to grant licenses denies access to "essential-facilities" which prevent the production of FDC drugs.

This decision would be the basis for administrative penalties but also for compulsory license for SA market and also for export market to other developing countries. Here it is important to note that since the SA competition Commission's decision to issue compulsory license was to remedy an anticompetitive practice, it would not be subject to limitation of Article 31(f) of the TRIPS Agreement, which provide that CL shall be used for satisfying domestic markets.

While the SA Competition Commission announced its preliminary decision in October 2003, it gave companies additional time to negotiate it on voluntary basis. If not, the commission would have made a detailed submission to the Competition Tribunal, which would have intern adjudicated on the matter. It should be noted that even before the complaint by the TAC, GSK had already granted a voluntary license to Aspen. But TAC complained that single exclusive license would not bring down competition, alleging that it represented only transfer of monopoly from the patent holder to the licensee. Hence the demand was for more licenses to be issued.

As per the new agreement, GSK agreed to bring down its royalty from 30% to 5% and BI from 15% to 5%. License being issued to multiple producers would mean that these companies would compete against each other to bring down prices further. It may be noted that even discounted prices offered by companies did not preclude the commission from assessing that GSK and BI engaged in excessive pricing. SA competition Act is meant to prohibit exclusionary acts and hence denying

access to medicines by excessive prices can be a ground for issue of compulsory license. The essential facility doctrine is applicable since the WHO recommended FDC as first line therapy in places that have poor access to resources. Since it precluded a different market in FDC from being operationalised, it would mean that certain essential facility was denied. The South African Competition Act 89 of 1998 provide remedies for anti-competitive practices and covers

4.5.18 **Predatory Pricing:** The EU Commission will generally intervene where there is evidence showing that a dominant undertaking engages in predatory conduct by deliberately incurring losses or foregoing profits in the short term, generally termed as "sacrifice", so as to foreclose or be likely to foreclose one or more of its actual or potential competitors with a view to strengthening or maintaining its market power, thereby causing consumer harm.[169] Thus the commission views conduct entailing a sacrifice if the dominant undertaking, by charging a lower price for all or a particular part of its output over the relevant time period, or by expanding its output over the relevant time period, incurred or is incurring losses that could have been avoided. The Commission will take AAC as the appropriate starting point for assessing whether the dominant firm incurs or incurred avoidable losses. Furthermore, the commission will also apply that test of harm to consumers, if sufficient reliable data are available. The efficiency argument will generally not hold well in predatory pricing cases. However, provided that the conditions mentioned above are fulfilled, the Commission will consider claims by dominant undertakings that the low pricing enables it to achieve economies of scale or efficiencies related to expanding the market.

4.5.19 The position in the US is substantially governed by the Supreme court decision in *Brooke Group Ltd v. Brown & Williamson Tobacco Corp.,*[170] where it held that price predation had pro-competitive effects since it benefited the consumers due to lower prices in a stage where predation is done and also post-predation where the price predator would not be able to recoup costs. However, this decision has come under heavy criticism because price predation leads to market power which can be abused during the post predation period leading to entry barriers. This is also being established by scholarship[171].

4.5.20 *Tying and Bundling:* A dominant undertaking may try to foreclose its competitors by tying or bundling. “Tying” refers to situations where customers that purchase one product (the tying product) are required also to purchase another product from the dominant undertaking (the tied product). Tying can take place on a technical or contractual basis. Tying occurs when the tying product is designed in such a way that it only works properly with the tied product (and not with the alternatives offered by competitors). Contractual tying occurs when the customer who purchases the tying product undertakes also to purchase the tied product (and not the alternatives offered by competitors).[172] “Bundling” usually refers to the way products are offered and priced by the dominant undertaking. In the case of pure bundling the products are only sold jointly in fixed proportions. In case of mixed bundling, often referred to as a multi-product rebate, the products are also made available separately, but the sum of the prices when sold separately is higher than the bundled price.[173] The EU Commission will take action under Article 82 where an undertaking is dominant in the tying market and where, in addition, the following conditions are met: (i) the tying and tied products are distinct products, and (ii) the tying practice is likely to lead to anticompetitive foreclosure[174].

4.5.21 The distinct products test enunciates whether the products will be considered by the Commission based on customer demand. As per commission’s guidance on Article 82, “two products are distinct if, in the absence of tying or bundling, a substantial number of customers would purchase or would have purchased the tying product without also buying the tied product from the same supplier, thereby allowing stand-alone production for both the

[169] Commission’ Guidance on Article 82
[170] 509 U.S. 209 (1993)
[171] *Joseph F Brodley* Predatory Pricing Strategic Theory and Legal Policy, 88 Georgetown Law Journal 2239 (2000)
[172]
[173] Commission’s Guidance on Article 82
[174] Case T-201/04 *Microsoft* v *Commission* [2007] ECR II-3601

tying and the tied_product." Tying or bundling may lead to anticompetitive effects in the tied market, the tying market, or both at the same time. However, even when the aim of the tying or bundling is to protect the dominant undertaking's position in the tying market, this is done indirectly through foreclosing the tied market. Furthermore, a multi-product rebate may be anticompetitive on the tied or the tying market if it is so large that as efficient competitors offering only some of the components cannot_compete against the discounted bundle. When the conditions mentioned herein are fulfilled, the EU commission will look into efficiency claims by dominant undertakings that their tying and bundling practices may lead to savings in production or distribution that would benefit customers.

4.5.22 *Exclusive Dealing:* Exclusive dealing refers to the strategy of a dominant undertaking which may try to foreclose its competitors by hindering them from selling to customers through use of exclusive purchasing obligations or rebates. It also includes exclusive supply obligations or incentives with the same effect, whereby the dominant undertaking tries to foreclose its competitors by hindering them from purchasing from suppliers. The EU Commission considers that such input foreclosure is in principle liable to result in anticompetitive foreclosure if the exclusive supply obligation or incentive ties most of the efficient input suppliers and customers competing with the dominant firm are unable to find alternative efficient sources of input supply[175]

4.5.23 An exclusive purchasing obligation requires a customer on a particular market to purchase exclusively or to a large extent only from the dominant undertaking.[176] The EU Commission focuses its attention on those cases where it is likely that consumer as a whole will not benefit. This would in particular be the case if there are many buyers and the exclusive purchasing obligations of the dominant undertaking, taken together, have the effect of preventing the entry or expansion of rival firms. Further, conditional rebates are rebates granted to customers to reward them for a particular form of purchasing behaviour. The Commission's Guidance on Article 82 explains conditional rebates as those "that the customer is given a rebate if its purchases over a defined reference period exceed a certain threshold, the rebate being granted either on all purchases (retroactive rebates) or only on those made in excess of those required to achieve the threshold (incremental rebates). Conditional rebates are not an uncommon practice". Thus such rebates, when granted by a dominant undertaking, can also have actual or potential foreclosure effects similar to exclusive purchasing obligations.

4.5.24 When applying the methodology explained above, the Commission relies to the extent that the data are available and reliable, whether the rebate system is capable of hindering the expansion or entry even of as efficient competitors by making it more difficult for them to supply part of the requirements of individual customers. In this context the Commission will estimate what price a rival would have to offer in order to compensate the customer for the loss of the conditional rebate if the latter would switch part of its demand ('the relevant range') away from the dominant undertaking. The effective price that the rival will have to match is not the average price of the dominant undertaking, but the normal (list) price less the rebate it loses by switching, calculated over the relevant range of sales and in the relevant period of time. The Commission takes into account the margin of error that may be caused by the uncertainties inherent in this kind of analysis.

4.5.25 Thus the investigation will consider an analysis that will be integrated in the general assessment, taking into account other relevant quantitative or qualitative evidence. It is normally important to consider whether the rebate system is applied with an individualised or a standardised threshold. In evaluating efficiencies, apart from conditions mentioned above are met, the Commission will consider claims by dominant undertakings that rebate systems achieve cost or other advantages which are passed on to customers. Thus it is generally presumed that transaction related cost advantages are often more likely to be achieved with standardized volume targets than with individualised volume targets. If those arrangements are necessary for the dominant undertaking to make certain relationship-specific investments in order to be able to supply those customers, under such conditions, the

[175] Commission's Guidance on Article 82

[176] Certain other obligations, such as stocking requirements, which appear to fall short of requiring exclusive purchasing, may in practice lead to the same effect. See, Case T-65/98 *Van den Bergh Foods* v *Commission* [2003] ECR II-4653. In this case the obligation to use coolers exclusively for the products of the dominant undertaking was considered to lead to outlet exclusivity.

Commission will consider evidence demonstrating that exclusive dealing arrangements result in advantages to particular customers.

4.5.26 Essential facility doctrine: There is no standard definition for the term 'essential facilities doctrine'. Advocate General (AG) Jacobs in Bronner, however, captures its essence thus:[177] [A] company which has a dominant position in the provision of facilities which are essential for the supply of goods or services on another market abuses its dominant position where, without objective justification, it refuses access to those facilities. Thus in certain cases a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed.

4.5.27 The existence of an essential facilities doctrine has been acknowledged both in the European Union and the United States. Though there are differences in the way the doctrine is applied on either side of the Atlantic, the basic premise is the same: that where access to a facility is essential in order for a person to operate on a certain market, the owner of the facility may, in certain circumstances, be obliged to grant access to that person.

4.5.28 The essential facilities doctrine has its origin in the US, and in particular in Section 2 of the Sherman Act, which prohibits monopolization and attempts to monopolize. This section has been used in the US to support the development of the essential facilities doctrine. Essential facilities cases are considered exceptions to the general principle that in the US. Companies are under no obligation to deal with others. In the EU, on the other hand, the European Court of Justice ("ECJ") has developed a general duty to deal, and the essential facilities doctrine can be seen simply as a particular application of this general duty. It has been recognized that any application of the essential facilities doctrine should satisfy the following:

- The facility must be controlled by a dominant firm in the relevant market
- Competing enterprises/persons should lack a realistic ability to reproduce the facility
- Access to the facility is necessary in order to compete in the relevant market; and
- It must be feasible to provide access to the facility.

4.5.29 It was first articulated by US Supreme Court in United States v. Terminal Railroad Ass'n[178]. In Terminal Railroad, a group of railroads controlling all railway bridges and switching yards into and out of St. Louis prevented competing railroad services from offering transportation to and through that destination. This, the court held, constituted both an illegal restraint of trade and an attempt to monopolize. Since Terminal Railroad, the Supreme Court has reached similar decisions in a series of cases:

4.5.30 In Associated Press v. United States,[179] the Supreme Court found that the Associated Press bylaws violated the Sherman Act by limiting membership in the organization and thereby access to its copyrighted news services. In Lorain Journal Co. v. United States,[180] the Supreme Court considered whether the defendant newspaper, the only local business circulating news and advertisements in the town, violated the Sherman Act by refusing to accept advertising from businesses that placed advertisements with a small radio station. The Court approved an order requiring the newspaper to accept advertisements. In Otter Tail Power Co. v. United States,[181] the Supreme Court found that the defendant, an electrical utility which sold electricity at both the retail level (directly to consumers) and the wholesale level (to municipalities who sought to resell electricity at retail), had monopolized in violation of the Sherman Act by refusing to supply electricity at wholesale and instead to service customers directly itself.

[177] Oscar Bronner v Media Print GmBH [1998] ECR I-7791 (AG opinion) [34].
[178] 224 U.S. 383 (1912).
[179] 326 U.S. 1 (1945).
[180] 342 U.S. 143, 146-49 (1951).
[181] 410 U.S. 366, 377-79 (1973).

4.5.31 In EC the concept of EFD derives its genesis to Article 82 of the EC treaty. It requires an abusive act[182] by a dominant'[183] undertaking within the EC or a substantial part of it.[184] Refusal to supply is seen as an importanat facet of the same. It is important to note in this context that the courts have never expressly used the term 'essential facilities doctrine'[185] rather it appears that most such issues were dealt with under the broad rubric of 'refusal to supply' cases, originating as far back as Commercial Solvents.[186] When considering the law of refusal to supply it is helpful to keep in mind the distinction suggested in DG COMP's Discussion Paper between horizontal and vertical foreclosure of the market.[187] ECJ has taken a very strict note of refusal to supply and there lies ample jurisprudence on the topic. The treatment of the same is very much similar to EFD and to my mind except terminology rest all the criteria seeked by court points in the same direction as EFD.[188] Following are some examples from EC jurisprudence on the topic. To be precise the test of indispensability is used by the commission to decide the question of essential facilities.[189]

4.5.32 These Supreme Court cases – and other cases – make clear that the "essential facilities" doctrine renders a unilateral refusal to deal subject to potential l liability as a monopolization violation. The 'essential facilities' doctrine is not an independent cause of action, but rather a type of monopolization claim.[190] Because it represents a divergence from the general rule that even a monopolist may choose with whom to deal, courts have established widely-adopted tests that parties must meet before a court will require a monopolist to grant access to an essential asset to its competitors. Specifically, to establish antitrust liability under the essential facilities doctrine, a party must prove four factors:[191]

- control of the essential facility by a monopolist;
- a competitor's inability practically or reasonably to duplicate the essential facility;
- the denial of the use of the facility to a competitor; and
- the feasibility of providing the facility to competitors.

4.5.33 Opinions of the United States courts also suggest that antitrust liability under the essential facilities doctrine is particularly appropriate when denial of access is motivated by an anticompetitive animus usually demonstrated by a change in existing business practices with the apparent intent of harming rivals.[192] Most recently, in Aspen Skiing, which it decided as a straight- forward "refusal to deal" case without reaching the question whether the defendant's facility was "essential," the Supreme Court found compelling the anticompetitive intent demonstrated by the "decision by a monopolist to make an important change in the character of the market."

4.6 Regulation of Combinations (Merger Control):

[182] Compagnie Maritime Belge Transports SA v Commission [2000] ECR I-1365, the list proposed in Article 82 is not exhaustive.
[183] The ECJ has defined 'dominance' as 'a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers'. Case 85/76 Hoffmann-La Roche [1979] ECR 461.
[184] see Case 40/73 Suiker Unie v Commission [1975] ECR 1663.
[185] Supra 75. The Commission has however referred to the essential facilities doctrine in some of its decisions, beginning with Sea Containers Ltd / Stena Sealink [1994] OJ L15/8 .
[186] [1973] ECR 223.
[187] Section 9 of DG COMP's Discussion Paper on the application of Article 82 of the EC treaty to exclusionary abuses, Sweet and Maxwell, edn. 2nd, 2002, Para 6.104 – 6.124.
[188] For eg. Termination of an existing supply relationship was taken to violate Article 82 in Commercial solvents v. Commission. Refusal to supply to a new customer is also in contravention of Artcile 82.
[189] See Volvo v Veng, [1988] ECR 6211; [1989] 4 CMLR 122; Magill v BBC, [1989] OJ L78/43, affirmed by the CFI in Case T-69/89 RTE v European Commission [1991] ECR II-485; Tierce Ladbroke v PMU, [1997] ECR II-923.
[190] " Kramer v. Pollock-Krasner Found., 890 F. Supp. 250, 257 (S.D.N.Y. 1995);
[191] Colonial Penn Group v. American Ass'n of Retired Persons, 698 F. Supp. 69, 72-73 (E.D. Pa. 1988); cf. Home Placement Serv., Inc. v. Providence Journal, 682 F.2d 274 (1st Cir. 1982).
[192] Supranote 36.

4.6.1 Competition law concerns itself with the possibilities of mergers and combinations (acquisitions and conglomerates) will lead to market being less competitive in future than it is currently [Whish, 2008, p. 799]. Mergers occur between previously independent firms into one single firm entity. The main concern of competition authorities the world over is about the harmful effects of horizontal mergers and combinations. There may also be concerns arising out of acquisitions. Horizontal acquisitions and mergers take place between actual and potential competitors in the same product or geographic markets and at the same level of the production or distribution cycles [Whish, 2008, p. 799]. The analogy that horizontal mergers are harmful is the same as those relating to cartels. Horizontal mergers can be scrutinized both from their 'unilateral' or non-coordinated' effects and for their coordinated effects. There are various motivations for merger, which include, interalia, to achieve economies of scale and scope, access to distribution and other networks, access to specific markets, to become national champions, efficient management and corporate control, existing an industry, to increase market power. Thus in terms of consequences that ensue from combinations they flow from the concentration in market power and strategically operating against competitive forces.

4.6.2 The main purpose of regulating mergers is essentially based on whether the new single entity has taken place formally [Elhauge and Geradin, 2007, p. 799]. In U.S the Sherman Act section 1 regulates mergers since mergers themselves are agreements. Although mergers allow merging firms to come together and fix prices and engage in other concerted practices leading to anticompetitive agreements, they're not considered as *per se* unlawful. Hence effects of merging firms on markets are considered under the rule of reason. In the US they are also covered under Section 5 of the FTC Act and they may raise dominance related issues under section 2 of the Sherman Act. Section 7 of the Clayton Act also governs mergers in US.[193]

4.6.3 The practice of reviewing mergers on *ex ante* basis is also because of the fact that it is difficult to undo effects of an already merged entity on the market. A prospective review of a merger/ combination would allow the competition authorities to prophylactically avoid certain combinations to get consummated. In the US parties planning to get merged must notify under the Hart-Scott-Rodino Act before consummating their merger (15 USC Section 18a). It must be noted that the US the parties merging must provide the authorities with an analysis of effects of proposed merger. The DOJ and FTC have divided amongst themselves based on industries. The pharmaceutical industry mergers are revived by the FTC. Unless the agencies make a second request seeking more information, a merger takes effect within 30days. There are hardly few cases where the agencies have stopped parties from merging in the recent years. This is also based on the dominant ideology the oligopolistic dominance is not by itself harmful to the market, however, the abuse of such dominance is, which can treated under abuse of dominance provisions. Even the Supreme Court of United States has hardly delilvered decisions under the Hart-Scott-Rodino Act which can assert the standard benchmarks for mergers and other combinations.[194]

4.6.4 Under the EC law, merger are governed under the not under the EC treaty Article 81 and 82 (as it proved in effective) but under the EC Merger Control Regulation. Article 2 of the 1989 EC Merger Regulation provides that : *"A concentration which creates or strengthens a dominant position as a result of which effective competition would be significantly impeded in the common market or in a substantial part of it shall be declared incompatible with the common market."*

4.6.5 In cases involving mergers and acquisitions, the competition authorities across the world have followed an approach to define the markets are broadly as possible. The basic premise behind merger control is that it may lead to market concentration. Hence it is essentially based on the effect such combination will create on competition within a particular jurisdiction. The pharmaceutical industry, as noted above, survives in an oligopolistic structure. Hence merger control and regulation of combinations have special importance in this sector. While the

[193] Section 7 of the Clayton Act

[194] See for e.g. *Brown Shoe* v. *United States* [370 US 294]. *United States* v. *Philadelphia National Bank* [374 US 321].

commonly applied test has been has been to look at whether a merger or acquisition is likely to result in "substantial lessening of competition", this tests has no more restricted in to the product range. In the European context, the Commission is taking a further step for an innovation approach in the Merger Control, studying not only competition *in the market* but also *for the market*. The competition *in the market* approach, on one hand, takes into account the existing products and considers the R&D efforts only like a part of the product market. The competition *for the market* assessment, on the other hand, considers the R&D efforts, like a separate market from the existing products. This approach is called "*Innovation Market",* and supposes that the projects for the development of new products/services are analysed as a different market. It has its origin in the American approaches. However, this tests has come under heavy criticism because innovation is non-predictable and may not be desirable at all times; Innovation is speculative and includes unidentifiable market participants; the relationship between R&D and innovation is unclear; the market structure most conducive to innovation is unclear.

4.6.6 However, despite severe criticisms the innovation market test in merger control has survived. Many cases examined in the US and EU context allude to this important fact. After having examined both the frameworks, it can be concluded that "*Innovation Market*" assessment has a very limited role in the European Merger Control where the R&D pipelines are focussed to new products and the rate of success is absolutely uncertain. Other characteristic of the European appraisal is that the antitrust Authority is only taking into consideration projects in Phase III of the Clinical Trials (also Phase II in few cases, where the situation is really clear).In European Merger practise, unless the parties are currently in a powerful position in the present markets (product market), the Commission is only going to consider as overlapping pipelines, those in advanced development. In this way the European authority tries to avoid playing the game of guessing the future.

4.6.7 The American approach is broader, and it is not limited to the European restrictions. The FTC is takes into account pipelines in early stages of the development process to define the *relevant "Future Market".* Actually, for the American Authority it is not necessary that the drug is in the stage III of the Clinical Trial to be included in the competition assessment. Other feature of the American approach, is that the Antitrust Authority is more meticulous when is assessing a merger that can *"restrict substantially competition in R&D ".* The FTC has defined, in a more detailed way, the relevant future markets, reducing their scope, in comparison with the European Authorities.

4.6.8 Thus, while in the American approach, the "*Innovation Market*" is intended to predict the future product market effects, the European approach, tries to establish the post-merger incentives to reduce R&D projects. The "*Innovation Market"* analysis is one instrument more in the hands of the Agencies to control the concentration operations. This extra-power is useful to avoid negative post-merger situations, which escape the traditional merger examination.

4.6.9 The following are some of the important merger orders reproduced from the FTC annotated collection of cases in pharmaceuticals, which have laid down some general principles relating to the tests to be followed:[195]

4.6.10 *Sun Pharmaceuticals Industries/Taro Pharmaceutical Industries,* C-4230 (consent order issued September 16, 2008). The complaint charged that Sun's acquisition of Taro would result in reduced competition and higher prices to consumers for three generic formulations of the anticonvulsant drug carbamazepine. The drugs named in the complaint were immediate-release carbamazepine tablets, chewable carbamazepine tablets, and extended-release carbamazepine tablets. The complaint alleged that the merger would reduce the number of firms producing the generic chewable tablet from three to two and reduce the number of firms producing the immediate-release form from four to three, leaving Teva as the only remaining significant competitor. In the market for the generic extended-release form, Sun and Taro were the only companies that had applied for FDA approval to market the drug, and as a result, the merger would eliminate future competition completely. The order requires that Sun divest

[195] See FTC Collection of order in pharmaceuticals (2008)s

all of its rights and assets related to the development, manufacture, and marketing of the three generic carbamazepine drugs to Torrent Pharmaceutical Limited or another Commission approved buyer. The order also requires that Sun provide transitional services including help obtaining necessary FDA approvals and technical transfer assistance.

4.6.11 *Schering-Plough Corporation/Organon BioSciences N.V.,* C-4211 (consent order issued December 28, 2007). The complaint charged that Schering's acquisition of Organon from Akzo-Nobel would harm competition in three highly concentrated markets for live poultry vaccines. According to the complaint, the merger created a monopoly in the market for vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus, and gave Schering-Plough a dominant share in the markets for live vaccines for the prevention and treatment of fowl cholera due to Pasteurella multocida, and live vaccines for the prevention and treatment of Mycoplasma gallisepticum in poultry. The order requires Schering-Plough to divest to the Fort Dodge division of Wyeth all of the assets, including research, development, customer, supplier and manufacturing contracts, and all intellectual property excluding trademarks, of its live vaccine for the Georgia 98 strain of infectious bronchitis and its live Mycoplasma gallisepticum vaccine, and Organon's live fowl cholera vaccine. The order also includes a supply and transition services agreement under which Schering-Plough will provide the vaccines for two years to Wyeth until Wyeth obtains the necessary regulatory approvals to bring the vaccines in-house.

4.6.12 *Mylan Laboratories/E. Merck oHG.,* C-4200 (consent order issued November 1, 2007). The complaint charged that Mylan's acquisition of a generic subsidiary of Merck would result in reduced competition and higher prices to consumers for five generic drugs produced by both companies to treat hypertension and cardiac problems. The drugs named in the complaint were: acebutolol hydrochloride capsules (a beta blocker used to treat hypertension), flecainide acetate tablets (an anti-arrhythmia drug used to treat heart problems), guanfacine hydrochloride tablets (an alpha blocker used to treat hypertension), nicardipine hydrochloride capsules (a calcium channel blocker used to treat hypertension), and sotalol hydrochloride AF tablets (a beta blocker used to treat hypertension). Mylan and Merck, through an agreement with Par Pharmaceuticals, were the only two suppliers of generic acebutolol hydrochloride capsules, and among a small number of suppliers for the other four drugs. The order requires that Merck divest its assets in the five drugs to Amneal. The order also requires that Mylan and Merck provide transitional services to help Amneal obtain necessary FDA approval.

4.6.13 *Johnson & Johnson/Pfizer,* C-4180 (consent order issued January 16, 2007). The Commission's complaint charged that Johnson & Johnson's acquisition of Pfizer's Consumer Healthcare business would increase concentration and reduce competition in the U.S. markets for four over the counter drugs. According to the complaint, the acquisition would have enabled Johnson & Johnson to raise prices and reduce the incentive to innovate and develop new products in the four markets: A) *Over-the-counter H-2 blockers*. The order requires the divestiture of Pfizer's Zantac assets to Boehringer. The order also contains provisions concerning to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Boehringer. B) *Over-the-counter* hydrocortisone *anti-itch products*. The order requires the divestiture of Pfizer's Cortizone product to Chattem. The order also contains provisions to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Chattem. C) *Over-the-counter night-time sleep aids*. The order requires the divestiture of Pfizer's Unisom sleep-aid assets to Chattem. The order also contains provisions concerning to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Chattem. D) *Over-the-counter diaper rash treatments*. The order requires the divestiture of Johnson & Johnson's Balmex diaper rash treatment product to Chattem. The order also contains provisions concerning to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Chattem.

4.6.14 *Teva Pharmaceutical Industries and IVAX Corporation*, C-4155 (consent order issued March 2, 2006): The complaint alleged that Teva's $7.4 billion acquisition of IVAX would lessen current and/or future competition

between the two companies in fifteen highly concentrated markets for generic pharmaceuticals, and result in the delay or elimination of additional price competition or higher prices for consumers: A) *Generic amoxicillin clavulanate potassium*. The order requires the divestiture of IVAX's amoxicillin clavulanate potassium assets to Par. B) *Cefaclor LA tablets*. Cefaclor tablets LA tablets are a cephalosporin antibiotic. The order requires the divestiture of Teva's Pergolide mesylate tablets to Par. C) *Estazolam tablets (*used to treat seizure disorders*)*. Teva (with 52% of the market), IVAX (with 13% of the market) and Watson were the only suppliers of generic estazolam tablets in the U.S. The order requires the divestiture of Teva's estazolam tablets to Par. C) *Leuprolide acetate*. The order requires the divestiture of IVAX's leuprolide acetate injection kits to Par. D) *Nabumetone tablets*.. The order requires the divestiture of IVAX's nabumetone tablets to Par. C) *Amoxicillin*. Amoxicillin is a penicillin antibiotic used to treat infections. Although five companies suppied various formulations of the drug, only Teva, IVAX and Ranbaxy supplied the 200 mg and 400 mg oral suspensions and the 875 mg tablet formulations. The order requires the divestiture of IVAX's amoxicillin to Par.

4.6.15 *Pfizer Inc. and Pharmacia Corporation*, 135 F.T.C. 608 (2003) (consent order). The complaint alleged that Pfizer's $60 billion acquisition of Pharmacia would lessen direct or potential competition between the two companies in nine highly concentrated markets, and result in the delay or elimination of additional price competition or higher prices for consumers: *Extended Release Treatments for Overactive Bladder (OAB).* Pharmacia's Detrol and Detrol LA and Johnson & Johnson's Ditropan XL were the only two extended release OAB products marketed in the U.S. Pfizer, one of two companies best-positioned to enter the market within the next two years, was in the process of seeking FDA approval for darifenacin, its extended release OAB product. The complaint alleged that the merger would eliminate potential competition between Pharmacia and Pfizer and increase the likelihood that Pfizer would delay the launch of darifenacin. The order requires Pfizer to divest darifenacin and certain other assets to Novartis AG and contains other provisions to ensure that the divestiture is successful; A) *Combination Hormone Replacement Therapies (HRT)*. Pfizer's femhrt and Pharmacia's Activella were two of the three leading combination HRT products marketed in the U.S. After the merger, Pfizer and Wyeth, the other leading competitor, would control approximately 94% of the HRT market. The order requires the divestiture of Pfizer's femhrt to Galen Holdings plc, and contains other provisions to ensure that the divestiture is successful; B) *Treatments for Erectile Disfunction (ED)*. With over 95% of the U.S. ED market and a second generation Viagra-like product in development, Pfizer dominated the research, development, manufacture and sales of prescription drugs for ED. Pharmacia, Pfizer's only significant potential competitor, had two products, IN APO and PNU- 142,774, in clinical development. The order requires Pharmacia to return all of its rights for IN APO to Nastech Pharmaceutical Company, and to divest all of its rights and interests for the field of human sexual for PNU-142,774 to Neurocrine Biosciences, Inc. The order also contains other provisions to ensure that the divestiture is successful; C)*Drugs for Canine Arthritis.* Three companies sold prescription drugs for the treatment of canine arthritis: Pfizer's product, Rimadyl, accounted for 70% of the market and Wyeth's product, EtoGesic, accounted for 30% of the market. Novartis began marketing Deramaxx in early 2003 under a licensing agreement with Pharmacia, which currently manufactured Deramaxx, and supplied it to Novartis. The complaint alleged that because of its license and supply agreement with Novartis, Pfizer, the leading competitor in the market, would control the manufacturing and supply of the competing product Deramaxx, and under the existing licensing agreement, have access to Novartis' sensitive confidential information on Deramaxx' pricing, forecasts, and marketing strategy. The order requires Pharmacia to renegotiate its license and supply agreement with Novartis to allow Novartis to operate as an independent competitor by eliminating the control Pfizer would have over Novartis's product, restricting the type of information Pfizer would be able to obtain about Deramaxx, and allowing Novartis to compete with Pfizer in the development of a second generation canine arthritis product; D) *Antibiotic Treatments for Lactating Cow Mastitis and Dry Cow Mastitis.* Pfizer, Pharmacia and Wyeth were the only significant competitors in the markets for lactating lcow and dry cow mastitis antibiotic products. After the merger Pfizer and Pharmacia would account for 50% of the sales of lactating cow mastitis products and 55% of the sales of dry cow mastitis products. The order requires Pfizer to divest all of its U.S. rights to its bovine mastitis antibiotic products to Schering-Plough Corporation; E) *Over-the-Counter Hydrocortisone Creams and Ointments.* Pfizer's Cortizone brand and

Pharmacia's Cortaid brand were the only two branded hydrocotisone creams on the U.S. market, and accounted for 55% of the over-the-counter sales of hydrocortisone creams and ointments. The order requires Pharmacia to divest its Cortaid business to Johnson and Johnson; F) *Over-the-Counter Motion Sickness Medications.* Pfizer, with its Bonine product and Pharmacia, with its Dramamine product were the two leading suppliers in this market and accounted for a combined market share of 77%. The order requires Pfizer to divest its U.S. and Puerto Rican Bonine assets to Insight Pharmaceuticals Corporation; and G) *Over-the Counter Cough Drops.* Pfizer, with its Halls brand and Pharmacia, with its Ludens brand, were the only two significant competitors in the over-the-counter cough drops market. The order requires Pfizer to divest its Halls cough drop business to Cadbury Schweppes. The Commission also appointed an interim monitor to oversee the asset transfer and to ensure that Pfizer and Pharmacia comply with all of the provisions of the order.

4.6.16 *Baxter International Inc., and Wyeth Corporation*, 135 F.T.C. 49 (2003) (consent order) The Commission's complaint charged that Baxter's acquisition of the generic injectable drug business from Wyeth's subsidiary, ESI Lederle, would reduce either current horizontal competition or potential competition in the market for five injectable drugs: A) *Propofol* Baxter, under a supply agreement with GenesiaSicor, marketed the only generic version of AstraZeneca's branded propofol Diprivan, an anesthetic preferred for outpatient surgery because of its short duration profile. Wyeth was in the process of seeking FDA approval and was one of two companies most likely to enter the market with its own generic version. The complaint alleged that new entry would be difficult and lengthy. Among other things, the preservatives used in the Baxter marketed propofol and in AstraZeneca's product are patent protected and the manufacturing process complex. In order to preserve the future competition and probable lower prices in the market that would have resulted from the entry of a Wyeth generic propofol, the order required the divestiture of Wyeth's propofol business to Faulding Pharmaceutical Company, as well as other requirements to ensure the success of the divestiture. B) *Pancuronium* In the market for pancuronium, a long-acting neuromuscular blocking agent used to freeze muscles during surgery and for patients who are mechanically ventilated, Baxter (under an exclusive marketing agreement with GenesiaSicor), along with Wyeth, and Abbott were the only suppliers. The complaint alleged that the acquisition would have reduced the number of competitors from three to two, leaving Baxter and Wyeth with a combined market share of 74% after the acquisition. New entry was unlikely because pancuronium was an older drug with limited usage. The order required Baxter to divest its pancuronium assets to GenesiaSicor. C) *Vecuronium* Wyeth discontinued its production of vecuronium, an intermediateacting neuromuscular blocking agent used during surgery or ventilation, in 2001, but planned to re-launch the product. Prior to stopping production, Baxter (under an exclusive supply agreement with GenesiaSicor) and Wyeth were the two largest of five vecuronium suppliers and held a 53% combined market share. The complaint charged that the acquisition would eliminate the price competition that would have resulted when Wyeth re-entered the market. The order requires Baxter to divest its vecuronium assets to GenesiaSicor. D) *Metoclopramide* The acquisition would have combined two of four companies supplying metoclopramide, an antiemetic used in certain types of chemotherapy and other post-operative treatments. Wyeth, manufacturer of the branded version of metoclopramide, and Baxter, the exclusive supplier of GenesiaSicor's generic metoclopramide drug, together accounted for over half of the U.S. market. The order requires Baxter to terminate its interests in and divest its assets to GenesiaSicor. E) *New Injectable Iron Replacement Therapies (NIIRTs*) The complaint alleged harm to potential competition and/or price competition in the market for NIRTs, including both iron gluconate and iron sucrose, which are used to treat iron deficiencyin hemodialysis patients. Baxter and Watson jointly marketed Ferrlecit, one of only two NIIRT's approved for sale in the U.S. Wyeth was the best positioned firm to successfully enter the market. The complaint charged that entry was difficult and lengthy. Among other things, a lack of raw material suppliers and complex manufacturing processes complicate entry. The order requires Baxter to terminate its co-marketing agreement with Watson and provides incentives for Baxter to proceed with development of Wyeth's iron gluconate product.

4.6.17 *Glaxo Wellcome plc and Smith Kline Beecham plc*, 131 F.T.C. 56 (2001) (consent order). The Commission's complaint charged that the merger of Glaxo Wellcome (Glaxo) and SmithKline Beecham (SB) would create the

world's largest research-based pharmaceutical manufacturer, substantially lessen competition in nine separate pharmaceutical markets, and result in fewer consumer choices, higher prices and less innovation. In six markets the order required divestiture: A) *5HT-3 Antiemetic Drugs* Glaxo and SB accounted for 90% of the sales of new generation drugs used in chemotherapy to reduce the incidence of side effects. The order required the divestiture of the worldwide rights of SB's drug Kytril to F. Hoffman LaRoche; B) *Injectable Antibiotic Ceftazidime* Glaxo and SB were the only two manufacturer of ceftazidime, and Glaxo was the largest of three firms marketing ceftazidime. The order required the divestiture of SB's U.S. rights to manufacture and market ceftazidime to Abbott Laboratories; C) *Oral and Antiviral Drugs for the Treatment of Herpes, Chicken Pox and Shingles* Glaxo's Valtrex and SB's Famvir were the only second-generation antiviral prescription drugs available on the market, and no other companies have similar products products in development. The order required the divestiture of SB's antiviral drug Famvir to Novartis; D) *Topical Antiviral Drugs for the Treatment of Herpes Cold Sores* SB's Denavir was the only FDA approved prescription topical antiviral drug sold in the US, and Glaxo, the only potential entrant into the market, was seeking FDA approval to market its European antiviral Zovirex in the U.S. The order required SB to divest Denavir to Novartis; E) *Prophylactic Vaccines for the Treatment of Herpes* Glaxo and SB were the leading two of only a few firms pursuing the development of a preventative vaccine. The order required Glaxo to return to its British collaborator, Cantab Pharmaceuticals, all rights to its technology for the development of a prophylactic herpes vaccine; and F) *Over-the Counter H-2 Blocker Acid Relief Products* Glaxo's Zantac 75 and SB's Tagamet were two of the four branded OTC H-2 acid blockers on the market. The order required the divestiture of Glaxo's U.S. and Canadian Zantac trademark rights to Pfizer. In three markets the order addressed competitive overlaps with other research and development firms where the merger was likely to result in delay, termination, or failure to develop as a competitor: G) *Topoisomerase I Inhibitor Drugs Used to Treat Certain Tumors* SB's Hycamptin was a second line therapy for non-small cell lung cancers and SB was developing a first line therapy for colorectal and other solid-tumor cancers. Glaxo, through a collaboration with Gilead Sciences, was developing a drug, GI147211C, which would would have been in direct competition with SB's Hycamptin. Only one other company manufactured similar anti tumor drugs. The order required Glaxo to assign all of its relevant intellectual property rights and relinquish all of Glaxo's reversionary rights to GI147211C to Gilead Sciences; H) *Migraine Headache Treatment Drugs* Glaxo's Immitrex and Amerge were the leading sellers of triptan drugs for the treatment of migraine headache. SB had an interest in another triptan drug, frovatriptan, which was being developed and scheduled for launch by Vernalis Ltd. in the second half of 2001. The order required SB to assign all of its intellectual property rights and relinquish all options to regain control over frovatriptan to Vernalis Ltd; and I) *Drugs to Treat Irritable Bowel Syndrome* Glaxo owned and was conducting clinical trials on Lotronex, which had been taken off the market because of possible side effects. SB had an option to acquire and market renzapride which was being developed by the British firm Alizyme Therapeutics plc. Because the merger would eliminate one of the few efforts underway to develop a drug for the treatment of irritable bowel syndrome, the order required SB to assign all of its intellectual property rights and relinquish all options to regain control over renzapride to Alizyme. After the Commission issued the proposed consent agreement, the Commission continued to investigate the potential effects of the merger in the smoking cessation products market where Glaxo sold the prescription drug Zyban, and SB marketed Nicoderm and Nicorette, two over-the-counter nicotine replacement products. In January 2001, the Commission closed the smoking cessation products investigation.

4.6.18 <u>*Fresenius Medical Care/Daiichi Sankyo*</u>**,** FTC File No. 0810146 (proposed consent order issued September 15, 2008). The complaint alleged that Fresenius' acquisition of an exclusive sublicense to manufacture and supply the intravenous iron drug Venofer to dialysis clinics would allow Fresenius, the largest provider of dialysis services and products in the United States, to increase Medicare reimbursement payments for Venofer. Venofer is used to treat iron deficiency anemia in patients undergoing chronic hemodialysis and is reimbursed by Medicare under the Medicare Part B end-stage renal disease program based on the manufacturer's average sales price ("ASP") plus six percent. Drug manufacturers are required to submit their ASP to the Center for Medicare & Medicaid Services ("CMS") each calendar quarter and that information is used to calculate the CMS reimbursement rate. According to the complaint, the acquisition would give Fresenius the ability and incentive to report higher prices for Venofer

used in its own clinics to CMS thereby increasing Fresenius'ASP. Under the proposed order, Fresenius would be restricted from reporting an intra-company transfer price higher than the level set in the order which is derived from current market prices. In addition, the order provides that if a generic Venofer product receives final approval by the FDA, Fresenius would be required to report its intra-company transfer price at the lowest of either the level set forth in the order or the lowest price at which Fresenius sells Venofer to any customer until December 31, 2011. On January 1, 2012, CMS will implement a new reimbursement methodology based on a new bundled pricing system which will eliminate the concerns raised by the transaction.

4.6.19 *Merck & Co., Inc.,* 127 F.T.C. 156 (1999) (consent order). The complaint alleged that Merck's ownership of Medco, a pharmacy benefits manager ("PBM"), would allow Merck to favor its own drugs on Medco's formularies. A PBM's formulary often affects drug choice and reimbursement under certain health plans. The order requires Merck/Medco to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee.

4.6.20 *Eli Lilly/PCS* 120 F.T.C. 243 (1985) (consent order). The complaint alleged that Lilly's acquisition of PCS, a pharmacy benefits manager ("PBM"), from McKesson Corp. would allow Lilly to favor its own drugs on PCS's formularies. A PBM's formulary often affects drug choice and reimbursement under certain health plans. The order requires Lilly/PCS to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee. The order was set aside in 1999 because Lilly sold PCS to Rite Aid.

4.7 Competition Law and Intellectual Property Rights:

4.7.1 Chapter III of the study specifically covered topics concerning intellectual property rights in general, including issues concerning its impact on innovation, R&D output and development dimension. In this section an evaluation of intellectual property rights is conducted through the lens of competition law and policy. Intellectual property rights are at the heart of controversial issues in competition law. The section will briefly deliberate on issues concerning licensing of intellectual property rights; anticompetitive concerns raised by technology transfer agreement to iron out what category of reasonable restraints through IPRs are permissible.

4.7.2 In some cases decided by US courts, there have been a host of consent orders in pharmaceutical cases. They largely pertain to drug settlements in the US. The US has a very unique system to patent term extension and parallel providing entry of generics. The Hatch Waxman Act requires that an 180 day exclusivity shall be given to the company first challenging the originators patent. As a consequence many generic companies and originator companies collude to give up the exclusivity or not to challenges patents. There have been conflicting decisions by the Federal circuits mostly emphasizing that such agreements may not be anticompetitive since it provides the originator companies an opportunity to exercise it lawful monopoly during the term of the patent- thus promoting innovation. However, commentators have argued that there can be a case of presumptive illegality in case of drug-patent settlements.

4.7.3 The issue of lawful exercise of Intellectual property is also under constant scanner. While both the jurisdictions treat IPR monopoly as not in fundamental conflict with competition law- as the object of both is to promote innovation and competition, it is not fully resolved if competition better facilities innovation or IPR does more so. However, the IP Licensing Guidelines issued by the US FTC_DOJ (1995) and the EU Technology Transfer Block Exemption provide a framework where IPRs are treated as not different from other forms of property. However, there are complex set of tests underlying the analysis of the relationship of IP vis-à-vis competition law.

4.7.4 Although intellectual property law and antitrust law are complementary, two divergent appellate decisions, *Image Technical Services, Inc. v. Eastman Kodak Co.* ("*Kodak*") and *In re Independent Service Organizations Antitrust Litigation* (*CSU*), illustrate the potential for conflict regarding unilateral refusals to license patents. Case law

jurisprudence in comparative jurisdictions assert that unilateral right to refuse to grant a patent license is a core part of the patent grant and that antitrust liability for mere unilateral, unconditional refusals to license patents will not play a meaningful part in the interface between patent rights and antitrust protections. It is noted that competition law liability for refusals to license competitors would compel firms to reach out and affirmatively assist their rivals, a result that is "in some tension with the underlying purpose of antitrust law." It is believed that such liability would restrict the patent holder's ability to exercise a core part of the patent—the right to exclude. Conditional refusals to license that cause competitive harm are subject to antitrust liability. In the EU, the *Magill and IMS* cases established the possibility of a claim to a license under Article 82 in exceptional circumstances, in particular where such licensee intended to produce a new product for which there is a potential consumer demand. It test was severely applied in the recent case of *EU* v. *Microsoft* (2007), where the CFI held that Microsoft was dominant in two markets and had abused its dominant position by refusing to supply interoperability information.

4.7.5 The new product test and unilateral refusal to license can have important application in bio-pharmaceutical research, where is it largely noted that existing patents block future inventions due to anti-commons in the biotechnology industry. Many other cases involving pharmaceuticals the US FTC and EU Commission have investigated cases of abuse of dominance. Specifically, of relevance is the Commission's decision in fining AstraZeneca AB and AstraZeneca plc (AZ) EUR 60 million for having infringed Article 82 EC and Article 54 EEA by misusing public procedures and regulations in a number of EEA states with a view to excluding generic firms and parallel traders from competing against AZ's anti-ulcer product Losec. There is also a possibility of emergence of super dominance patented products market leading to monopolistic pricing. While there is no *per se* presumption of dominance in case of patented products, however, many reports have indicated that pharmaceutical price regulation scheme should be reformed in order to make the prices reflect the therapeutic value to patients of the drug in question. While in Abuse of Dominance cases, the approach has been that competition authorities do not turn up to be price regulators, but where existence of patents leads to large market shares that ECJ for example has held in *Hoffman-La Roche v Commission* (1979) that large market shares may in themselves be evidence of a dominant position, save exceptional circumstances. However, the South African commission has had the distinction for being some sort of a price regulator. In a case involving the pharmaceutical companies, *GSK* and *Boehringer-Ingelheim* were asked to issue licenses on anti-retrovirals after threat from SA Competition Tribunal. The royalty decided at the rate of 5%.

4.7.6 The Commission will generally intervene where there is evidence showing that a dominant undertaking engages in predatory conduct by deliberately incurring losses or foregoing profits in the short term referred to as "sacrifice"), so as to foreclose or be likely to foreclose one or more of its actual or potential competitors with a view to strengthening or maintaining its market power, thereby causing consumer harm. Conduct is viewed by the Commission as entailing a sacrifice if the dominant undertaking, by charging a lower price for all or a particular part of its output over the relevant time period, or by expanding its output over the relevant time period, incurred or is incurring losses that could have been avoided. In general it is considered unlikely that predation will create efficiencies. However, provided that the conditions mentioned above are fulfilled, the *EC* Commission will consider claims by dominant undertakings that the low pricing enables it to achieve economies of scale or efficiencies related to expanding the market. [Case T-83/91 *Tetra Pak International* v *Commission (Tetra Pak II)* [1994] ECR II-755 , upheld on appeal to the ECJ in Case C-333/94 P *Tetra Pak International* v *Commission* [1996] ECR I-5951, where the Court of First Instance stated that proof of actual recoupment was not required.

4.7.7 The nature of inherent conflict between grant and exploitation of IPRs vis-à-vis the resolve to keep the markets competitive has been traditional. Many economists of the Chicago and Post-Chicago school of thought remark that IPRs may not be in inherently conflicting with competition law. It is emphasized that the object of both the laws is to promote innovation by creating dynamic efficiencies. And yet, there is tension in the means in which rights conferred under IPRs may conflict with principles of competition law. Thus commentators on patents and antitrust

essentially frame the question as raising an inherent tension between IP and competition.[196] The tension is presumably because economic thought and evidence has not been able to substantially and conclusively provide evidence that IP in general and patents in particular are the best modes to incentivize creativity or to promote disclosure of inventions. The relationship amongst patents working as property and the structure of innovation is based on the *premise* that patents promote innovation, and not that it actually does so. Be it as may be, at least in case of pharmaceuticals, as noted in chapters above, it is an argument that without patent protection new medicines would not be invented. However, this view is at best, controversial. But one important aspect would be to consider what the possible situations if one were to depart from a static view of markets. As Ward Bowman explains:

> In terms of the economic goals sought, the supposed opposition between these laws is lacking. Both antitrust law and patent law have a common central economic goal: *to maximize wealth by producing what consumers want at the lowest cost*. In serving this common goal, reconciliation between patent and antitrust law involves serious problems of assessing effects, but not conflicting purposes. Antitrust law does not demand competition under all circumstances. Quite properly, it permits monopoly when monopoly makes for greater output than would the alternative of an artificially fragmented (inefficient) industry. The patent monopoly fits directly into this scheme insofar as its central aim is achieved. It is designed to provide something which consumers' value and which they could not have at all or have as abundantly were no patent protection afforded. . . .
>
> The goal of both antitrust law and patent law is to maximize allocative efficiency (making what consumers want) and productive efficiency (making these goods with the fewest scarce resources). In achieving this goal under either antitrust or patent law the detriment to be avoided is output restriction. This may arise from monopolization which diverts production from more urgent to less urgent use or from legal rules requiring inefficient methods of production. The evil then may be viewed as net output restriction after efficiency increases are accounted for. Both antitrust and patent law seek output expansion not output restriction. Competition deserves support insofar as it brings about this result. And so it is with patents. The temporary monopoly afforded by a patent, once a particular invention has come into being, will have all the output restrictive disabilities of any monopoly. The argument for patents is that without this temporary monopoly there would be insufficient profit incentives to produce the invention, and that because an invention is profitable only if consumers are willing to pay what the patentee charges, the consumers are therefore better off than they would be without the invention, even if they are charged "monopoly" prices. If this is so, a trade-off (some monopoly restraint for greater output in the long run) is in the interest of socially desirable resource allocation. An appraisal of alleged conflicts between antitrust law and patent law depends upon understanding the role of profits in providing the incentive for undertaking efficient production of those things consumers value.[197]

4.7.8 Thus one view is that both the laws are not in conflict but complementary. Thus one may resort to a conclusion to that patents are like other form of properties and hence no distinction between must be made between real property and intellectual property for the purposes of competition law.[198] In fact the current US and EU understanding of the relationship between IP and competition law heavily relies on such a view. European Commission's *Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*[199] states:

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[196] See Luios Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*' (1984) 97 *Harv. Law Review* 1817.
[197] WARD BOWMAN JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL (1973);
[198] Elhauge, *Defining Better Monopolisation Standards'*(2003) 56 Stanford Law Review 253, 304- 05
[199] OJ(2004) C 101/2

"Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy"

Even the US FTC-DOJ Guidelines on Licensing of IPRs (1995)[200] state that these Guidelines embody three general principles:

a. for the purpose of antitrust analysis, the Agencies regard intellectual property as being essentially comparable to any other form of property;

b. the Agencies do not presume that intellectual property creates market power in the antitrust context; and

c. the Agencies recognize that intellectual property licensing allows firms to combine complementary factors of production and is generally precompetitive.

4.7.9 In case of presumption of market power, the FTC_DOJ guideline note: "Market power is the ability profitably to maintain prices above, or output below, competitive levels for a significant period of time. The Agencies will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner. Although the intellectual property right confers the power to exclude with respect to the ***specific*** product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power. If a patent or other form of intellectual property does confer market power, that market power does not by itself offend the antitrust laws. *As with any other tangible or intangible asset that enables its owner to obtain significant supra-competitive profits, market power (or even a monopoly) that is solely "a consequence of a superior product, business acumen, or historic accident" does not violate the antitrust laws. Nor does such market power impose on the intellectual property owner an obligation to license the use of that property to others.* As in other antitrust contexts, however, market power could be illegally acquired or maintained, or, even if lawfully acquired and maintained, would be relevant to the ability of an intellectual property owner to harm competition through unreasonable conduct in connection with such property".

4.7.10 It is clear that as per the above, the EU and U.S authorities do not presume market power in case of patents and other intellectual property rights. It is presumed that they work like real properties. However, there is sufficient difference between real properties and intellectual properties, which the guidelines fail to note.[201] This distinction has been traditional. One reason behind treating IPRs and real properties distinctly is also because of the very nature of IP, which fails to set clear boundaries of innovation. Patent laws especially, doesn't provide sufficient note of the proper scope of rights.[202] In case of IP, subsequent innovation is built upon the earlier ones.

4.7.11 On the issues of licensing restrictions, the guidelines note that "Field-of-use, territorial and other limitations on intellectual property licenses may serve pro-competitive ends by allowing the licensor to exploit its property as efficiently and effectively as possible. These various forms of exclusivity can be used to give a licensee an incentive to invest in the commercialization and distribution of products embodying the licensed intellectual property and to develop additional applications for the licensed property. The restrictions may do so, for example, by protecting the licensee against free-riding on the licensee's investments by other licensees or by the licensor. They may also increase the licensor's incentive to license, for example, by protecting the licensor from competition in the licensor's own technology in a market niche that it prefers to keep to itself. These benefits of licensing restrictions apply to patent, copyright, and trade secret licenses, and to know-how agreements". Thus the US approach warrants that most forms of licensing restrictions are always pro-competitive. It approaches the issue of

[200] Antitrust Guidelines for the Licensing of Intellectual Property Issued by the U.S. Department of Justice and the Federal Trade Commission, April 6, 1995

[201] Patent Failure (2008). Analyzing why patents do not perform like properties.

[202] *Ibid.*

licensing arrangements by assuming that they promote integration because as they facilitate the combination of the licensor's intellectual property with complementary factors of production owned by the licensee. As per the A restraint in a licensing arrangement may further such integration by, for example, aligning the incentives of the licensor and the licensees to promote the development and marketing of the licensed technology, or by substantially reducing transactions costs. If there is no efficiency-enhancing integration of economic activity and if the type of restraint is one that has been accorded per se treatment, the Agencies will challenge the restraint under the per se rule. Otherwise, the Agencies will apply a rule of reason analysis.

4.7.12 In the many of the cases, restraints in intellectual property licensing arrangements are evaluated under the rule of reason. The Guidelines approach in analyzing a licensing restraint under the rule of reason is to inquire whether the restraint is likely to have anticompetitive effects and, if so, whether the restraint is reasonably necessary to achieve procompetitive benefits that outweigh those anticompetitive effects.[203] But the courts may also conclude that a restraint's "nature and necessary effect are so plainly anticompetitive" that it should be treated as unlawful per se, without an elaborate inquiry into the restraint's likely competitive effect.[204] Among the restraints that have been held per se unlawful are naked price-fixing, output restraints, and market division among horizontal competitors, as well as certain group boycotts and resale price maintenance.

4.7.13 To determine whether a particular restraint in a licensing arrangement is given per se or rule of reason treatment, the Agencies will assess whether the restraint in question can be expected to contribute to an efficiency-enhancing integration of economic activity. (*See Broadcast Music*, 441 U.S. at 16-24). Apart from the goods and technology markets, the 1995 guidelines introduced the concept of "innovation markets". As per the guidelines "An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development. The close substitutes are research and development efforts, technologies and goods that significantly constrain the exercise of market power with respect to the relevant research and development, for example by limiting the ability and incentive of a hypothetical monopolist to retard the pace of research and development. The Agencies will delineate an innovation market only when the capabilities to engage in the relevant research and development can be associated with specialized assets or characteristics of specific firms". However, as noted in a document issued by the Department of Justice and the Federal Trade Commission in the US in April 2007, wherein it clarifies that such an approach is of recent origin.

4.7.14 A patentee may decide to license the patent for many reasons and in this connection the question of what conditions the patentee should be allowed to assert in the licensing agreements is of primal importance to the study of interaction between IP and competition law. Some patentees may even refuse to license as it is within the power of the patent holder to do so, except in certain cases (as discussed later). Generally, IP licensing agreements contain clauses relating to territorial exclusivity, royalties, duration, filed of use restrictions, best endevours and non-competition clauses, no challenge clauses, improvements and grant back provisions, tying and bundling, and clauses relating to prices and other terms and conditions.[205]

4.7.15 It must be noted that in early 1960's the commission adopted an conservative approach to the issue of IP-competition law interface pertaining to agreements (Whish, 2008, p. 762). However, since the *Commission's Notice on Patent Licensing Agreements of 1962* the position began to change and many agreements were challenged as violative of Article 81 (1). The argument was that IPRs licensing could be used as a mechanism to enable the distributor to enjoy absolute territorial protection.[206] That set the tone for much other type of restrictive agreements to be in violation of article 81(1), however, some of the clauses were individually exempted under

[203] *See Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447 (1986); *NCAA v. Board of Regents of the University of Oklahoma,* 468 U.S. 85 (1984); *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.,* 441 U.S. 1 (1979)

[204] *Federal Trade Commission v. Superior Court Trial Lawyers Association*, 493 U.S. 411, 433 (1990); *National Society of Professional Engineers v. United States*, 435 U.S. 679, 692 (1978).

[205] See *Technology Transfer Guidelines* (2004). Also see, Whish, 2008, p. 760-762.

[206] *See, the judgement of the ECJ in Grundig v Commission {cases 56/84 ad 58/64.*

Article 81 (3). Thus the EU Commission maintained a formalistic approach in subsequent regulations issued clarifying the position of restrictive agreements (Whish, 2008 p. 763). However, the block exemption, Regulation 772/2004 adopts a less formalistic approach and is in line with convergence with the US approach in this area.

4.7.16 Regulation 772/2004 on Technology Transfer agreements confers block exemption on technology transfer agreements pursuant to article 81(3) of the EC treaty. The underlying dictum in regulation 772/2004 is that technology transfer agreements usually improve economic efficiency and are pro-competitive (recital 5). However, it also notes that it also depends on the degree of market power and also on the degree of competition that will be faced by undertaking with substitute technologies or products (Whish, 2008, p. 771). Unfortunately, there isn't much guidance through cases on the interpretation of allowable restrictions under the block exemption.

4.7.17 Article 2 of the block exemption states that Article 81 shall not apply to technology transfer agreements entered into between two undertakings permitting the production of contract products. In many ways, the article suggests that many technology transfer agreements do not violate article 81(1). Paragraph 9 of the Technology transfer guidelines state that there is no presumption that licensing agreement gives rise to competition concerns. In fact paragraph 17 of the guidelines also state that license agreements have substantial pro competitive potential and that the vast majority of them are pro-competitive. Recital 12 also states that there is no presumption that agreements above the market share thresholds infringe article 81(1). Under the regulation what is not forbidden is specifically permitted. This is noted in recital 4 of the regulation which has removed the 'white list' of what must be included in the technology transfer agreement. Instead, the regulation adopts an approach of a market share cap in article 3 and a 'black list' of what must not be included in Article 4. Further the exempted agreement must be bilateral. The block exemption is effective until 30 April 2014.

4.7.18 The regulation prescribes that the combined market share of the parties to the agreement must not be more that 20% in case of horizontal agreements and 30% in case of vertical agreements. In order to determine whether the agreement is horizontal it should be inquired if the parties to such agreement are 'competing undertakings' as defined in article 1(1) (j) of the regulation. Such undertakings may compete in a product market or a technology market. As per article 1(1)(j) (i), undertaking compete in a technology market if they license out competing technologies without infringing each other's intellectual property rights. Such relevant technology markets include technologies which are regarded as interchangeable and substitutable for the licensed technology by reason of their characteristics, royalties, intended use etc… Product markets include products which are regarded as interchangeable and substitutable for the contract products by reason of product characteristics, their prices and their intended use. Where an agreement is not horizontal, it is regarded as vertical. An agreement will not be horizontal where one party can use its IP to prevent the other entering the market, or where both parties need the other's technology to operate on the market: these are referred to as 'one way' and 'two way' blocking positions, which will be evaluated by independent experts as per the technology transfer guidelines.

4.7.19 Article 4 of the regulation defines what are called as 'hard-core' restrictions. Recital 13 of the regulation states that technology transfer agreement should not enjoy block exemption when they contain 'severely anti-competitive restraints such as the fixing of prices charged to third parties… irrespective of the market shares of the undertakings concerned'. In such cases the block exemption ceases to apply in full and not just in case of offending provisions. The regulation, for the purposes of ascertaining hard-core restrictions divides the class of agreements as between competing undertakings and between non-competing undertakings- primarily as horizontal and vertical. The major concern in case of agreement between competing undertakings is that they might lead or have an effect of a horizontal cartel. Hence article 4(1) state that block exemption shall not be available for agreements that directly or indirectly, in isolation or in combination with other factors, have as their object restrictions concerning prices, output the allocation of markets or customers and the exploitation of the licensee of its own technology. While price and output restriction are straight forward, allocating customers and markets raise complex questions. Article 4(1) (C) provides certain exceptions to provisions in the agreement that allocates

market or customers. They are around seven in number. In case of agreements that prohibit the licensee from exploiting its own technology, such agreements can impeded research and development and hence are considered as hard core restrictions with an exception to prevent third party disclosure of know-how. However, in case of non-competing undertakings, such restrictions is excluded from the block exemption under Article 5, but is not listed as a hard-core restrictions under article 4.

4.7.20 For agreements between non-competing undertakings, the block exemption is not available under Article 4(2) of the regulation where the non-competing undertakings directly or indirectly in isolation or in combination with other factors have as their object restrictions concerning prices territories and customer groups or sales within a selective distribution system. Again allocating territories or customer groups have six exemptions. In case of restrictions is selective distributive systems Article 4(2) (C) provides that the block exemption does not apply where an agreement between competing undertakings restricts active or passive sales to end-users by a licensee which is a member of a selective distribution system and which operates at the retail level, without prejudice to the possibility of prohibiting a member of the system from operating out of an unauthorized place of establishment.

4.7.21 Article 5 of the regulation lists three excluded restrictions for which the block exemption is not available. They are exclusive grant back[207], assignment back, and no –challenge clauses. Article 6 provides the commission the power to withdraw the block exemption in individual cases in cases where access to third parties' technologies is restricted, access to potential licensees to the market is restricted; the parties do not exploit the licensed technology and have no objective justification or not doing so.

4.7.22 ***Pay for delay (reverse payments):*** Competition Authorities across the world have sought to use competition law enforcement to stop "pay-for-delay settlements" (also called "exclusion payments" or "reverse payments"). These are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost generic product. Such settlements effectively buy more protection from competition than the assertion of the patent alone provides. This is because patent protection does not lead to a situation where the patent can remain unchallenged, but reverse payments does so. It is pertinent to note that this comes at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years. Anticompetitive agreements to eliminate potential competition and share the resulting profits are at the core of what competition laws proscribe. It is for this reason that pay-for-delay settlements should be prohibited under the competition laws since they amount to market allocation. But since 2005, court decisions have treated such agreements in drug patent settlements too leniently. As a result, it has become increasingly difficult to bring antitrust cases to stop pay-for-delay settlements, and such settlements have become a common industry strategy.

4.7.23 It would be pertinent to note that not all settlements are bad. Some settlement can abate litigious waste. Such agreements could be justified by objective assessments of patent validity. However, increasingly it is noted pharmaceutical patents have more chances of being held invalid. Such recent agreements have more frequently included large payments from brand patentees to generic challengers. These pay for delay agreements, which differ from typical licensing payments that flow from challengers to patentees, may even exceed what the generic could have earned by entering the market. Despite the concerns presented by reverse payment settlements, courts in the US have recently been favourable to such settlement. Courts have reasoned that such agreements reduce costs and increase innovation. They have referred to settlements as "natural by-products" of the Act. And they have pointed to patents presumption of validity in demonstrating the agreements reasonableness. Although scholars and the Federal Trade Commission (FTC), which enforces the antitrust laws in the drug industry, have

[207] Exclusive grant back refers to an obligation on the licensee to grant an exclusive license to the licensor or a third party designated by the licensor in respect of its own severable improvements to or its own improvements of the licensed technology. (Article 1(1)(n) of the regulation)

voiced strong arguments against courts leniency, these have fallen on judicial deaf ears. The FTC has also filed a brief with the US Supreme Court.

4.7.24 In this context it would be important to discuss the major conclusions of the EU pharmaceutical sector inquiry report published in July 2009. On 8 July 2009 the European Commission adopted the final report on its competition inquiry into the pharmaceutical sector, which largely confirms the findings of the preliminary report released in November 2008. The final report notes that market entry of generic drugs is delayed and there is a decline in the number of novel medicines reaching the market. The report has clearly identified that company practices are among the important causes for such an outcome, including shortcomings in the regulatory framework. The report has brought into light how originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible. The inquiry notes that the R&D based pharmaceutical sector is engaged in defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts, which as per the commission will remain under further scrutiny. It is expected that the EU competition commission would now intensify its scrutiny of the pharmaceutical sector under EC competition law, including continued monitoring of settlements between originator and generic drug companies.

4.7.25 Contextualizing the EU report, some key points which led to the inquiry emerge. They specifically relate to decline in pharmaceutical productivity- novel medicines; delays in generic entry – insufficient generic price competition; need to keep public budgets on drugs in control; red tape in patent filing and enforcement strategies by originator companies; contracts, disputes and litigations between originator and generic companies; thorough review of opposition procedures and appeals before patent offices; patent settlements and other agreements between originator and generic companies; interventions of originator companies before national authorities deciding on marketing authorization; pricing and reimbursement of generic products. In respect of promotional activities the report raises it as an important ground, but does not address in detail potential shortcomings in the distribution chain. The context was also grounded in the introduction of second generation products to counter generic copies of first generation products. The report has noted that all these issues are interlinked. However, the report only pertained to prescription drugs market only.

4.7.26 As per the report, from 2000 – 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide. Approximately 1.5% of turnover was spent on basic research to identify potential new medicines. 15.5% of turnover was spent on clinical trials and to obtain marketing approval. Strikingly, expenditure on marketing and promotional activities accounted for 23% of their turnover. Since generic entry is vital for price competition, the report has noted that it took more than seven months, on a weighted average basis. For the highest selling medicines, it took four months on average. On the issue of pharmaceutical innovation, the report has noted that originator companies substantially rely on the acquisition of compounds from third parties.

4.7.27 The report notes that in the year 2007 about 35% of originator companies' molecules where marketing authorization was pending had been acquired or in-licensed. This is mostly from small bio-tech companies. There were significant price reductions upon entry by Generic companies. On an average 25% lower than the price of the originator medicines. Two years after entry this was reduced by 40%. The report has reaffirmed that Prices of originator products appear to drop following generic entry. (This was earlier confirmed by *the Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002).

4.7.28 The EU report has noted that generic companies share in off-patented market was about 30% at the end of the first year and 45% after two years. Average savings on health was 20% in the first year ending and 25% in the second year ending. The report has distinctly noted the importance of mandating pharmacists to dispense generic medicines. EU Member States which oblige pharmacists to dispense the cheapest generic medicines whenever possible appear to show earlier entry and greater savings for their health budgets.

4.7.29 Among the most important findings, the EU report notes that pharmaceutical patent applications have doubled in between 2000-2007. The report confirms the distinction between "primary" and "secondary" patents. However, secondary patents need not necessarily be of lower quality. However, it must be noted that secondary patents, if not in all cases, are bound to be filed for incremental innovations. Hence there are more chances that they would fall within the lower category of inventions. In case of blockbuster drugs, the report finds that patent filings are increasingly higher throughout the life cycle of the product and also at the end of expiry of the first patent. This certainly causes uncertainty for generic manufacturers, the report notes distinctly. During litigation, originator companies often rely on patents that were not yet filed when their product in question was launched. This is one of the oft used strategies by originator companies. On the issue of patent filing strategies, the report notes: "*Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines"*

4.7.30 Average number of patents and patent applications for the top selling medicines is 140% higher (i.e. 237) than the average of the overall sample (98.5). Strikingly, individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States. Generic challenge becomes difficult in Europe. During the course of the sector inquiry, the Commission noted that companies are aware that many of such patents might not be strong. Filing of divisional patent applications is also a strategy adopted for creating legal uncertainty for generic manufactures. Sending warning letter and citing primary patents was another strategy used by originator companies for patent enforcement litigation. During litigation, generic companies won 62% of the 149 cases. The average duration of the court proceedings was 2.8 years. Secondary patents were invoked during litigation when compared to primary patents raised during pre-litigation. Interestingly, in 11% of the final judgments reported, two or more different courts in different EU Member States gave conflicting final judgments on the same issue of patent validity or infringement. Validity issues, except for procedural irregularities, are largely based on issues on substantive patent law thresholds. This should amply clarify how differences in standards of patentability still exist among developed county jurisdictions. Highlighting the importance of oppositions at patent offices, the report notes that pharmaceutical patent opposition rates higher at the patent offices. Generic companies largely opposed secondary patents and prevailed in 60% cases at the patent office appeals.

4.7.31 As noted earlier, all does not seem to be fine with reference to the perverse relationship between generics and originator companies. Patent settlements are a major cause for concern. They are in the nature of reverse payments (also called as pay for delay in the United States)- as payments flow from originators to generics. The issue of reverse payments is figured prominently in the report since 200 settlement agreements were concluded between originator and generic companies, which covered 49 medicines (31 medicines (i.e. 63%) were best-selling medicines) that lost exclusivity between 2000 and 2007. Such settlements are done during litigation or in opposition proceedings or out of courts settlements. In half of the settlements in question the generic company's ability to market its medicine was restricted. Thus the report has noted the reverse payments can cause considerable delays in generic entry. In fact, the fallacy of the contracts between generics and originator is that direct settlements amounted to Euro 200 million in value! There can be indirect settlements also. Originator companies also had a low success record in cases concerning data exclusivity. The final court judgments confirmed claims of originator companies in 19% cases only.

4.7.32 The sector inquiry has produced "indications" that some originator companies sought to put into question the quality of generic medicines, as part of a marketing strategy, and even after the generic product was authorized by the relevant authorities and was available on the market. This report is first of its kind to authoritatively confirm that originator companies engage in the strategy of confusing the general public about quality of generic medicines by putting them in question. However, the net impact of such a wrong campaign on consumer behavior and

acceptability of generic medicines in not known. The report also notes that originator companies have used the different strategies for launching secondary product and to ward off generic entry.

4.7.33 More specifically, the report has made an important finding that originator companies engage in "defensive patent strategies" to create uncertainty for other originator companies. The EU sector inquiry reveals at least 1,100 instances where the patents held by an originator company potentially overlap with the medicines, R&D programmes and/or patents held by another originator company for their medicine. As a follow up to the report, it is now expected that the commission will intensify its scrutiny of practices of particular companies and will take action under EU Competition laws. Some cases discussed below could provide additional guidance on the tests to be adopted in certain specific case of patent abuse. However, they may be only persuasive in nature.

4.7.34 *Bristol-Myers Squibb Company*, 135 F.T.C. 444 (2003) (consent order).The Commission charged in its complaint that Bristol engaged in a pattern of anticompetitive activity over the past decade in order to delay generic competition and maintain its monopoly over three highly profitable branded drugs with total net annual sales of two billion dollars. As a result of Bristol's illegal conduct, consumers paid hundreds of millions of dollars in additional costs for these prescription drugs. The order requires general prohibitions concerning conduct relating to Orange Book listings (detailed in the FTC's recent study, *Generic Drug Entry Prior to Patent Expiration*), enforcement of patents, and the settlement of patent litigation when that conduct is designed to delay or prevent generic competition. For example Bristol is prohibited from late listing patents after competitors have filed applications with the FDA for generic entry. The order also contains prohibitions relating specifically to the listing and enforcement of patents relating to Taxol and BuSpar, including listing any patent in the Orange Book relating to products with the same active ingredient, or taking any action that would trigger an additional 30-month statutory stay on final FDA approval of a generic form of Taxol or BuSpar (the order does not provide specific relief for Platinol because a court held the only unexpired patent on Platinol was invalid).

4.7.35 *Cephalon, Inc.*, Civil Action No.: 1:08-cv-00244 (D.C.D.C.) (complaint filed February 13, 2008). The Commission filed a complaint in U.S. District Court for the District of Columbia seeking a permanent injunction against Cephalon for engaging in an overall course of anticompetitive conduct to prevent generic competition to Provigil, a drug used to treat sleep disorders, and which accounted for more than 40% of Cephalon's total sales. The complaint alleged that four generic manufacturers (all considered first filers by the FDA for generic Provigil) were involved in patent litigation over the only remaining patent covering Provigil, and Cephalon paid the generic manufacturers over $200 million dollars to abandon the patent litigation and agree to refrain from selling a generic version of Provigil until 2012. According to the complaint, the agreements not only prevented competition from the four first filers but also blocked competition from other generic manufacturers because of the 180-day exclusivity held by the first filers under the Hatch-Waxman Act. As a result of the agreements, Cephalon denied consumers access to lower-cost generic versions of Provigil and forced consumers to pay hundreds of millions of dollars more a year than they would have if generic Provigil entered the market. The Commission is asking the Court to order that Cephalon's conduct, including entering into the agreements, violates Section 5 of the FTC Act. The Commission is also asking the Court to order a permanent injunction stopping Cephalon from enforcing or maintaining the agreements, and enjoining Cephalon from engaging in similar conduct in the future.

CHAPTER V

COMPETITION LAW AND ITS INTERACTION WITH THE PHARMACEUTICAL INDUSTRY: POSITION IN INDIA

5.1 Introduction:

5.1.1 The Monopolies and Restrictive Trade Practices Act (MRTP) was enacted in 1969 as per the recommendations of the Monopolies Inquiry Committee. The MRTP Act aimed to provide structural remedies in its attempt to curb monopolistic behaviour as such structural nature of the law, by which it was understood that beyond a particulatr threshold such anticompetitive behaviour affected competition adversely. However, it was restricted to the private sector. Later, in the year 1984, Sachar committee looked into changes requires in MRTP to make it more effective. The committee, among other things suggested that certain type of cases should be compulsorily referred to the MRTP Commission. But this view did not find favour within the government (Kumar, 2007). The committee was also of the opinion to introduce the concept of deemed illegality in case of many trade practices.

5.1.2 The reforms of 1991 changed many perceptions about the MRTP, as it was thought that many provisions in the law were not favourable for create an environment for private investments. Certain provisions were off the Act. However, a further need to change the structural approach of the MRTP was felt by the Government and hence Raghavan Committee was appointed to look in to Competition Law and policy. Set up in 1999, the Raghavan committee reviewed the existing MRTP and found that there was no provision within MRTP to deal with anticompetitive practices, and thus declared that MRTP could not be amended without substantial changes. It suggested a new competition law for India. The Committee found fewer reasons to adopt a structural approach and suggested *per se* illegality rule only in few instances. In many other conducts, it as prescribed a *rule of reason approach.* Moreover, the Raghavan Committee also suggested greater role for competition awareness and advocacy for the new CCI. (Committee Report, 2000).

5.1.3 In the thick of all these changes the pharmaceutical industry in India grew. The industry saw that many of its practices being challenge and susceptible to the practices falling under MRTP. In this section we evaluate the law and policy under the MRTP and also review pertinent case laws relating to pharmaceuticals as decided by the Commission, High Courts and the Supreme Court.

5.2 The MRTP Law: Provisions and their effectiveness

5.2.1 The mixed economy patterns, with a pinch of Fabian socialism during the yester years viewed that economic concentration in few private hands was a bane to the society and public interest. This was well in tune with Article 39 of the Constitution of India.[208] which states:

5.2.2 Using the concentration ratio in measuring state of competition as per the Monopolies Inquiry Committee (Monopolies Inquiry Committee) it set certain norms (Kumar, 2007). It categorized them into high concentration; medium concentration; low concentration; no concentration. Within the list of 100 products that the MIC considered of importance to ordinary consumers, 64 exhibited high concentration. This list, *interalia,* included

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[208] Article 39: Certain principles of policy to be followed by the State: The State shall, in particular, direct its policy towards securing

(a) that the citizens, men and women equally, have the right to an adequate means to livelihood;

(b) that the ownership and control of the material resources of the community are so distributed as best to subserve the common good;

(c) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment;

even medicines- vitamins, penicillin, hormones (Kumar, 2007). It was evident that the committee considered such products based on the fact that such products were not affordable to the larger section of the Indian population. The MIC made a clear distinction between industry wise concentration and nation-wise concentration. These concepts essentially meant that when an enterprise invested in the same line of business, it was termed an industry wise concentration, and for investments in another line of business, it referred to as nation wise concentration. The MIC viewed that "every monopolistic practice is on the fact of it a restrictive practice". During the proceedings of the MIC many instances of monopolistic practices and entry barriers, issues of predatory pricing was brought to its notice.

5.2.3 It may be noted that the MIC did not prefer big businesses and instead asked the government to follow a policy of encouraging public sector participation in the economy. This many have argued led to wealth concentration and inefficiency (Kumar, 2007). However, certain recommendations of the MIC were not included in the MRTP Bill. Benchmarks were established to deter over investments and to avoid dominant enterprises expanding out. An approval procedure was maintained. The Sachar Committee than looked into the working of the MRTP for eight years and felt the need for including provisions relating to consumer protection and against unfair trade practices. The relevant context also pertained to the new Companies Act, 1956 and its harmony with the MRTP Act. However, the committee tried to maintain a structural definition, even while trying to seek some changes. It recommended terms for dominance of enterprises based on market shares of 25% or more. The Sachar committee relying of evidence that raised some concerns, then sought to provide for powers to MRPT Commission to deal with Monopolistic Trade Practices as in case of Restrictive Trade Practices (Kumar, 2007). The committee also emphasized on unfair trade practices and its effects on consumers. However, the amendments carried out in 1984 did not include all of the recommendations of the committee. The MRTPC remained as an advisory body.

5.2.4 The 1984 amendment brought in the concept of "deemed" illegality under section 2(o) of the MRTP dealing with restrictive trade practices. Some appellate court rulings had interpreted that even in cases where trade practices attracted section 33(1), the MRPTC had to establish that it was a restrictive trade practices under section 2(o). Some of such court decisions involved issues of resale price maintenance, bid rigging, market allocation, boycotts, predatory pricing. So any economic analysis of such practices on competition was avoided. Section 36 A was introduced through the 1984 amendment, which provided for "unfair trade practices". Cases relating to misrepresentation and misleading advertisements resulting into injury or harm to the consumer was however necessary before MRTPC could take it up.

5.2.5 The economic reforms of 1991 ushered a new era of policy thought over possible entry barriers created by the MRTP law as it retrained enterprises from expansion. Thus provisions concerning monopolistic trade practices were off the statute. Hence the MRTP dealt only with unfair trade practices and restrictive trade practices.

5.2.6 While in the section below, we briefly review some important cases decided by the MRTP Tribunal and the courts in the pharmaceutical sector so as to understand how the MRTP law evolved with time and practices of the industry and markets. However, a brief mention of the relevant sections defining unfair trade practice and restrictive trade practice may be necessary.

5.2.7 It must be noted that the MRTP Act did not apply to an undertaking either owned by the Government or by a government-owned company until 1991. Undertakings controlled under any central or state law was also excluded. However, a notification in 1991 removed these restrictions [Notification GSR No 605 (E) dated 27.9. 91]. It also excluded operation of banks and insurance companies since they were regulated otherwise. Many definitions and clauses had some interesting consequences to follow.[209] Many cases that came up before the

[209] As defined originally, the MRTP has powers to conduct inquiry into monopolistic as well as restrictive trade practices. It had the following elements:

- practice of maintaining prices at unreasonably high level by limiting or reducing or controlling production, supply, or distribution of goods and also supply of services.
- Limiting technical development, and
- Unreasonably preventing or lessening competition in production, supply or distribution.

MRTP were private complaints of non-performance of contracts. Obstruction of flow of resources into production, manipulation of prices or conditions of delivery which imposed unjustified costs or conditions on the consumer was within the meaning of RTP. This led to a lot of consumer complaints. Many commentators have criticized that the MRTP laws was used as consumer protection legislation, which was not akin to the object sought to be achieved by the MRTP law. (Bhattacharjea, 2007).

5.2.8 The MRTP could proceed on a complaint or *Suo-moto* or on a complaint or on a reference made by the central of state Government. The MRTPC also had powers of the civil court, including a power to grant temporary injunction included by the 1984 amendment and also *ex parte* injunctions since 1991. The MRTPC also as extra-territorial reach and could pass orders against parties situated outside India to the extent that such anticompetitive are carried on in India. A recent Supreme Court decision endorses this position.

5.2.9 In ***Haridas Exports V. All India Float Glass Mfrs. Association and Ors.*** (AIR 2002 SC 2728) Some Indonesian Companies were manufacturing float glass in Indonesia and were selling the same at predatory prices in India, and were hence resorting to restrictive and unfair trade practices. The complainant gave figures indicating the estimated cost of float glass internationally as well as the cost of production of float glass in India with a view to demonstrate that the Indian manufacturers of float glass would not be able to compete with the price at which the Indonesian manufacturers were presently selling or intending to sell to Indian consumers. The issues before the Hon'ble Supreme court was (i) Whether MRTP commission will be applicable over goods outside India. (ii) Whether MRTP Act will be applicable over any agreement happening extra territorially (iii) Whether MRTP Act has provision encapsulated for Anti Dumping issues (iv) Whether MRTP Act addresses issues related to predatory pricing, and (v) Whether the MRTP Commission has the jurisdiction to Cartel agreements happening outside India.

5.2.10 With respect to the first issue the court was of the opinion that MRTP Commission does not hold any extra territorial operational jurisdiction. However, only the goods imported into India will fall within the definition of the word "goods" as encapsulated in Section 2 (e) of the Act. As such for the commission to exercise any jurisdiction, goods must be those which are imported into India - As long as the import has not taken place and the goods are merely intended for export to India the same will not fall within the definition of word "goods" - Only that agreement would require registration in India if at least one party thereof carries on business in India. If the business operation is in India, then the MRTP Commission has the full authority to exercise its jurisdiction.

5.2.11 With respect to the second issue, the court was of the opinion that if an action taken place and agreement entered into outside the territorial jurisdiction of the commission but results in a restrictive trade practice in India then the MRTP Commission will have jurisdiction under Section 37 to pass appropriate orders in respect of such restrictive trade practice. The court was of the opinion that Competition law like the M.R.T.P. Act is a mechanism to counter cross borders economics terrorism - Section 2(o). 2(u), 33, 35, 37, and 38 of M.R.T.P. Act, 1969

- This definition was expanded by adding unreasonable increase in cost of production or charges for providing services, unreasonable increase in prices or charges or profits and adoption of unfair methods or unfair or deceptive practices.

An "agreement" was defined under section 2(a) to mean: ""agreement" includes any arrangement or understanding, whether or not it is intended that such agreement shall be enforceable (apart from any provision of this Act) by legal proceedings". This definition is broad enough to cover agreements that are not written, including arrangements which need not be in the form of agreements.

The term "goods" was also defined in section 2(e) of the Act. It states: ""goods" means goods as defined in the Sale of Goods Act, 1930 (3 of 1930), and includes, - (i) products manufactured, processed or mined in India;

(ii) shares and stocks including issue of shares before allotment

(iii) in relation to goods supplied, distributed or controlled in India, goods imported into India;]

This definition of the term "goods" was recommended by the Sachar Committee, primarily to harmonise the then existing definition of "goods" with that of the Sale of Goods Act. It was noted that the then existing definition of goods did not include stocks and shares, mining, processing, etc..,

Restrictive trade practice (RTP) was defined as a trade practice that has or likely to prevent, distort or restrict competition in any manner.

5.2.12 The court was also of the opinion that it was possible for persons outside India indulge in trade practices which effects prices within India, and have the effect of preventing, distorting or restricting competition within India, then in respect of that restive trade practice, MRTP Commission will have jurisdiction. The court looked in to the question of effects doctrine and commented that effects doctrine will clothe the powers of the MRTP Commission which has the jurisdiction to pass an appropriate order even though a transaction exporting goods to India at a predatory price has the power to effect at the Indian domestic Price market. The court was also of the opinion that Anti Dumping provisions will be dealt specifically with the Customs Act and that will not interfere with the MRTP Act, nor will it affect the provisions of the MRTP Act. It also held that if at all any cartels have been agreed upon outside India, but the effect of the Cartel Agreement is felt within India, then in that case the MRTP Act will have the power to interfere in the proceedings of the cartel under section 37(1) of the Act.

5.2.13 Reasonable exercise of Intellectual property right was not excluded within the MRTP. However, exercise of patent rights was to be excluded from the ambit of the law. Section 15 of the MRTP which provides for restriction of application of orders in certain cases excluded patents and exports within the ambit of monopolistic or restrictive trade practice. However, it restricted such exclusion in respect of patent laws only to the extent of the right of any person to restrain any infringement of a patent granted in India and to conditions that the patentee can attach to a license, which but for such license would be an infringement of a patent. The MRTP commission in Godfrey phillips case ruled that manipulation, distortion, contrivances and embellishments etc by way of misuse of trade mark also invite the application of the MRTP Act. (Vallal Peruman and Dileep Singh Bhuria vs. Godfrey phillips (india) 91/92 in UTPE 180/92 -MRTP commission)

5.2.14 Some other landmark judgments have interpreted very crucial provisions in the MRTP. The courts at times have resorted to interpretations that required the Commission to make a nuanced economic assessment of practices in question. ***RAJASTHAN HOUSING BOARD VS. SMT. PARVATI DEVI (***AIR 2000 SC 1940) The court while giving the decision opined that under S. 2(o) "restrictive trade practice" means a trade practice which has, or may have the effect of preventing distorting or restricting competition in any manner. Therefore whenever there is a question before the court as to the reasoning for a restrictive trade practice, it should not be one the basis of a priori reasoning or theoretical reason but be concentrated more on the factual reasons. It cannot be said that every restraint imposed by a trade practice necessarily prevents, distorts or restricts competition and, is, therefore a restrict trade practice. The court stated that the Commission has to find out whether the representation, complained of contains the element of misleading the buyer and whether buyers are mislead or they are informed in advance that there is likelihood of delay in delivering the possession of constructed building and also increase in the cost. For this purpose, terms and conditions of the agreement are required to be examined by the Commission. If the findings concur with that what has been alleged, then it will be necessarily a violation of the Act.

5.2.15 ***Raymond Woollen Mills Ltd. V. M.R.T.P. Commission and Anr***. [1993]78 CompCas471(SC). A notice of inquiry was issued suo motu by the Commission *interalia* alleging that the appellant was indulging in the trade practice of re-sale price maintenance by not mentioning in its price lists that the prices lower than those prices may be charged. It was alleged that it amounted to restrictive trade practices within the meaning of Section 33(1)(f) of the Act. Whether the act of indulging in selling drugs in resale maintenance price is a violation of section 33(1)(f) of the MRTP Act 1969.The court while giving the decision said that the definition of restrictive trade practice in Section 2(o) of the Act "is a pragmatic and result-oriented definition". It went on to say that the legality of an agreement or regulation does not depend upon whether or not it restrains competition but the test is whether the restraint imposed is such as merely regulates, and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. It said that the definition of restrictive trade is an exhaustive one, and not an inclusive one. The commission also went into the question of the objective of section 33 (1)(f) of the MRTP Act and said that the object of the said clause is that when specified rates are mentioned in the price list issued by the manufacturer including the resale price, there should be a clear mention in the price list that the dealers can sell at prices lower than those shown therein so that the ultimate consumers may not be led or misled by the fact that the prices mentioned IS in the price list are final and not subject to

negotiation. Hence to the fact, that some of the retailers have had sold the drugs at a price lower than that of the retail price, that could be seen as a violation of the said provision.

5.2.16 *UNION OF INDIA AND OTHERS VS. HINDUSTAN DEVELOPMENT CORPN. AND OTHERS* (AIR1994SC988). The issue arose, that whether railway carriage agreements between manufacturers were actually in contravention of the MRTP Act-1969. The court was of the opinion that whether the formation of any cartel restricts trade and competition has to be determined by the facts and the circumstances therein. Only suspicion is not enough to determine restrictive agreements. It was also agreed that mere quotation of identical price and offer of further reduction would not entitle monopoly over entire market.

5.2.17 ***MESSRS PREMIER ENGINEERS VS. MESSRS TAJ RUBBER INDUSTRIES AND ANOTHER -*** JT 2005 (7) SC 384 The court in the case opined that actual material loss or injury to the consumers is not necessary for invoking the sections of MRTP Act. If there is a factual evidence of more prices being charged or there is evidence of prices effectuating competition and restrictive trade practices, then Act is to be invoked.

5.3 The MRTP Experience in the Pharmaceutical Sector: Some Cases and Analysis

5.3.1 Some interesting cases have come up before the courts and tribunals during the MRTP regime. Although not all cases led to rationale outcomes, sometime the courts juggling with the application of certain provisions, it essentially remains the fact that economic analysis was not always an important ingredient in arriving at conclusions. Even though it relied on factual assertions, the case laws tend to adopt a structural approach. However, the courts when it came to interpretation of the Act went for the purposive interpretation. The cases mentioned here bears the testimony.

5.3.2 ***Director-general (i & r)* v. *All india organization of chemists and druggists and ors*** (Restrictive Trade Practices Trade Enquiry No. 193 of 1986)**:** Respondent No. 1 was the All India Organization of Chemists and Druggists which is an apex body operating from its office in Madras. The other respondent numbers are from 2 to 33. Respondents Nos. 2 to 19 are State Associations and members of the apex body (respondent No. 1). Respondents Nos. 20 and 21 are the Retail and Dispensing Chemists Association and pharmaceutical whole sellers association Respondents Nos. 22 to 33 are associations of manufacturers of pharmaceutical products and manufacturers of such products. The complaint by the DG stated that the respondents numbering from 1 to 21 are compelling respondents Nos. 22 to 33 to obtain no objection certificates (NOC)/letters bf co-operation (LOG), before marketing a new product, discontinuing an existing stockist and/or appointing new or additional stockists in any area. It is a usual practice that the NOC/LOC can only be obtained after having complied with the required procedures and practices. The DG also complained that the guidelines so prescribed are also in violation of section 33(1) (a) and 33(1) (j) of the Act, thereby prejudicial to public interest. Based upon the following facts an enquiry was commissioned. The issues where

(i) Whether the petition of the Director-General not maintainable for reasons stated in the preliminary objections of respondents.

(ii) Whether the DG really indulged in transactions which will invite violations of section 33(1)(a) and Section 33(1)(j) of the MRTP Act.

(iii) Whether those violation are prejudicial to public interest.

The Tribunal decided that with respect to the first two issues, the first was decided in the negative and the second to the affirmative. With respect the third issue, the court said that since the Government fixes the price of the drugs, section 33(1)(j) will not be attracted. However, as far as the second violation was concerned regarding section 33(1)(a) the Tribunal said that the restriction so imposed on the drugs and pharmaceutical products, fail to qualify the term so used as 'reasonably necessary'**.** It also opined that the new system of obtaining NOC/LOC will prove to be a detriment to the consumers as it will deny them the use of new pharmaceuticals and drugs and thus will be hit by the provisions of section 33(1)(b). Also the Tribunal failed to see, how the system as claimed will be affecting in the rise in unemployment in the sector.

5.3.3 ***Director General (Investigation and Registration) V. Biddle Sawyer Ltd.*** R.T.P.E. No. 59 of 1999: Respondent a company engaged in the manufacturing of drugs. On an enquiry based on a complaint received, a report was submitted which charged the respondent with acts in violation of MRTP Act under section 2(o)(ii) and section 2(i) respectively. Pursuant to the notice of enquiry, the respondent replied that the pharmaceutical

companies are controlled by the Drug Price Control Order prescribing the maximum pre-tax return on sales. Different price tax mechanisms are encapsulated for these different categories of companies. There was a slight increment in the sales of one of the categories, usually with the lowest sale proceeds, and in respond to that rise such a claim was brought forward. The issues before the commission were:
(1) Whether the present enquiry is maintainable in view of the preliminary objections taken by the respondents in their respective replies ?

(2) Whether the respondents have been indulging in restrictive trade practices as alleged in the Notice of Enquiry?

(3) Whether the alleged restrictive trade practices are not prejudicial to public interest?

The Tribunal was of the opinion that the case appeared to be based on under-utilization of installed capacity of the unit. It was coupled with falling sales leading to the maintenance of the price at an unreasonable level and high ratio of the profits to the share capital. In this connection, the Court was of the opinion that while the sale is dependent on the demand of the product in the market, the production of the product in turn depends on various factors. It was found that the price prevalent at the relevant period of time was stated to conform to the prices fixed by DPCO. Thus the charge of monopolistic trade practice does not find support in material placed and so the charge is not maintainable.

5.3.4 ***Director General (Investigation and Registration) V. Fulford India*** RTPE No. 63 of 1999

Fulford India had imposed unjustified cost on the consumers within the meaning of Section 2(o)(ii) of the Monopolies and Restrictive Trade Practices Act, 1969 . The charges were on the ground that by distributing the samples of Garamycin injections of the value of Rs. 8.90 lakhs in 1991 and Rs. 9.55 lakhs in 1992, the cost of which is included in the price of the drug, extra cost has been imposed on the consumers which is in violation of the Act. The issues before the commission were:

(1) Whether the present enquiry is maintainable in view of the preliminary objections taken by the respondents in their respective replies.

(2) Whether the respondents have been indulging in restrictive trade practices as alleged in the Notice of Enquiry?

(3) Whether the alleged restrictive trade practices are not prejudicial to public interest?

Since the drug so concerned has to be prescribed by the registered practitioner, the court believed that samples of drugs are to be tested first and then medicated. It was also agreed by the Tribunal that, *since marketing is one of the essential concomitant of sale, considerable cost is also incurred in the same.* However no record was placed before the court as to showing the actual increase in the cost of the drugs owing to the samples being issued. The charges that were framed in the court held no actual ground whatsoever and were decided to be non-maintainable. In many ways, this decision has tacitly justified the issuing of free samples by drug companies to physicians, one of the methods in drug promotion.

5.3.5 ***DIRECTOR-GENERAL (INVESTIGATION AND REGISTRATION) VS. INDIAN DRUGS MANUFACTURERS ASSOCIATION AND ANR***
[1992]73 compcas663 (null)

The fact was with regard to an increase in the price of drug owing to an agreement reached between the respondents for fixing uniform discount over the whole-sellers and the retailers. Also alleged was that the respondents have entered into a supplementary agreement under which one of the respondents had to pay a 20% margin on the maximum recommended price to the retailers and a 10% margin to the stockiest. The issues in this case were:

(1) Whether, by virtue of the impugned clauses of the agreement, the respondents are indulging in the restrictive trade practices as alleged in the notice of enquiry?

(2) If the answer to issue No. (1) is in the affirmative, then whether the said trade practices are not prejudicial to public interest as alleged.

The Tribunal looked into the provision so encapsulated in the MRTP act, section 33(1) (d) and said that it deals with an agreement between the sellers or an agreement between the buyers. It however does not say that about any agreement between the buyer and the sellers. The whole "concerted effort" of the section is to prevent sellers coming together and selling commodity at a fixed price or the buyers coming together and buying goods at particular prices. It is therefore clear, that the provision cannot be brought into something where there exists an agreement between the buyer and the seller. It was also agreed that such type of agreements does not grant any concession to either of the parties to the agreement. So the notice of enquiry was discharged. The impact of this decision is on those types of vertical agreements like resale price maintenance where fixing margins on recommended prices could lead to price escalation thereby reducing competition.

5.3.6 ***Director General (Investigation and Registration) V. Infar (India) Limited*** R.T.P Enquiry No. 320 of 96
The DG moved in an application of enquiry charging the respondent with adoption and indulgence in restrictive trade practices on the ground that the price list of the respective drugs cannot be sold less to that as been prescribed in the list. This brought forth a typical case of resale price maintenance, but without sufficient evidence to suggest if the list circulated was for maximum or minimum ceiling of prices. Whether the price so enumerated lower than that prescribed in the list, will in effect be in violation of section 33(1)(f) of the MRTP Act.

The Tribunal was of the opinion that since the prices are mentioned as maximum retail prices, it is obvious that the retailers are authorized to sell the drug less than what has been prescribed in the list. Since the price has been so mentioned in the list, it is believed that such price as prescribed in the list is the maximum. So retailers are in complete freedom fix the price below the price so mentioned in the list. The tribunal stated that there is no need to create such a legal fiction that price if fixed lower than the price enlisted in the list, then it is not necessarily a violation of section 33(1)(f) of the MRTP Act.

5.3.7 ***YOUNG MEDICOS CULTURAL ORGANIZATION V. PHARMACEUTICALS WHOLESALERS association***, [1993] 3 Comp LJ 123 (MRTPC)it was held that the boycott of the life saving drugs brought about by the active connivance and encouragement of the errant parties is a restrictive trade practice as it causes to consumers and general public considerable suffering because of non-availability of the medicines. In the said ruling, the Commission rejected the argument of the charged parties that the boycott was only a non-co-operation movement. The boycott was held to be a clear restrictive trade practice warranting a cease and desist order applying Section 2(o) and Section 37 of the Act.

5.3.8 ***Director General (Investigation and Registration)V. Pfizer Ltd.***(Restrictive Trade Practice Enquiry No. 15 of 1997)The case reiterates what has been said in the *Infra* Case.

5.3.9 ***Director-General (Investigation and Registration)V. Zandu Pharmaceutical Works Ltd. [1994]81CompCas 377(NULL).*** In this case the prices of the drugs were sold at a rate that was lower than that mentioned in the list. The Director General for that matter, initiated a complaint saying that it was violative of section 33(1)(f) of the MRTP Act 1969. The DG also made a complaint for an enquiry to be initiated for that regard, and orders to be passed against the company. The issue was whether the respondent is indulging in the restrictive trade practice as alleged in the Director-General's application under Section 10(a)(iii) and the notice of enquiry issued pursuant thereto. The commission was of the view that the price enumerated less than what has been prescribed in the list is no way in violation of the act. Furthermore giving discounts or issuing free items along with the drug is not deemed to be prejudicial to public interest or is violation of restrictive trade practices act. The commission did not affirm with the charges so leveled in the case.

5.3.10 ***Director General (Investigation and Registration) V. Parke Davis India Ltd. and Ors*** I(2004)CPJ15(MRTP). The respondent in the case entered into a Loan License Agreement with the Small Scale Unit for manufacturing the impugned formulations with the sole purpose of circumventing the need for prior approval of price fixation. Whether the above practice so involved by the respondent is restrictive of trade or not. The commission has to

prove that the alleged trade practice can be called a restrictive trade practice only, if it has the effect of preventing, distorting or restricting competition, has to be satisfied. The commission was dissatisfied with the enquiry proceedings and did not find any substantial material in the matter and decided in the negative.

5.3.11 ***East Line Projects Pvt. Ltd. V. Dr. B. Borooah Cancer Institute and Ors*** AIR 2005 Gau 5, 2005 (1) CTLJ 285 (Gau). The case dealt with the establishment of a Pharmacy at a Cancer Institute. The institute floated a tender for the establishment of a Pharmacy Centre for the convenience of the patients undergoing treatment in the hospital. The petitioner has challenged the issuance of the tender on certain grounds. The court was of the opinion that the terms of the invitation of the tender are not subject to judicial scrutiny. The government always has a free hand in setting the terms of the tender. It is necessary concomitant in an administrative sphere. The Court was of the opinion that it can and would interfere with administrative policy decisions only if it is arbitrary, discriminatory, *malafide* or actuated by bias. It is entitled to pragmatic adjustments which may be called for by the particular circumstances. The court also held that it doesn't retain the power to strike down the terms of the tender prescribed by the Government because it feels that some other terms in the tender would have been fair, wiser or logical.

5.3.12 ***Director General (I & R) v. Knoll Pharmaceuticals Ltd.*** *[2001 CTJ 250 (MRTP)]* revealed a case of juridicitional conflict between NPPA as a price regulator and MRTP as a Commission deciding on reasonability of prices and its impact on competition. The respondent was accused of increasing the prices of its products, namely, Dygiene Tablets, Dygiene Syrup, Cremaffin and Eptoin by 120 percent, 70 percent, 45 percent and 86 percent respectively. It was repeatedly asserted by the respondents in that case issues of pricing are considered by the NPPA that commission should look into pricing only when it has implications for competition. While the case was dismissed on grounds of the accused company having negligible market share, the issue of jurisdiction was not addressed.

5.3.13 ***Director general (I&R) v. Jagson Pal Pharma Ltd***. [2005 CTJ 82 (MRTP)] It was held that excessive pricing or pricing pattern having no relationship with the cost of the input is not anti-competitive if such a trade practice does not have the effect of preventing, distorting or restricting competition in the market. Increasing prices of drugs *per se* is therefore not an anti-competitive practice.

5.4 Competition Act, 2002: Is the State of Art Law Prepared for the Uncertain?

5.4.1 Introduction:

5.4.1.1 The reforms of 1991 brought in the necessity of a new law dealing with issues concerning competition. The Raghavan committee report noted that most countries had modern legislations for preserving competition. It also noted that the existing MRTP was grossly ineffective to deal with new situations. It noted that:

> *"7.1-3 Unlike the competition laws of the countries mentioned above, which address engendering competition in the market and trade, and which address anti-competition , practices, the existing Indian competition law, namely, the MRTP Act falls considerably short of squarely addressing competition and anti-competition practices. One could argue that the restrictive trade practices listed in the MRTP Act are all anti-competitive practices and thus it constitutes the country's competition law. But the extant MRTP Act, in comparison with competition laws of many countries is inadequate for fostering competition in the market and trade and for reducing, if not eliminating, anti-competitive practices in the country's domestic and international trade".*

5.4.1.2 The object of the new Act is also clear from the preamble which states that it's an Act "An Act to provide, keeping in view of the economic development of the country, for the establishment of a Commission to prevent practices having adverse effect on competition, to promote and sustain competition in markets, to protect the interests of consumers and to ensure freedom of trade carried on by other participants in markets, in India, and for matters connected therewith or incidental thereto".

5.4.1.3 Certainly, consumer welfare is one of the important objectives of the Act. However, it appears from the Raghavan committee report that it would not want the Commission to over intervene in the markets for a greater degree. The amount of intervention will of course be a matter to be decided by the interpreting the law. In respect of price control, which were initiated as measure for protecting consumers against exploitative abuse, the committee noted that :

"2.4-2 Price controls-In addition to the fact that certain key raw materials were produced in the public sector, a number of commodities were subject to price and quantity controls. Industries providing important commodities, such as edible oils, sugar, fertilizers, pharmaceuticals, aluminium (sic), cement, steel, coal and petroleum products were subject to price controls and quantity controls of varying degrees. This implied that even in sectors where there was a private sector presence, conditions and outcomes were far from competitive. A complex system of excise and corporate taxes further distorted the incentives".

5.4.1.4 On the issue of standardisation and quality issues, the Ragahavan committee was of the opinion that:

"4.3 Quality and safety standards for goods and services ensure a certain minimum quality and are generally for the benefit of consumers. This is often necessary even if it leads to some restrictions on competition. In other words, only goods and services that satisfy the minimum criteria are allowed to compete. However, there are situations where firms or groups of firms, of ten times in positions of dominance may use standards and specifications to prevent entry of other firms into the market. Such practices, if designed to prevent market access, should attract the attention of the relevant section on abuse of dominance and/or exclusionary practices".

5.4.2 In the light of the above, long-term implications for assessing the consequences of standardisation related to pharmaceuticals (schedule M) on small scale pharmaceutical may need nuanced consideration. The argument is not that schedule M should compromise with safety standards. However, it needs to be noted that it has to be scientific and not arbitrary in prescribing standards. It must also provide more certainty to allow better compliance. Sufficient advocacy around this issue may be needed to allow rationalization of standards pertaining to pharmaceuticals so as to preserve *ex ante* competition.

5.4.3 The Indian competition Act, 2002 is clear to the extent that it is the effect of the monopoly that is the target of regulation and prohibition. The Act prohibits or regulates three type of activities:

- *Anticompetitive agreement (section 3)*
- *Abuse of Dominant Position (Section 4)*
- *Regulation of Combination (section 5 and 6)*

5.4.4 Since the Act was to a large extent a response to economic reforms and globalisation process and hence to maintain a standard law dealing with type of practices regarded as raising competition concerns is also responsible for the new law. After a long wait, on 15 May, 2009, the Ministry of Corporate Affairs notified certain sections of the Competition Act, 2002 by powers vested in it under section 1(2). Sections 3 and 4 are operational from the 20th day of May, 2009.

5.4.5 It is pertinent to note that the CCI may inquire into any alleged contravention of the provisions contained in subsection (1) of section 3 or sub-section (1) of section 4 either on its own motion or on—

- receipt of any information, in such manner and] accompanied by such fee as may be determined by regulations, from any person, consumer or their association or trade association; or
- a reference made to it by the Central Government or a State Government or a statutory authority.

5.4.6 Before dealing into the type of practices, it would be essential to understand the conceptualization and definition of relevant market under the Competition Act, 2002. Section 2(r) defines: "relevant market" means the market which may be determined by the Commission with reference to the relevant product market or the relevant geographic market or with reference to both the markets". While this definition allows that the Commission may adopt the relevant product market criterion, relevant geographic market criterion or both, it would be important to consider the mandate under section 19(5) of the Act which states that "[F]or determining whether a market

constitutes a "relevant market" for the purposes of this Act, the Commission shall have due regard to the "relevant geographic market" and "relevant product market". Hence, it would be important that the commission considers both the prongs on an equal footing in pharmaceutical cases- a precedent set by courts in comparative jurisdictions. Without determining the scope of such markets, it would be futile to come to any conclusions on market power possessed by firms.

5.4.7 Relevant product market is defined in section 2(t): "relevant product market" means a market comprising all those products or services which are regarded as interchangeable or substitutable by the consumer, by reason of characteristics of the products or services, their prices and intended use. Thus the present definition considers interchangeability and substitutability test for finding out relevant product market. Section 19(7) of the Act requires that the "commission shall, while determining the "relevant product market", have due regard to all or any of the following factors, namely:—

(a) physical characteristics or end-use of goods;
(b) price of goods or service;
(c) consumer preferences;
(d) exclusion of in-house production;
(e) existence of specialised producers;
(f) classification of industrial products.

5.4.8 In case of pharmaceuticals, the following questions may be pertinent. The physical characteristics test would require the commission to consider the drugs have the same dosage and delivery forms such as injectable, liquid, capsule, tablets, or topical; the end use test suggests and inquiry if drugs have the same frequency of dosage, such as once -a- day or extended release; whether drugs have the same strength of dosage, distinguishing, for example, 10mg and 30mg tablets;

5.4.9 Consideration of the price of goods or services would require an inquiry if the drugs are branded or generic; price constraints through price controls and negotiations may be considered as a constraint on supra normal pricing. However, price negotiations can add to the deceptive element since it does not fully constrain the alleged monopolist from pricing. Currently, since most drugs (except 74 drugs) from the National Essential Drug List are not under price controls, it would mean that price control may also not be an essential consideration.

5.4.10 The distinction between prescription drugs and OTC drugs may have substantial difference in assessing relevant markets. In case of prescription drugs, since information asymmetries are greater, it would require that such an important constraint on consumer choice be taken into consideration. Further, whether drugs are currently marketed or are in development; whether drugs treat the same disease, condition, or indication; whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same "mechanism of action"); whether drugs have the same specific chemical compounds. The commission may thus inquire into a variety of factors. Generally, in case of pharmaceuticals, ATC classification is considered as standard for understanding the class of therapeutics. As seen above, ATC is classified into five levels. ATC 3-4 level classification is considered to be the most relevant in defining the relevant product market in case of pharmaceuticals.

5.4.11 It may be noted that the SSNIP test may not be of much help in defining relevant markets. It is so because cross elasticity in demand in very low in case of prescription drugs. Hence this test must be used with caution in the pharmaceutical context. Further, the question is if *cellophane fallacy* applies in case of pharmaceuticals. It is interesting to note the consequences of the application of *Cellophane Fallacy* in determining the scope of relevant product market in case of pharmaceuticals. *Cellophane fallacy* is inapplicable when there are excellent substitutes. In most cases, it is difficult to envision a situation where doctors would prescribe alternate medicines to cure a disease. Interchangeability is highly impossible given that patient needs can be addressed only through particular drugs. In a prescription market situation, it is evident that there does not exist a high cross-elasticity of demand. At a high enough price, interchangeability with poor substitutes may not look good to doctors who prescribe the medicine. Thus the *Cellophane fallacy* does not apply in case of pharmaceuticals. Pharmaceutical

companies also compete in marketing drugs. Several different market participants are involved today in purchasing pharmaceuticals, which may complicate market definition analyses.

5.4.12 Relevant geographic market is defined under section 2(s) of the Act. It states: "relevant geographic market" means a market comprising the area in which the conditions of competition for supply of goods or provision of services or demand of goods or services are distinctly homogenous and can be distinguished from the conditions prevailing in the neighbouring areas". In defining the relevant geographic market. The Commission shall, while determining the "relevant geographic market", have due regard to all or any of the following factors, namely:—

(a) regulatory trade barriers;
(b) local specification requirements;
(c) national procurement policies;
(d) adequate distribution facilities;
(e) transport costs;
(f) language;
(g) consumer preferences;
(h) need for secure or regular supplies or rapid after-sales services.

5.4.13 Generally, in pharmaceutical case, *sans* intervention by state governments, geographic markets are national markets. In the Indian context, it is unlikely that drug procurement can sufficiently alter conditions in the relevant market. However drug procurement by state authorities may constrain the demand for pharmaceutical products. But this is more often than not the case with government procurement in India. Supply side constraints imposed by transportation costs and local requirement relating to manufacturing and sale. In terms of consumer preferences, not much of a difference may be found in terms of Thus in the context of pharmaceuticals the relevant geographic market would mean national markets unless there is huge variation in prices due to local procurement schemes by the government.

5.4.14 **Anticompetitive agreements:** Section 3(1) states that: "No enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India". Such agreements have been declared void under section 3(2). It is pertinent to note that such agreements need not be enforceable by law. As per section 19(2) the Commission shall, while determining whether an agreement has an appreciable adverse effect on competition under section 3, have due regard to all or any of the following factors, namely:
(a) creation of barriers to new entrants in the market;
(b) driving existing competitors out of the market;
(c) foreclosure of competition by hindering entry into the market;
(d) accrual of benefits to consumers;
(e) improvements in production or distribution of goods or provision of services;
(f) promotion of technical, scientific and economic development by means of production or distribution of goods or provision of services.

5.4.15 From the above, it is pertinent to note that the Commission must follow factors specified under section 19(3) are compulsory. However, it creates a confusing situation if all agreements under section 3 must undergo this scrutiny. It is so because certain horizontal hardcore cartel agreements are per se void. In such situations it is evident that factors under section 19(3) need not be taken into consideration. More importantly, terms used in the factors specified in section 19(3) require an economic analysis, where only further regulations can clear the haze.

5.4.16 Section 3(3) states that "Any agreement entered into between enterprises or associations of enterprises or persons or associations of persons or between any person and enterprise or practice carried on, or decision taken by, any association of enterprises or association of persons, including cartels, engaged in identical or similar trade of goods or provision of services, which—

(a) directly or indirectly determines purchase or sale prices;

(b) limits or controls production, supply, markets, technical development, investment or provision of services;
(c) shares the market or source of production or provision of services by way of allocation of geographical area of market, or type of goods or services, or number of customers in the market or any other similar way;
(d) directly or indirectly results in bid rigging or collusive bidding, shall be presumed to have an appreciable adverse effect on competition:
Provided that nothing contained in this sub-section shall apply to any agreement entered into by way of joint ventures if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services.

Explanation.—For the purposes of this sub-section, "bid rigging" means any agreement, between enterprises or persons referred to in sub-section (3) engaged in identical or similar production or trading of goods or provision of services, which has the effect of eliminating or reducing competition for bids or adversely affecting or manipulating the process for bidding

5.4.17 In its application to the pharmaceutical sector section 3(3) can prove helpful in dealing with hardcore agreements more specifically in the supply chain. Mass boycott of products, medicos agreeing to prescribe or not to prescribe a particular brand etc… are within the purview of section 3(3) prohibitions. Some agreements under section 3(3) are *per se* void if they are in the nature of hardcore cartels and do not require any factors to be considered under section 19(3). It is pertinent to note that section 3(3) can be used in effectively deterring collusive practices in drug procurement. While there is no direct evidence of bid rigging practices in Indian drug procurement, it must be noted that there is less effective competition prevailing in bidding of speciality drugs. They can be in the nature of market allocating agreements. Section 3(3) however, does not prohibit combinations which are in the nature of acquisitions, merger or conglomerates. They are governed by sections 5 and 6 of the Act. It is pertinent to note that joint ventures are kept out of the application of section 3 provided such joint venture agreements increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services. It is pertinent to note that many market / R&D agreements in the nature of joint ventures are routinely entered in pharmaceutical will be kept out of the purview if such agreements if such agreement increases efficiency. However, there is no clear definitional understanding of what accounts to efficiency and hence one may retort to section 19(3) for guidance.

5.4.18 Vertical restraints can be challenges under section 3(4) which states that “Any agreement amongst enterprises or persons at different stages or levels of the production chain in different markets, in respect of production, supply, distribution, storage, sale or price of, or trade in goods or provision of services, including—
(a) tie-in arrangement;
(b) exclusive supply agreement;
(c) exclusive distribution agreement;
(d) refusal to deal;
(e) resale price maintenance,
shall be an agreement in contravention of sub-section (1) if such agreement causes or is likely to cause an appreciable adverse effect on competition in India.[210]

[210] Explanation.—For the purposes of this sub-section,—
(a) "tie-in arrangement" includes any agreement requiring a purchaser of goods, as a condition of such purchase, to purchase some other goods;
(b) "exclusive supply agreement" includes any agreement restricting in any manner the purchaser in the course of his trade from acquiring or otherwise dealing in any goods other than those of the seller or any other person;
(c) "exclusive distribution agreement" includes any agreement to limit, restrict or withhold the output or supply of any goods or allocate any area or market for the disposal or sale of the goods;
(d) "refusal to deal" includes any agreement which restricts, or is likely to restrict, by any method the persons or classes of persons to whom goods are sold or from whom goods are bought;
(e) "resale price maintenance" includes any agreement to sell goods on condition that the prices to be charged on the resale by the purchaser

5.4.19 As noted in this study the pharmaceutical supply chain is best with practices that can be regarded as vertical restraints. Certain tie in practices, especially combinational theraphies can be validly challenged. However, this must note be confused with fixed dose combination (FDCs) which are directed to a single patient required different doses of different medicines. However, tie-in practices which require a retailer or consumer to purchase some other good along with the one demanded falls within the mischief of this section.

5.4.20 It is pertinent to note that section 3(5) partially excludes the operation of agreements concerning intellectual property rights as antithesis to competition. Section 3(5) states that "Nothing contained in this section shall restrict—

(i) the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under—

(a) the Copyright Act, 1957 (14 of 1957);
(b) the Patents Act, 1970 (39 of 1970);
(c) the Trade and Merchandise Marks Act, 1958 (43 of 1958) or the Trade Marks Act, 1999 (47 of 1999);
(d) the Geographical Indications of Goods (Registration and Protection) Act, 1999 (48 of 1999);
(e) the Designs Act, 2000 (16 of 2000);
(f) the Semi-conductor Integrated Circuits Layout-Design Act, 2000 (37 of 2000);"

5.4.21 Much is yet to be desired from the guidelines as to what practices are prohibited. It must be specifically noted that certain anti competitive practices which lead to the prohibition of protection of the existing trade and industry, development of new industrial activities, promotion of export, availability of the product at affordable price, can be successfully challenged under the Patents Act, 1970. A compulsory license may be issued for after such allegations are satisfactorily proved before the patent controller. The patents act also allows issuance of compulsory licence where prevention of unreasonable terms–such as grant-back requirements, packaging, prevention of challenges–in voluntary licences, exploitation of the market based only on import etc. led to anticompetitive fallouts. However, there is no necessity of the rule of reason analysis to be applied in case of the patent law. Suffice it would be to prove that such provisions do exist in the agreements. It must also be noted that for a successful application under the patents act, there is no consideration for an inquiry in to the relevant market. This illustrates that compulsory licensing provision under patent laws are in the nature of public interest provisions and not based on stricter competition law analysis. As stated above, the regulation from the CCI will have to clarify the caps and thresholds that would be kept for regarding agreements to fall within the mischief of this section. The EU block exemptions on technology transfer may only provide an illustrative guide. However, the competition commission is bestowed with full powers to reasonably fix the thresholds. However, it is evident that section 19(3) factors will have to be considered.

5.4.22 Exception to exclusion under section 3 category also pertains to entering into anticompetitive agreements for the purpose of export market. Section 3(5) also allows for the right of any person to export goods from India to the extent to which the agreement relates exclusively to the production, supply, distribution or control of goods or provision of services for such export.

5.4.23 **Prohibition of abuse of dominant position**: Dominance, per se is not illegal but its abuse is. The vexed question which is to be answered is "determination of dominant position'. Cases analyzed in the context of US and EU jurisdictions amply assert that willingness of the courts to understand that law does not make mere size of a corporation, however impressive, or the existence of unfettered power on its part, an offence, when accompanied by unlawful conduct in the exercise of its power. It may be noted that the competition laws of all jurisdictions do not contain a general prohibition on the abuse of dominance or on the misuse of market power. Some laws only prohibit specified conducts by undertakings in a dominant position or having a substantial degree of market power.

5.4.24 Section 4 (1) of the Indian Competition Act states, "No Enterprise shall abuse its dominant position". There are however certain differences in these basic provisions. While the Indian law prohibits abuse of dominant position by enterprises in general, the certain countries may have provisions in the law that prohibits the "abusive exploitation of a dominant position". Needless to say dominance has been traditionally defined in terms of

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shall be the prices stipulated by the seller unless it is clearly stated that prices lower than those prices may be charged.

market share of the enterprise or group of enterprises concerned. However, a number of other factors play a role in determining the influence of an enterprise or a group of enterprises in the market. These include, besides market share, the size and resources of the enterprise; size and importance of competitors; economic power of the enterprise; vertical integration; dependence of consumers on the enterprise; extent of entry and exit barriers in the market; countervailing buying power; market structure and size of the market; source of dominant position viz. whether obtained due to statute etc.; social costs and obligations and contribution of enterprise enjoying dominant position to economic development. The Commission is also authorized to take into account any other factor which it may consider relevant for the determination of dominance.

5.4.25 There are primarily three stages in determining whether an enterprise has abused its dominant position. The first stage is defining the relevant market. As noted above, the analysis in case of pharmaceutical products in complex. The second is determining whether the concerned undertaking/enterprise/firm is in a dominant position/ has a substantial degree of market power/ has monopoly power in that relevant market. The third stage is the determination of whether the undertaking in a dominant position/ having substantial market power/monopoly power has engaged in conducts specifically prohibited by the statute or amounting to abuse of dominant position/monopoly or attempt to monopolize under the applicable law.

5.4.26 Explanation to section 4 define dominance as "a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to— (i) operate independently of competitive forces prevailing in the relevant market; or (ii) affect its competitors or consumers or the relevant market in its favour". It is pertinent to note that the act does not distinguish between passive or active market power. An effect based test would allow the application of this section if the enterprise has become dominant due to existence of passive market power. The Act clearly states that there shall be an abuse of dominant position if an enterprise or a group directly or indirectly, imposes unfair or discriminatory condition in purchase or sale of goods or service; or price in purchase or sale (including predatory price) of goods or service. Predatory pricing is also included. It is pertinent to note that the Commission take note of unfair prices in case of pharmaceuticals also. Nothing in Act mandates the Commission not to intervene in price regulation only because of the existence if NPPA or issue compulsory license because of the existence of provisions for compulsory license under Patents Act, 1970. In cases of unfair pricing the recourse taken by the South African commission may be considered.

5.4.27 Pharmaceuticals suffer from the problem of excessive pricing and predatory pricing cases are very rare except where patents are about to expire and brand manufacturer wanting to preserve his long held monopoly. In case of application of the essential facilities doctrine, the Act deals with EFD under section 4 and Section' however the treatment is different.[211] Our Supreme Court has imposed certain obligations which are similar to EFD like in Binnin Limited and Anr. V. Sadasivan and Ors. The court held that writ can't be issued in the matter of contractual obligation. Moreover no writs can be issued if the rights are of a private character.[212] The court recently held in ABL Industries that writ can be passed in contract matters if one the parties is Govt. and it's *essential* for the govt. to work fairly. Furthermore, Indian law has institutionalized the entire concept of Essential Facilities through certain Acts.[213] As applied to the pharmaceutical sector, the EFD can prove helpful in accessing patented knowledge. The remedy is generally in the nature of compulsory licensing.

5.4.28 It is pertinent to noted that section 4 analysis requires under section 19(4) the Commission shall, while inquiring whether an enterprise enjoys a dominant position or not under section 4, have due regard to all or any of the following factors, namely:—

(a) market share of the enterprise;
(b) size and resources of the enterprise;
(c) size and importance of the competitors;
(d) economic power of the enterprise including commercial advantages over competitors;
(e) vertical integration of the enterprises or sale or service network of such enterprises;
(f) dependence of consumers on the enterprise;
(g) monopoly or dominant position whether acquired as a result of any statute or by virtue of being a Government company or a public sector undertaking or otherwise;
(h) entry barriers including barriers such as regulatory barriers, financial risk, high capital cost of entry, marketing entry barriers, technical entry barriers, economies of scale, high cost of substitutable goods or service for consumers;

[211] Section 3(4)(d) deals with refusal to deal whereas S. 4 deals with Abuse of dominant position (which is the focus of the paper).
[212] AMSSMVSSJM Samrak Trust v. V. R. Rudani and Ors, AIR 1989 SC 1607.
[213] See S.2(m) 'Common Carrier Regime' Under PNGRB Act 2006; Open Access regime under Electricity Act, 2003, Interconnection regime for Telecommunication networks etc.

(i) countervailing buying power;
(j) market structure and size of market;
(k) social obligations and social costs;
(/) relative advantage, by way of the contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have an appreciable adverse effect on competition;
(m) any other factor which the Commission may consider relevant for the inquiry.

5.4.29 Three important factors can be understood to have positive implication for section 4 analysis. What are social costs is not defined. Again, section 4 may warrant development dimension to the understanding of dominant position. However, most importantly the commission may consider any factor that is relevant for an abuse of dominant inquiry within the scope of section 19(4).

5.4.30 **Regulation of Combinations:** Section 5 prescribes the thresholds under which combinations shall be examined. While the threshold prescribed have a potential to include many medium and big size acquisitions in the Indian pharmaceutical market, it is important to note that section 5 and 6 provisions have not been notified. Section 6 states that "No person or enterprise shall enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void". Section 6 mandates a pre combination review notice to be given to the commission within 30 days of the decision of the companies to enter into a combination.

5.4.31 Section 20(4) requires that for the purposes of determining whether a combination would have the effect of or is likely to have an appreciable adverse effect on competition in the relevant market, the Commission shall have due regard to all or any of the following factors, namely:—

(a) actual and potential level of competition through imports in the market;
(b) extent of barriers to entry into the market;
(c) level of combination in the market;
(d) degree of countervailing power in the market;
(e) likelihood that the combination would result in the parties to the combination being able to significantly and sustainably increase prices or profit margins;
(f) extent of effective competition likely to sustain in a market;
(g) extent to which substitutes are available or arc likely to be available in the market;
(h) market share, in the relevant market, of the persons or enterprise in a combination, individually and as a combination;
(i) likelihood that the combination would result in the removal of a vigorous and effective competitor or competitors in the market;
(j) nature and extent of vertical integration in the market;
(k) possibility of a failing business;
(/) nature and extent of innovation;
(m) relative advantage, by way of the contribution to the economic development, by any combination having or likely to have appreciable adverse effect on competition;
(n) whether the benefits of the combination outweigh the adverse impact of the combination, if any.

5.4.32 Without provisions relating to combinations being notified, it would be difficult to put on hold acquisitions that might have adverse effect on competition in India. It is important to note that the tests developed in comparative jurisdictions can only provide a guide in the absence of specific regulations issued by the CCI. What is important for review of combinations is also an assessment of impact of combination on innovation markets. It is pertinent to note that acquisitions which involve takeover of generic companies may lead to change in priorities of generic companies. Overall effective competition in generic markets may thus be reduced.

CHAPTER VI

COMPETITION ADVOCACY IN THE PHARMACEUTICAL SECTOR

6.1 **The Need for Advocacy** Section 49(3) Chapter VII dealing with Competition Advocacy in the Act states that "The Commission shall take suitable measures for the promotion of competition advocacy, creating awareness and imparting training about competition issues". In this light the Competition Commission is bestowed with the responsibility of creating advocacy and awareness and in this regard may advise the Central Government may, in formulating a policy on competition (including review of laws related to competition) or any other matter, and a State Government may, in formulating a policy on competition or on any other matter, as the case may be, make a reference to the Commission for its opinion on possible effect of such policy on competition and on the receipt of such a reference. In this connection, the Commission shall, within sixty days of making such reference, give its opinion to the Central Government, or the State Government, as the case may be, which may thereafter take further action as it deems fit. However, such an opinion given by the Commission under shall not be binding upon the Central Government or the State Government in formulating such policy.

6.1.1 However, this in itself does not explain the need for role of advocacy in the pharmaceutical sector. The following can be the main reasons that could be outlined for the need for advocacy in the pharmaceutical sector.

- First, the competition Act in India is itself new and its possible application is a complex analysis.
- Second, not all government functionaries consider elements in formulating policies relating to pharmaceuticals. The classic example in this case is the Draft National Pharmaceutical Policy of 2006 issued by the Department of pharmaceuticals which does not mention the use of competition law as an instrument to abate excessive pricing by pharmaceutical companies.
- Pharmaceutical sector, as it stands, is a highly regulated sector and various regulatory authorities govern different aspects of the industry
- The pharmaceutical industry heavily relies on the patent system where possibilities of abuse of patents stand a higher chance. This is specifically because legal monopolies through patents are market interventions to cure market failures in innovation. Abuse adding to it may aggravate concerns for competition.
- There is high amount of scrutiny in the pharmaceutical sector globally. Incidences of pharmaceutical companies abusing patents and dominant position prevail widely. This is also confirmed by the recently concluded EU Pharmaceutical sector Inquiry (July 2009)

6.1.2 Hence there is a need for a muliti-pronged strategy for creating awareness about competition issues on ex ante basis. Since there are different actors in the Pharmaceutical industry and healthcare markets, strategies can be specifically with reference to:

- The need that generic companies must take initiatives in effectively challenging patent grants. Industry associations must be made aware about possible anticompetitive effects of acquisitions and mergers of generic companies.
- Need for generating awareness among patent offices about anticompetitive effects due to wrong application of patentability standards prescribed under the law

- Need for generating awareness among S&T authorities about the implications on normative IP framework in case of Publicly funded Pharmaceutical R&D in the light of experiences from comparative jurisdictions and with specific implications for pharmaceutical R&D dissemination
- Concerted efforts for generating awareness about the loopholes in the law regulating actors and activities in the pharmaceutical supply chain
- Need to create awareness among the Drug regulatory authorities about possible impact of Drug-patent linkages and issues around Data Exclusivity and Competition
- Need to sensitize the NPPA about pricing issues connected to patented drugs and other branded generic medicines where there exists substantial price differences
- Need to create awareness among the Drug regulatory authorities about possible impact of standardisation on the competitiveness of small scale enterprises
- Need for creating awareness among government Agencies involved in drug procurement so as to adopt best practices in drug procurement largely based on the Tamilnadu model.
- Need to sensitize Government agencies about impact of minimum turnover requirement in case of drug procurement
- Need for Generating awareness among various actors in the supply chains
    - Medical Practioners should be sensitized about the importance and efficacy of generic medicines for prescription
    - Marketing reps. and companies must be made aware of ethical standards of marketing, drug promotion and awareness and must built around direct to consumer advertising. A proper statutory framework must be proposed.
    - Wholesalers and retailers must be made aware of possible actions against them for keeping supra-normal margins through anticompetitive agreements.
    - Hospitals with drug outlets must be asked to streamline their procurement policies and adopt best practices in procurement. Issues for advocacy involve excessive pricing and profit margins maintained by such outlets
- Need for greater consumer awareness about generic drugs
    - Jan Aushadhi must be popularized on an all India basis.
- Need for greater consumer awareness about health insurance
    - Rashtriya Swasthya Bima Yojana, 2008 must be popularized
- Other Government agencies must be made aware of evaluating their actions by keeping in mind the competitive structure of the Indian pharmaceutical industry and consumer access from a health care perspective

CHAPTER VII

CONCLUSIONS AND RECOMMENDATIONS

This study has examined from the perspective of competition law and policy various issues pertaining to the pharmaceutical sector in India. This study has applied that Competition Assessment Framework for analysing pertinent issues of competition in developing countries. At the outset it is important to understand that the study does not focus on all aspects of health care industry. Competition issues in pharmaceuticals largely pertain to the area of prescription medicines. It must be noted that there is an inherent development dimension in the application of competition law and policy to economic activity and its application to the pharmaceutical industry is more so important.

The pharmaceutical industry is an important source of health care for billions of population globally and in India. Hence it is a highly regulated sector. The pharmaceutical industry is influenced by a host of practices which may primarily relate to price regulations, insurance and reimbursements, drug procurement by government agencies, patent laws, innovation polices, biotechnology and safety policies, drug regulation, data protection, trademarks and use of international non-proprietary names, drug promotion regulation, drug advertising regulation etc... Hence competition law has to work in tandem with all such diverse set of laws, polices and regulation governing the pharmaceutical sector.

At another level, information asymmetry does lead to erratic working of competitive forces in the pharmaceutical markets. In prescription drug industry (also referred to as the ethical drug industry), the physician selects the drug and the patient-consumer only pays. Drug promotion and direct to consumer marketing also adds to the passive exploitative situation created by information asymmetries. Hence the idea of a rational consumer making rational choices based on prices and availability of substitutes in not akin to the working of the prescription drug market. Thus the very notion of consumer choice leading to price competition, fails in the prescription drug market. It may be noted that even in the presence of effective substitutes, the most expensive brand is also the top selling brand. Consumer drug information availability and acceptability is inherently very low in case of pharmaceutical products. The root cause lies in the nature of the product consumed- where consumers have least information about the drugs being prescribed and the therapeutic efficacy of one drug over another. Further, perverse incentive linkages in the pharmaceutical supply chain are a cause of greater concern. While not many studies have flagged the multiplicity of relationships among different actors – viz., the manufacturer, wholesaler (stockiest), retailers (pharmacists) and physicians- the very structure of profitability and profit distribution, coupled with a lax regulatory structure allowing unethical drug promotion does lead to a skewed consumption pattern and hence impacts effective competition in pharmaceutical markets.

The study has examined issues concerning working of pharmaceutical sector both from a horizontal and vertical point of view. It should not be lost sight of the fact that the pharmaceutical sector in India has grown out of policy patronage adopted since 1970s. The most important policies decisions were to limit the grant of patent only to process and not to products and the drug policy of 1970. Subsequent to this pharmaceutical prices came to be regulated through the Drug Price Control Orders which have been amended from time to time. The pharmaceutical industry is currently divided in to a three tier structure. Large MNCs operate as originator drug companies and generic companies along with large Indian generic companies. Medium and small scale industries are also engaged in production of branded generics and contract manufacturing related activities. Much of the units in small scale sector are engaged in production of generic-generic medicines. India is the 4th largest manufacturer of pharmaceutical products and it ranks 14th in terms of value. Indian generic export have shown a steady increase since 1990's and are a major supplier of generic drugs to both developed and developing countries. At the same time generic price competition offered by Indian companies has been globally recognised.

The study has examined market shares of top companies based on sales. It is noted that sales are largely driven by nature, operation and brand of the firm. While there is *primafacie* no evidence for such market shares having been gained through direct exercise of market power, it is evident that in the pharmaceutical industry passive market power and information asymmetries can lead to higher market shares. The pharmaceutical industry has also witnessed higher levels of FDI, but it

does not share a larger % of the total FDI inflows. However, Indian companies have made a host of strategic acquisitions abroad. However, there has been a decline in the said trend over the last couple of years.

Interestingly, there is a reversal of trend in acquisitions. The past two years have witnessed a lot of consolidation activities within the Indian pharmaceutical industry. Most of these acquisitions are strategic, largely to capture the growing Indian market. Many generic firms have been acquired in the process. Many joint collaborative ventures have also taken of- largely for marketing purposes. However, such acquisitions have also been a host of potential concern due to their long term effect on generic competition. The current trend in acquisitions which started with the acquisition of Ranbaxy is expected to stay for long. The concern is due to possible change in strategies of generic companies to engage in price competition in domestic market. Such consolidation is also witnessed due to drastic change in patent norms- now allowing for product patents since 2005. Polices of open FDI is also acting as an incentive for increasing consolidation and market concentration.

On the innovation front, the R&D based pharmaceutical industry globally is running through productivity crises. Very few new chemical entities have come out. However, the innovative pharmaceutical industry is actively engaged in incrementally modified drugs and other forms of derivatives are under rapid development and introduction. Patents are generally regarded as the source of medical innovation. The pharmaceutical industry heavily relies on the patent system and hence the patent system is increasingly under stress due to flux of applications. In India, most patent applications filed on products are foreign owned. The introduction of the product patent regime in 2005 has paved the way for increase in foreign filings. However, the relation between patents and innovation structure still remains a challenged paradigm. It is noted that India's performance in generating new inventions has been low even considering patents filed by Indians at the USPTO. However, this must not be attributed as competitive weakness in the pharmaceutical sector. The Indian industry is slowly witnessing a catch-up in high end drug discovery and innovation.

The pharmaceutical markets in India are growing at an exponential rate. However, price competition among retailers can be hardly witnessed. The Indian pharmaceutical market has three types of substitutable drugs being sold. The first category includes originator drugs (patented or newly innovated) - they have a brand name. The second category includes brand name generic drugs. The third category is generic-generic drugs- which are sold without a brand name. As per ORG IMS research provisional estimates, India's pharmaceutical market may grow 12-13 percent in 2009; ORG IMS had earlier forecast a 14-15 percent growth but has revised it down, given the current global economic turmoil. However, the pharmaceutical supply chain is beset with problems. Many problems may occur, however, whenever consumers find it difficult to evaluate the qualities of the products, as is the case in the pharmaceutical sector. The problem is that the information asymmetries may prevent effective brand name generics from competing with innovator products, generic-generics competing with brand name generics and innovator drugs etc… In the pharmaceutical sector, it is known that the innovator drug is the standard of quality; the issue is not whether the innovator is effective, the issue is whether the generic is as effective as the innovator. There is a real danger, therefore, that consumers/ physicians who find it difficult/ costly to evaluate the qualities of generics might develop a strong preference for innovator medication or have a brand preference among the generics. This is true especially for the physician who has had a bad experience prescribing one generic medication in the past and decided to shun all generic medication.

The drug promotion matrix reveals that there are various unfair trade practices prevailing in the industry. Considerable amount is spent in such activities. In fact, authoritative studies, including those by the EU competition commission have noted that pharmaceutical companies spend more on promotion and advertising and less on research and development. Such practices are also recorded through existing reports and experiences in the pharmaceutical sector. Studies have reported that there is some anecdotal evidence, and there have been news reports in popular media, including medical and other journals highlighting the nexus between different actors in the supply chain emphasizes the need for a further comprehensive study examining various issues. There is evidence of inefficient allocation of resources in the distribution of pharmaceutical products as studies available indicate that the profitability margins of different actors is quite high and keep huge mark-ups for non-DPCO drugs and non-scheduled drugs in the pharmaceutical industry in India. This has implications on competition in the sector and unfair enrichment through wealth transfers.

The study has made an attempt to capture the attitudes and opinions of major stakeholders about the substitutability of prescription medication. Certain evidence pertaining to materials used in drug promotion and advertising is also studied. This is to suggest that consumer preference for branded and generic prescription medication is related to relative prices, reputation and budget constraints. The study has brought out some interesting facts about how various actors in the supply chain influence preference for a particular drug.

Drug procurement in India is done largely by the government. However, it is not more that 10% of the overall expenditure on health. Hence it constitutes a small but significant figure in consumption of pharmaceuticals in India. Drug procurement on behalf of the government is undertaken by various ministries, primarily the Ministry of Health. There are special programmes undertaken by the government. They are also actively involved in procurement. Prior to 90's drug procurement in most states was decentralized. However, problems in shortage and wastage have led to centralization of drug procurement in most states. The study has examined the most popular drug procurement model of the Tamil Nadu Medical Services Corporation, popularly called as the "Tamil-Nadu model". Established in 1995, the model has proved to be one of the most efficient ones in drug procurement.

The success of the model is because it has larger involvement of multi-stakeholders in selection and finalization of the drug requires to be procured. The tendering process is based on the TN Transparency in Tenders Act, 1998 and rules of 2000. After due advertisement, tenders are sought in two covers- one for the technical bid and other for the price bid. There are clear guidelines and forms for submission of both the bids. Once the bids are received, as series of finalization and evaluation process is undertaken. It is interesting to note that the TN model allows for a flexibility margin of 15% as earnest bid required from the small scale industry. The study notes that there is considerable price difference between prices retail prices and TNMC prices. While there is general downward trend in prices, studies show that the year 2007-2008 saw an increase in prices of more than 50% of drugs procured. It is noted that competition is low in case of high-priced specialty drugs.

Issues concerning regulation are at the heart of competition. The study starts with the current structure of Intellectual property law and the issues they pose to e*x ante Competition*. Patents are a major source of market power in the absence of effective product market competition. It must be noted that patent system is at the core of price competition related issued among branded and generics. Generic entry after the expiry of the patent is a major reason for drastic fall in prices. The Patent Act, 1970 since its inception did not provide for product patents. This was in the light of experience prior to 1970 when product patents led to aggressive monopolies by pharmaceutical MNCs. It was noted that the prices were one of the highest in the world. Hence two expert studies conducted by the government resolved in favour of withdrawal of product patent regime for pharmaceuticals. The TRIPS Agreement (1995) as a cornerstone Agreement in setting common binding standards has mandated that both products and process patents in all fields of technology shall be available. Hence the 2005 Amendment to the Patents Act, 1970 reintroduced product patents for pharmaceuticals.

The study discusses the content of patent law in relation to pharmaceuticals. It notes that section 3(d) of the Patents Act is a major public health safeguard. It is noted by experts that out of 68 cases so far where a pharmaceutical patent application was opposed by generic companies and/or public health groups, the patent office rejected the patent in 46 cases (i.e. approximately 68% of the time). In these 46 rejections, around 60% (28) were based on failure to comply with section 3(d). This briefly illustrates the importance of section 3(d) in preventing "evergreening" of pharmaceutical inventions. However, the section is best with legal complexities and has been a subject matter of dispute since its inception. The Novartis case is now appealed to the Supreme Court. The working of the pre-grant and post-grant opposition mechanism has also proved to be beneficial. An appeals court decision has made it mandatory to hear the request for a pre-grant opposition even while it was mere discretionary on the part of the patent office. It is noted that pre-grant opposition is a right and a right granted under a statute cannot be enforced without the remedy of hearing. While pre-grant opposition acts as a screening to weed out questionable patents, it may not act as a full proof mechanism. Other limitations and exceptions are also important-mainly, scope of research exemptions, government use, bolar provisions and parallel imports. Although there are no judicial decisions calling to question the scope of such exceptions, the study has argued for a broader interpretation advocating the fill use of flexibilities under TRIPS Agreement. Recent landmark judgments reviewed during the course of this study reveal

increasing restraint on the part of the judiciary in granting temporary injunction when the validity of the patent is called into question.

The Patents Act, 1970 also allows for compulsory licensing in certain cases. It must be noted that compulsory license is based on a payment of a certain agreed royalty rate to the patent holder. Unlike other exceptions, the use of compulsory licnese cannot be without patent to the patent holder. The compulsory licensing provisions available under the Indian Patent Act could be broadly classified into (a) general compulsory licensing provisions, (b) a provision relating to pharmaceutical patents in case of emergency, and (c) a licence to export pharmaceuticals to countries with insufficient manufacturing capabilities. The grounds on which a general compulsory licence can be requested by an interested person after the expiry of three years of granting of patent are: (a) the reasonable requirements of the public have not been satisfied; (b) the patented invention is not available to the public at a reasonably affordable price and (c) the invention is not worked in the territory of India. The section also explains the circumstances that result in not satisfying the reasonable requirement of the public. Protection of the existing trade and industry, development of new industrial activities, promotion of export, availability of the product at affordable price, prevention of unreasonable terms–such as grant-back requirements, packaging, prevention of challenges–in voluntary licences, exploitation of the market based only on import etc. are the circumstances covered in this provision.

While the three year rule is only because of an international commitment under Paris Convention, which states that in case of non-working of the patent a compulsory license shall be issued only after the expiry of three years. However, the Patents Act, 1970 makes such a rule applicable in all cases, except in cases of emergency. It is evident that current CL provisions does not allow for grant of CL prior to three years even in case of anticompetitive practices provided for that Act. Next, the effectiveness of CL can be questioned since the mechanism is not time bound. Further, the emergency provisions can do away with rigid procedural formalities by a mere notification by the government. It is expected that compulsory licensing provisions may act as a deterrent to the ability of patent holders to set high prices.

The introduction of the Protection and Utilization of Public Funded Intellectual Property Rights Bill, 2008 in the Rajya Sabha in December 2008 has triggered debates among public interest organizations, science policy makers, academia, and other stake holders including some sections of the industry on issues of Intellectual Property (IP) protection of public funded research as envisaged in the Bill. The PUPFIP Bill proposes the mandatory creation of intellectual property on all public funded research. It further provides that the ownership of such intellectual property rights shall lie with the university/institution which has got government funding which can then license the IPR to private parties. These private parties can then commercialize the research and bring it to the market. These proposals have led to concerns that there are few safeguards in the Bill to ensure that the public interest is paramount in setting research priorities or that products of such public funded R&D are available and affordable. Experiences in comparative jurisdictions show that the Bayh Dole (US law) law has not lived up to the virtues of providing general stimulus to all research based institutions. The results are highly skewed. Further there were also problems relating to licenses and price related considerations. Experts from the US have sounded an alarm for developing countries against the Bill and have recommended developing countries not to imitate the Bayh Dole as it was not a complete success. Apart from this, the long term implication of this law on publicly funded R&D is not clearly examined. Hence the Bill may prove to be a primarily reason for higher prices of patented products generated out of publicly funded research.

Many countries regulate drug price directly or indirectly. It is understood that some form of price regulation is necessary to maintain price competition in pharmaceutical markets. Some countries also effectively regulate prices of patented drugs through different means, including price negotiations and other methods of price control. On issues concerning price controls it is noted that prior to 1962 there was no price control, price of medicines were high, domination of MNC. First Price regulation in Medicines was introduced in 1962. Drug Prices Control Order issued under the Essential Commodities Act, 1955 has been in place since 1970s. Subsequently DPCO was revised in 1979, 1987 and 1995. Currently there are 74 drugs under price controls. The Hon'ble Supreme Court in the *K.S. Gopinath case* (2003), directed the government to ensure that "… essential and life-saving drugs do not fall out of price control". However, the dwindling numbers from the list of scheduled drugs under price control conveys a different story. Prices are controlled both for bulk drugs and formulations

which are scheduled drugs. They are taken from the national essential drug list. There are formulas and procedures which the NPPA takes into consideration. The NPPA is also mandated to monitor prices for non-scheduled drugs including patented drugs and control prices thereof.

There have been recent attempt to bring out a formula for price negotiations of patented drugs. While there is committee constituted under the department of pharmaceuticals, no relevant background papers are available in the public domain. As per interviews and informal sources, the price negotiations of patented drugs will be based on lowest market price available. There are three categories envisaged for this purpose. First category: Patented drugs where drugs are of significant therapeutic efficacy and substitutes are not available. Second Category: Patented drugs where drugs are of significant therapeutic efficacy but substitutes are available. Third category: Patented drugs without significant therapeutic efficacy. Under price negotiations for patented drugs, only the first category will be considered. If the prices marked by companies is lowest in the world (market price as reference price), than further negotiations will not ensue. However, if not, then negotiations will be made to bring it down to lowest world market price. Further 40-70% reduction is envisaged for prescriptions generating out of public facilities. Price negotiations as opposed to price control may not bring down the costs so as to make it accessible to the public at large. It may also undermine the use and willingness to utilize safeguards available viz., compulsory licensing under the Patents Act, 1970. Without effective price control, it is noted that the skewed nature of pharmaceutical markets would allow firms to fix prices without the acting of market forces. Hence price controls which duly acknowledge costs and certain amount of profits are a prerequisite in the pharmaceutical industry.

Drug regulation can play a significant role in enhancing or reducing ex ante competition in the pharmaceutical market, including the early entry of generic drugs. The Drugs and Cosmetics Act, 1940 is one of the major regulatory norms based framework which actively decides on entry of pharmaceutical products into the market. The purpose of the Drugs and Cosmetics Act is to regulate the sale, manufacture, distribution and sale of drugs in the country. The main objective is to prevent substandard drugs for maintaining high standards of medical treatment and to eradicate the dilution of the necessary concomitants of medical or surgical treatment The Act clearly mentions that its provisions have to be implemented in addition to other laws existing in relation to drugs. There have been concerns about the certain definitions in the Act which have defined the term "spurious". It is apprehended that this will be used as a potent weapon to enforce intellectual property rights which are private in nature. While it is true that drug safety issues are a core concern, the misuse of certain recent amendments is also apprehended. All this has come in the light of some studies claiming that 35% of fake drugs in the world were from India. However, no systematic study has been undertaken to generate any credible data. The Indian Government's own estimates for the extent of spurious drugs vary between 0.24 to 0.47 per cent and for substandard drugs from 8.19 to 10.64 per cent.[214]

Good manufacturing practices are in the form of drug safety standards. GMP standards are laid down by the WHO. Schedule M, which implements the GMP deals with requirements for plant, equipment and premises for pharmaceutical products. The National Human Rights Commission in 1999 made certain recommendations regarding manufacture, distribution and storage of drugs and the need to upgrade good manufacturing practises under schedule M. WHO had also prescribed guidelines. The Parliamentary Standing Committee on Health and Welfare in their 12th report on Drugs and Cosmetics (Amendment) Bill, 2005 had recommended stringent measures against manufacturing spurious and sub standard medicines and drugs. Following such practises, it felt, was necessary for sustaining export of drugs. This called for an amendment of Schedule M. Amendment of Schedule M was done at the Bureaucratic Level, as only the Drugs Act Amendments need Parliament approval. But its implications are immense. The pretext of amendment was improvement of quality but SSIs claim that there are unreasonable clauses of the Amendment which are not acceptable to the SSIs as they may eliminate SSI. There arose a huge debate with respect to these amendments and the Najma Heptullah Committee was constituted to study the impact of implementation of the revised schedule M on the small scale pharma units in the country.

[214] A report of the Expert Committee on "*A Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs",* Ministry of Health, Government of India, November 2003.

The Committee put forth certain questions to the Ministry of Health with regard to new amendments and it impact on SSIs. The Ministry was of the opinion that the amendments would not be detrimental to small scale units.

The regulation of biologicals in India is controlled by the Drug Controller General of India (DCGI) and Central and State Drugs Control departments like Central Drugs Standard Control Organisation (CDSCO) and Drug Regulatory Authorities (DRAs). There are no special guidelines for approval of biosimlars in India. The regulations that are in force are the Drugs and Cosmetics Act, 1940 and rules therein (Schedule-M), WHO current Good Manufacturing Practices (cGMP) requirements, Indian Council of Medical Research's (ICMR) Good Clinical Practices (GCP) guidelines, and the Indian Pharmacopoeia. All regulations fall under the Schedule M of the Drugs and Cosmetics act and the relevant ICH guidelines on manufacturing of drug substances. Currently, there are no separate guidelines in India for biotechnology products. Though, there are certain relevant US Food and Drug Administration (US FDA) and European Medicines Agency (EMEA) guidelines that cover these products. The MNC groups have requested to consider establishing regulatory criteria for the approval and consideration for comparability to the innovator product. These would be on the basis of 'prescribability' and 'switchability'. The battleground for the approval of biological drugs is still unsettled in the US. The FTC is looking into the issues to ensure early entry of bio-generics.

Clinical test data generated by originator companies have come to be of special significance when read with Article 39.3 of the TRIPS agreement. However, the terms in Article 39.3 provide flexibility to countries, allowing them to interpret the provision in the manner that would suit them best. As per 'data exclusivity', the regulatory authority cannot rely on data submitted by the originator for approving the second and subsequent applications for the same product. The approach to be taken under this provision in India gave rise to a huge debate. Data exclusivity would also affect the generic pharmaceutical industries in the country and also lead to an increase in prices in the country. The Satwant Reddy Committee was set up to address this issue and to recommend appropriate measures in this regard. But they have not recommended date exclusivity. A Parliamentary report has confirmed the same position that India need not provide for data exclusivity at this juncture as a matter of policy choice. The issue has been at the heart of debate since the MNCs are strongly lobbying for the same. In a recent development, pharma Major Bayer sought to restrain generic competitors from getting their patent infringing version from marketing approval. This was an attempt to bring in patent linkage within the Indian drug regulatory framework. However, a HC decision has settled the position that a drug regulatory forum cannot be used to police patents and hence the concept of linkage cannot be read within the Drugs and Cosmetics Act or in the Patents Act, 1970. Patent linkage can have tremendous implications for generic entry since test data may then not be relied under the expiry of the patent.

Consumer drug information includes all information directed to patients and consumers regarding drugs and treatments used by them with a view to enabling them to take informed decisions. The need for such information emanates from the basic right to the health of individuals. The availability of consumer drug information in India is very low in terms of quantity. Information is not provided in a user-friendly manner in most cases. The current law and policy regime does not deal comprehensively with issues of consumer drug information.

The supply chain and interactions among various actors in the supply chains reveals a web of unfair practices. Examining various regulations in place it is noted that there is no practical legal distinction made between prescription and non-prescription medicines in many cases. As per the law, the direct to consumer advertising of OTC pharmaceuticals is allowed in India. Certain advertisements may run afoul of the law. There is no adequate regulation on prohibiting promotion of drugs inconsistent with approved information. There is no adequate regulation on prohibiting disguised drug promotion. There is no statutory framework, except the code of ethics of the Medical council of India to suggest that no gifts/financial benefits/benefits in kind should be offered to health care professionals as inducements to prescribe particular medicines. Drugs and Magic Remedies Act does not have a full proof mechanism to require that promotional materials are submitted for pre-approval. Except for the Advertising standards council of India code, no other statutory provision can be pointed out that sets out specific standards in relation to information available on the internet i.e. to prevent consumers from gaining inappropriate access to information. Further, the pharmacy Act does not allow for generic drug substitution. Many studies have noted that countries which have allowed for drug substitution have seen low consumer spending on drugs. All such

loopholes in the regulatory framework can have both long and short term implications on prices and pharmaceutical consumption.

In examining the competition law, the study has undertaken an overview of the conceptual, policy and practical foundations for the application of competition law in the pharmaceutical industry and markets. The study reviews the positions in comparative jurisdictions (primarily United States of America (US) and European Union (EU). Positions in comparative jurisdictions are examined by referring to respective legislative provisions and through the developments in case law jurisprudence. The starting point with reference to the EC treaty and application of Articles 81, 82 along with council regulation 139/2004 (the Merger Regulation) and block exemptions are looked in to. Similarly the Antitrust law in the US governed by the *Sherman Act, 1980, Clayton Act, 1914 and the FTC Act, (1914), Title 15 U.S.C. §§ 41-51and the Robinson-Patman Act of 1936* (as amended up-to date) are among the legal texts considered.

From both the demand and the supply side perspective, any drug that is marketed for human use should have some therapeutic effect. A therapeutic effect is a consequence to a medical treatment on any type or degree, the results of which are judged to be desirable or beneficial. This is irrespective of the intended benefits of the drug in question and its actual working, and includes side effect or undesirable effects also. It is not necessary that both the US and the EU follow similar therapeutic classification- for e.g. the European Commission follows the European Pharmaceutical Market Research Association (EPhMRA) classification system, which is structurally similar to the standardized Anatomical Therapeutic Chemical Classification System. The US has not officially subscribed to the classification.

The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses (ATC/DDD) system classifies therapeutic drugs. The Anatomical Therapeutic Chemical (ATC) classification system divides the drugs into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

Defining relevant market is *sine qua non* in assessing the market power/share of the violator in question. Thus the key question would be to define the relevant market in question and identification of the market power in the particular market. Defining the concept and practice of 'relevant market' is essentially an economic one. However, competition law and case law developments in comparative jurisdictions do provide the necessary framework essential for legal certainty and for defining the thresholds. However, they are only persuasive in nature. Experience in comparative jurisdictions suggests that in non-merger cases, the FTC/ Commission and private plaintiffs generally argue for narrow markets, limited to a single drug and its generic equivalent in some cases and to generic drugs excluding the bioequivalent 'brand-name' (all drugs under valid patents are called brand name drugs in the US) drug in other cases. In its merger challenges, on the other hand, the FTC has alleged markets ranging from those based upon a particular chemical compound, to broader markets based upon various drugs' manner of interaction or dosage form, to still broader markets of all drugs used to treat a disease or condition. In numerous pharmaceutical merger challenges, the competition authorities have included in the market not only currently marketed drugs but also other drugs under development, by considering "innovation market". As market definition issues are extremely factual and often resolved in appeals, there are only few pertinent court decisions providing guidance about how to define markets in the pharmaceutical industry.

Certain relevant product markets identified in the US context involving combinations have included: drugs for the treatment of a particular disease or condition; drugs; that have the same mechanism of action, and (iii) specific compounds. Various commentators have emphasized that the FTC-DOJ decisions on defining pharmaceutical markets lack consistency. It has been noted in many cases that the SSNIP test could apply only with major variations. A brief summary of review of FTC Cases would suggest that there can be a variety of factors that the FTC-DOJ may consider for defining relevant product markets in pharmaceuticals, including but not limited to, for example, whether drugs have the same dosage and delivery forms such as injectable, liquid, capsule, tablets, or topical; whether drugs have the same frequency of dosage, such as

once -a- day or extended release; whether drugs have the same strength of dosage, distinguishing, for example, 15mg and 50 mg tablets; whether drugs are branded or generic; whether drugs require a prescription or are sold over-the counter; whether drugs are currently marketed or are in development; whether drugs treat the same disease, condition, or indication; whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same "mechanism of action"); whether drugs have the same specific chemical compounds. It is pertinent to note that patented product may in itself form a relevant product market provided other factors are fulfilled. The above tests adopted have at times considered some or few of these above mentioned considerations in defining relevant product markets. It points to the flexible nature of tests that have emerged in comparative jurisdictions. Thus fundamentally, the tests to determine relevant product market in case of pharmaceuticals are not static. Relevant policy consideration may go into determining the exact nature and scope of the definition.

On the other side of the Atlantic, few other cases have tried to define what should constitute relevant product markets within the context of EU Competition Law. In one of the high profile merger cases, although allowing the merger, the Commission in its opinion relying on past cases and practices the commission applied the ATC classification devised by EphMRA and has stated that the *third level of the ATC classification* allows medicines to be grouped in terms of their therapeutic indications and can therefore be used as an operational starting point for market definition. However, in certain cases it may be necessary to analyze pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC 3 classes on the basis of demand-related criteria. The Commission also defined separate markets for OTC (as opposed to prescription) pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories. A review of case laws defining relevant product markets in pharmaceuticals essentially suggests that pharmaceutical markets are fundamentally different from other markets. Who is the customer- since doctor chooses and the patient pays? Does price matter at all- since costliest drug is the top selling? Should a single drug define the market in-itself? Should generic drugs be in the same market as pioneer drugs or a distinct product market? Further there is little guidance from comparative jurisdictions whether the "*Cellophane* trap" applies in case of pharmaceutical product. Defining pharmaceutical product markets requires a thorough understanding of the role of government regulation, technological innovation, and competition in the industry.

It is vital to the assessment of relevant market to know the geographical boundaries where the market power is alleged to have been exercised in an anticompetitive manner. The definition of relevant geographic markets has had impact on the outcome of many cases. There may be legal, technical or practical reasons as to how one market may differ from the other. Market power is commonly defined as the ability to profitably charge prices above the competitive level for a significant period of time. Evaluation of the presence or absence of market power is a key element of most antitrust and competition analysis and many Competition commissions have issued guidelines on the evaluation of market power in the merger context and other areas. These guidelines typically follow the framework of market definition followed by calculation of market shares along with a summary measure of market concentration—typically the Herfindahl- Hirschman Index (HHI), which sums the squared market shares of firms in the relevant market. In performing market power analysis, other structural features of the market are also considered.

Business undertakings get into routine agreements for carrying on economic activities. While not all agreements can be termed as anticompetitive, certain agreements between competing firms or among firms in the supply chain may constitute a violation of competition law. Agreements can either be horizontal or vertical. Mergers are a form of horizontal agreement but they raise distinctive competitive concerns. The concept of restriction on competition is an economic one. Thus generally economic analysis is needed to determine whether an agreement could have an anticompetitive effect. A small class of agreements may be considered to have as their object restriction of competition. Article 81 of the EC Treaty deals with the treatment of anticompetitive Agreements. The US law on anticompetitive agreements is contained in section 1 of the Sherman Act.

Article 81 is applicable both to horizontal and vertical agreements. Horizontal agreements are those between undertakings at the same level of market, while vertical agreements are between undertakings at different levels of market. The policy of Article 81 is to prohibit cooperation between independent undertakings which prevents, restricts or distorts competition.

More specifically, it is concerned with the eradication of cartels and 'hardcore' restrictions of competition. Article 81(1) prohibits agreements 'which have as their *object* or *effect* the prevention, restriction or distortion or competition'. Thus either of the conditions is necessary for the application of article 81 (1). Thus it is important to classify agreements that have anticompetitive object vis-à-vis agreements where the effect is anticompetitive. This is also similar to section 1 of the Sherman Act in the US where agreements are characterized based on *per se* rule or *rule of reason* analysis. It is important to note that in case of agreements where the object is anticompetitive, it is not necessary to prove that anticompetitive effects would follow. Thus under Article 81(1) the EC evaluates agreements relating to price fixing, exchange of current or future price information, sharing or allocating markets, limiting outputs, collective exclusive dealing as forming part of horizontal agreements where the object in itself is anticompetitive. Among vertical agreements, the EC evaluates fixing of minimum resale prices and imposing of export bans. In case of agreements which have possible adverse effect on competition, the evaluation of such agreements shall depend upon extensive analysis of the agreement in its market context is required to be done. There is also a need to establish the counterfactual in such cases so as to show what the position would have been in the absence of the agreement, of that the agreement could have effects on competition. Furthermore, not all agreements (horizontal or vertical) have actual effects on markets. This is due to their weak position in the market concerned. This is called as the *deminimus* doctrine. A general exemption from the application of Article 81(1) is contained in the legal exception created by Article 81 (3). Article 81 (3) of the EC treaty is satisfied when an agreement contributed to improving the production or distribution of goods or to promoting technical development or economic progress; or while allowing consumers a fair share of the resulting benefits. Such agreements to qualify Article 81 (3) must not impose on the undertakings concerned restriction which are not indispensable to the attainment of these objectives, nor, afford such undertakings the possibility of eliminating competition in a substantial part of the product in question. Article 81(3) can also be satisfied if the agreement in question falls into one of the block exemptions issued by the EC or by the Commission. There is a worldwide consensus against hard core cartels. Horizontal agreements between undertakings to fix prices, divide markets, to restrict output and to fix the outcome of competitive bidding are the most contentious among the variety of targets of competition authorities in comparative jurisdictions. It is clear from the decisions of the commission that price fixing in any form is caught, including the obvious blatant price fixing. Thus there is a body of decisions that have condemned agreements which might directly or indirectly facilitate level price fixing.

The *Vitamins case* (2003) is one of the most severe cartels that occupied considerable attention of competition authorities' world over. The EC Competition Commission fined eight undertakings totaling to Euro 855.23 million (reduced to Euro 790.50 million) for running the vitamins cartel. Foreign MNCs like Roche, BASF, Aventis were found to be involved in cartels. However, Aventis paid substantially less as it turned out to be the whistle blower. It must be noted that price fixing in any form is caught. Article 81 (1) and its application in any cases have led to the emergence of a set of jurisprudence that it is not just blatant price fixing that is caught, but also any agreement that might directly or indirectly suppress price competition. Cases also suggest that it is not a defence that a participant in a cartel sometimes does not respect the agreed price increases. However, the most important aspect of the cartel is that the leniency programme helped a great deal in ascertaining the cartel. The prosecution in the vitamins case is the cornerstone of treatment of complexity presented by cartels. This study has comprehensively discussed the Vitamins case. Quota restrictions may also take form of cartels. If output is limited or reduced, price will rise- and hence output restrictions have the same effect as price cartels.

Collusive tendering agreements also form part of horizontal agreements that pose significant anticompetitive effects on the market. However, it is not necessary that such collusive tendering agreements do affect the markets in reality. Such agreements are condemned *per se*. A review of collusive bidding cases in the EU does not show action taken against pharmaceutical companies. There may be many forms of collusive bidding. The firms may agree to quote identical prices, or parties may rotate the bid, form complementary bidding, subcontracting etc... Information exchanges may at times result in action under Article 81 of the EC treaty. It is important to note that this issue has been given thoughtful consideration over many years. There are relevant test the ECJ jurisprudence lays down in identifying what type of information sharing should be exempted from the application of Article 81 (1). Thus in case of information agreements a full market analysis may be warranted since such an agreement is not condemned by object but by effects on the market.

Since competition law cannot prohibit all horizontal agreements outright because of efficiency gains that may follow from cooperation that are sufficient to outweigh any restriction on competition that might ensue, the Commission adopted *Guidelines on Horizontal Cooperation Agreements* in the year 2000. The guidelines state that horizontal cooperation agreements may lead to substantive economic benefits, in particular given the dynamic nature of markets, globalization and the speed of technological progress. In particular, of much importance to pharmaceutical sector is the treatment of R&D agreements under the Commission's guidelines. Such agreements are evaluated on the basis of their effects, rather than objects, since the object of such agreements are not among the hard core restrictions on competition. The Commission shall evaluate agreements based on their nature. The starting point in the Commission's approach to evaluating R&D agreements is to see whether an agreement could have the effect of restricting competition by analyzing the position of parties in the market. This would essentially require the evaluation of relevant markets as evolved by the Commission through its guidelines and practices.

The commission considers that R&D agreements would normally fall outside the scope of Article 81(1). But those R&D agreements which have in them elements that can effect or restrict competition may well fall within the scope of Article 81(1). Thus Regulation 2659/2000 provides for a block exemption on R&D agreements. Horizontal agreements between unrelated rivals not to business with another firm/s are also considered *per se* illegal boycotts under EU and US antitrust law. While there are no case laws from comparative jurisdictions on group boycotts in pharmaceuticals, some guidance can be deduced from cases in other products.

Producers of goods will distribute their products into the market either directly to consumers or through a supply chain in the market. At the same time there can be consumers who purchase goods for their own use or for further selling. Contracts are the basis for such transaction and the legal tradition has been responsive for valuing such contracts. Thus there may be concerns that vertical agreements can have appreciable adverse effect on competition. Not all vertical agreements can be categorized as restraints, but certain agreements surely will. Since such contractual agreements cannot be avoided as a matter of practice, they need to be evaluated based on their impact in the market. However, there can be *per se* invalidation of certain type of vertical agreements. In fact, until very recently, the US followed an approach to condemn resale price maintenance on *per se* basis until it was overruled by decision in 2007. Thus it would be pertinent to evaluate each of such possible agreements from a comparative jurisdictional point of view.

The oft cited pro-competitive benefits of vertical agreements in promoting a healthier distribution system are well known. In one of the seminal decisions of the US Supreme Court where the validity of resale price maintenance was questioned, RPM were held to be unlawful per se. In this case retail druggists were fixing prices and using manufacturers as their "enforcer". Here the US Supreme Court implicitly noted in the decision that the enforcement of prices through examination of the record led to facilitating cartels, which was the main function of imposing RPMs. However, the decision did not address situations where RPM may not have been used to facilitate collusion or where economic understanding of the effects of RPMs was that they produced pro-competitive benefits.

In the EU, the Block exemptions provided by regulation 2790/99 OJ [1999] L 336/21 provides useful guidance on the type of practices exempted under the category of vertical restraints. These exemptions typically provide 'safe havens' for considering the scope of application of Article 81(1). Further, the *Guidelines on Vertical Restraints* are to be read in conjunction with the block exemptions. There are both pro-competitive and anticompetitive of such form of agreements. The combined effect of the *deminimus* doctrine and the block exemption is that most vertical agreements where the market share of each of the parties is below 15% will fall outside the scope of article 81 (1). Further, most vertical agreement that might violate Article 81(1) will be block exempted under the above mentioned regulation provided that the supplier's market share is less than 30% and that the said agreement does not contain any hardcore back listed provisions mentioned in the block exemption. The block exemptions also provide that the exemption shall be apply to vertical agreements "containing provisions which relate to the assignment to the buyer or use by the buyer of IPRs, provided that those provisions do not constitute the primary object of such agreements and are directly related to the use. Sale or resale of goods or services by the buyer or its customers". However, the application of such a rule is fraught with difficulties. The most common form of vertical restraints are single branding agreements, exclusive distribution agreements, exclusive customer allocation

agreements, selective distribution agreements, franchising agreements, exclusive supply agreements, tying agreements, recommended and maximum resale price agreements. The four factor test is applicable in evaluating whether such agreements have pro-competitive effects on the market.

Abuse of dominance basically concerns itself to the unilateral acts of dominant firms as it might infringe competition laws. Article 82 of the EC Treaty prohibits abuses of a dominant position. As per the case-law developments, it is not in itself illegal for an undertaking to be in a dominant position and such a dominant undertaking is entitled to "compete" on the merits. However, the undertaking concerned has a special responsibility not to allow its conduct to "impair genuine undistorted competition" on the common market. In the US, section 2 of the Sherman Act makes it unlawful for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations . . . ." The first step in the application of Article 82 requires the assessment of whether an undertaking is in a dominant position and of the degree of market power it holds. Developments in case-law emphasize that holding a dominant position confers a special responsibility on the firm concerned, the scope of which must be considered in the light of the specific circumstances of each case. Dominance has been defined under EC law as a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on a relevant market, by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers. The Commission may consider a combination of several factors to ascertain the dominant position derives from a combination of several factors which, taken separately, are not necessarily determinative. It may also consider that effective competitive constraints are absent even if some actual or potential competition remains.

In case of price base exclusionary conduct leading to anticompetitive foreclosure, the approach of the EU Commission is to intervene only where the conduct concerned has already been or is capable of hampering competition from competitors which are considered to be as efficient as the dominant undertaking. Thus to determine whether even a hypothetical competitor as efficient as the dominant undertaking would likely be foreclosed by the conduct in question, the EU Commission will examine economic data relating to cost and sales prices, and in particular whether the dominant undertaking is engaging in below-cost pricing, on the condition that sufficiently reliable data are available. The cost benchmarks that the Commission is likely to use are average avoidable cost (AAC) and long-run average incremental cost (LRAIC). If the data suggest that the price charged by the dominant undertaking has the potential to foreclose as efficient competitors, then the Commission will integrate this in the general assessment of anticompetitive foreclosure also by taking into account other relevant quantitative and/or qualitative evidence. Further, the EU Commission in the enforcement of Article 82, considers efficiency claims put forth by dominant firms will form part of the examination.

There are certain specific forms of abuse that need special consideration. A lot of jurisprudence has evolved since the implementation of the EC treaty and interpretation given by the Commission, CFI and the ECJ. Such practices are in the nature of: Price related abuse of dominance and non-price related abuse of dominance. In price related abuse of dominance exploitative pricing practices, predatory pricing, rebates that have similar effects to single branding agreements , margin squeezing, price discrimination are the major forms of conduct that form part of abuse of dominance under Article 82. In non-price related practices, tying and bundling, exclusive dealing, refusal to supply are considered as the type of conduct demanding the application of Article 82.

Again, excessive prices can be detrimental to more than a single market when the owner of an essential facility charges an excessively higher price for granting access to such facility and this could be regarded as constructive refusal to supply consequently leading to the abuse of dominant position. The best example for this is the Commission's finding that Microsoft had charged unreasonably for accessing interoperability information. While it is difficult to assess costs, it is not totally impossible as explained by some reports of the UK OFT also confirmed by a decision in the UK. However, Competition commission's in comparative are averse to price regulation. The South African Competition Commission has showed that there can be abuse of dominance through excessive pricing of patented pharmaceutical products. It was under pressure from South African Competition Commission that GSK, which was the world's largest producer of AIDS medicine holding a 50 percent stake of the $5 billion market, was forced to issue licenses on two major antiretroviral (ARV) drugs-

known as AZT and Lamivudine- to four generic producers. In another similar case, Boehringer-Ingelheim (BI) was forced to license nevarapine – a major ARV to prevent mother to child transmission of HIV infection- to three producers. This led to forced but voluntary licenses being issued by drug companies to other producers at a low royalty rate of 5%. This case has turned out to be a trend-setter for developing country jurisdictions to follow a nuanced policy on addressing unfair and exploitative pricing policies adopted by drug companies in case of patented drugs.

The EU Commission will generally in cases of predatory pricing intervene where there is evidence showing that a dominant undertaking engages in predatory conduct by deliberately incurring losses or foregoing profits in the short term, generally termed as "sacrifice", so as to foreclose or be likely to foreclose one or more of its actual or potential competitors with a view to strengthening or maintaining its market power, thereby causing consumer harm. Thus the commission views conduct entailing a sacrifice if the dominant undertaking, by charging a lower price for all or a particular part of its output over the relevant time period, or by expanding its output over the relevant time period, incurred or is incurring losses that could have been avoided. The Commission will take AAC as the appropriate starting point for assessing whether the dominant firm incurs or incurred avoidable losses. Furthermore, the commission will also apply that test of harm to consumers, if sufficient reliable data are available. The efficiency argument will generally not hold well in predatory pricing cases. However, provided that the conditions mentioned above are fulfilled, the Commission will consider claims by dominant undertakings that the low pricing enables it to achieve economies of scale or efficiencies related to expanding the market.

A dominant undertaking may try to foreclose its competitors by tying or bundling. “Tying” refers to situations where customers that purchase one product (the tying product) are required also to purchase another product from the dominant undertaking (the tied product). Tying can take place on a technical or contractual basis. Tying occurs when the tying product is designed in such a way that it only works properly with the tied product (and not with the alternatives offered by competitors). Contractual tying occurs when the customer who purchases the tying product undertakes also to purchase the tied product (and not the alternatives offered by competitors). “Bundling” usually refers to the way products are offered and priced by the dominant undertaking. In the case of pure bundling the products are only sold jointly in fixed proportions. In case of mixed bundling, often referred to as a multi-product rebate, the products are also made available separately, but the sum of the prices when sold separately is higher than the bundled price. The EU Commission will take action under Article 82 where an undertaking is dominant in the tying market and where, in addition, the following conditions are met: (i) the tying and tied products are distinct products, and (ii) the tying_practice is likely to lead to anticompetitive foreclosure. Exclusive dealing refers to the strategy of a dominant undertaking which may try to foreclose its competitors by hindering them from selling to customers through use of exclusive purchasing obligations or rebates. It also includes exclusive supply obligations or incentives with the same effect, whereby the dominant undertaking tries to foreclose its competitors by hindering them from purchasing from suppliers. The EU Commission considers that such input foreclosure is in principle liable to result in anticompetitive foreclosure if the exclusive supply obligation or incentive ties most of the efficient input suppliers and customers competing with the dominant firm are unable to find alternative efficient sources of input supply.

There is no standard definition for the term ‘essential facilities doctrine’. Generally, it may be understood as a company which has a dominant position in the provision of facilities which are essential for the supply of goods or services on another market abuses its dominant position where, without objective justification, it refuses access to those facilities. Thus in certain cases a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed. The existence of an essential facilities doctrine has been acknowledged both in the European Union and the United States. Though there are differences in the way the doctrine is applied on either side of the Atlantic, the basic premise is the same: that where access to a facility is essential in order for a person to operate on a certain market, the owner of the facility may, in certain circumstances, be obliged to grant access to that person. Refusal to supply is seen as an important facet of the same. It is important to note in this context that the courts have never expressly used the term ‘essential facilities doctrine’ rather it appears that most such issues were dealt with under the broad rubric of ‘refusal to supply’ cases. Opinions of the United States courts also suggest that antitrust liability under the essential facilities doctrine is particularly appropriate only when denial of access is motivated

by an anticompetitive animus usually demonstrated by a change in existing business practices with the apparent intent of harming rivals. In general, the US Supreme Court has shown reluctance to apply the EFD doctrine. However, the EU position might be considered as more flexible after its decision in Microsoft. While the EFD can be especially helpful in accessing patented knowledge, especially in biotechnologies.

Competition law concerns itself with the possibilities of mergers and combinations (acquisitions and conglomerates) will lead to market being less competitive in future than it is currently. However, there are hardly few decisions rendered by the Apex courts on mergers and combination. Most of the principles are set the competition commissions and settled through consent orders. In cases involving mergers and acquisitions, the competition authorities across the world have followed an approach to define the markets as broadly as possible. The basic premise behind merger control is that it may lead to market concentration. Hence it is essentially based on the effect such combination will create on competition within a particular jurisdiction. The pharmaceutical industry, as noted above, survives in an oligopolistic structure. Hence merger control and regulation of combinations have special importance in this sector. While the commonly applied test has been has been to look at whether a merger or acquisition is likely to result in "substantial lessening of competition", this tests has no more restricted in to the product range. In the European context, the Commission is taking a further step for an innovation approach in the Merger Control, studying not only competition *in the market* but also *for the market*. The competition *in the market* approach, on one hand, takes into account the existing products and considers the R&D efforts only like a part of the product market. The competition *for the market* assessment, on the other hand, considers the R&D efforts, like a separate market from the existing products. This approach is called "*Innovation Market",* and supposes that the projects for the development of new products/services are analysed as a different market. It has its origin in the American approaches. However, this tests has come under heavy criticism because innovation is non-predictable and may not be desirable at all times; Innovation is speculative and includes unidentifiable market participants; the relationship between R&D and innovation is unclear, likewise the market structure most conducive to innovation is unclear.

However, despite severe criticisms the innovation market test in merger control has survived. Many cases examined in the US and EU context allude to this important fact. After having examined both the frameworks, it can be concluded that "*Innovation Market*" assessment has a very limited role in the European Merger Control where the R&D pipelines are focussed to new products and the rate of success is absolutely uncertain. The American approach is broader, and it is not limited to the European restrictions. The FTC is takes into account pipelines in early stages of the development process to define the *relevant "Future Market".* Thus, while in the American approach, the "*Innovation Market*" is intended to predict the future product market effects, the European approach, tries to establish the post-merger incentives to reduce R&D projects. The "*Innovation Market"* analysis is one instrument more in the hands of the Agencies to control the concentration operations. This extra-power is useful to avoid negative post-merger situations, which escape the traditional merger examination.

The issue of lawful exercise of Intellectual property is also under constant scanner. While both the jurisdictions treat IPR monopoly as not in fundamental conflict with competition law- as the object of both is to promote innovation and competition, it is not fully resolved if competition better facilities innovation or IPR does more so. However, the IP Licensing Guidelines issued by the US FTC-DOJ (1995) and the EU Technology Transfer Block Exemption provide a framework where IPRs are treated as not different from other forms of property. However, there are complex set of tests underlying the analysis of the relationship of IP vis-à-vis competition law.

Although intellectual property law and antitrust law are complementary, there are divergent decisions possible. Case law jurisprudence in comparative jurisdictions assert that unilateral right to refuse to grant a patent license is an integral part of the patent grant and that antitrust liability for mere unilateral, unconditional refusals to license patents will not play a meaningful part in the interface between patent rights and antitrust protections. It is noted that competition law liability for refusals to license competitors would compel firms to reach out and affirmatively assist their rivals, a result that is "in some tension with the underlying purpose of antitrust law." It is believed that such liability would restrict the patent holder's ability to exercise a core part of the patent—the right to exclude. Conditional refusals to license that cause competitive harm are subject to antitrust liability. In the EU, the *Magill and IMS* cases established the possibility of a claim to a license under

Article 82 in exceptional circumstances, in particular where such licensee intended to produce a new product for which there is a potential consumer demand. It test was severely applied in the recent case of *EU* v. *Microsoft* (2007), where the CFI held that Microsoft was dominant in two markets and had abused its dominant position by refusing to supply interoperability information.

In some cases decided by US courts, there has been a host of consent orders in pharmaceutical cases largely pertaining to drug settlements in the US also called as pay for delays. The US has a very unique system to patent term extension. Similarly they have a unique system for providing parallel entry of generics. The Hatch Waxman Act requires that 180 day exclusivity shall be given to the company first introducing the generic equivalent. As a consequence many generic companies and originator companies collude to give up the exclusivity or not to challenges patents. There have been conflicting decisions by the Federal Circuits mostly emphasizing that such agreements may not be anticompetitive since it provides the originator companies an opportunity to exercise it lawful monopoly during the term of the patent- thus promoting innovation. However, commentators have argued that there can be a case of presumptive illegality in case of drug-patent settlements. Currently, the US-FTC has petitioned the US supreme Court to declare them as illegal.

The nature of inherent conflict between grant and exploitation of IPRs vis-à-vis the resolve to keep the markets competitive has been traditional. Many economists of the Chicago and Post-Chicago school of thought remark that IPRs may not be in inherently conflicting with competition law. It is emphasized that the object of both the laws is to promote innovation by creating dynamic efficiencies. And yet, there is tension in the means in which rights conferred under IPRs may conflict with principles of competition law. The relationship amongst patents working as property and the structure of innovation is based on the *premise* that patents promote innovation, and not that it actually does so. Be it as may be, at least in case of pharmaceuticals, as noted in chapters above, it is an argument that without patent protection new medicines would not be invented. However, this view is at best, controversial. But one important aspect would be to consider what the possible situations if one were to depart from a static view of markets. It is clear that the EU and U.S authorities do not presume market power in case of patents and other intellectual property rights. It is presumed that they work like real properties. However, there is sufficient difference between real properties and intellectual properties, which the guidelines in US and EU fail to note. This distinction has been traditional. One reason behind treating IPRs and real properties distinctly is also because of the very nature of IP, which fails to set clear boundaries of innovation. Patent laws especially, doesn't provide sufficient note of the proper scope of rights.[215] In case of IP, subsequent innovation is built upon the earlier ones.

On the issues of licensing restrictions, the guidelines note that "Field-of-use, territorial and other limitations on intellectual property licenses may serve procompetitive ends by allowing the licensor to exploit its property as efficiently and effectively as possible. These various forms of exclusivity can be used to give a licensee an incentive to invest in the commercialization and distribution of products embodying the licensed intellectual property and to develop additional applications for the licensed property. The restrictions may do so, for example, by protecting the licensee against free-riding on the licensee's investments by other licensees or by the licensor. They may also increase the licensor's incentive to license, for example, by protecting the licensor from competition in the licensor's own technology in a market niche that it prefers to keep to itself. These benefits of licensing restrictions apply to patent, copyright, and trade secret licenses, and to know-how agreements". Thus the US approach warrants that most forms of licensing restrictions are always pro-competitive. It approaches the issue of licensing arrangements by assuming that they promote integration because as they facilitate the combination of the licensor's intellectual property with complementary factors of production owned by the licensee. As per the A restraint in a licensing arrangement may further such integration by, for example, aligning the incentives of the licensor and the licensees to promote the development and marketing of the licensed technology, or by substantially reducing transactions costs. If there is no efficiency-enhancing integration of economic activity and if the type of restraint is one that has been accorded per se treatment, the Agencies will challenge the restraint under the per se rule. Otherwise, the Agencies will apply a rule of reason analysis. Regulation 772/2004 on Technology Transfer agreements confers block exemption on technology transfer agreements pursuant to article 81(3) of the EC treaty. The underlying dictum in regulation 772/2004 is that technology transfer agreements usually improve economic efficiency and are pro-

[215] *Ibid.*

competitive (recital 5). However, it also notes that it also depends on the degree of market power and also on the degree of competition that will be faced by undertaking with substitute technologies or products. Unfortunately, there isn't much guidance through cases on the interpretation of allowable restrictions under the block exemption.

In India, the Monopolies and Restrictive Trade Practices Act (MRTP) was enacted in 1969 as per the recommendations of the Monopolies Inquiry Committee. The MRTP Act aimed to provide structural remedies in its attempt to curb monopolistic behaviour as such structural nature of the law, by which it was understood that beyond a particular threshold such anticompetitive behaviour affected competition adversely. However, it was restricted to the private sector. Later, in the year 1984, Sachar committee looked into changes requires in MRTP to make it more effective. The reforms of 1991 changed many perceptions about the MRTP, as it was thought that many provisions in the law were not favourable for create an environment for private investments. Certain provisions were off the Act. However, a further need to change the structural approach of the MRTP was felt by the Government and hence Raghavan Committee was appointed to look in to Competition Law and policy. Set up in 1999, the Raghavan committee reviewed the existing MRTP and found that there was no provision within MRTP to deal with anticompetitive practices, and thus declared that MRTP could not be amended without substantial changes. It suggested a new competition law for India. The Committee found fewer reasons to adopt a structural approach and suggested *per se* illegality rule only in few instances. In many other conducts, it as prescribed a *rule of reason approach.*

In the thick of all these changes the pharmaceutical industry in India grew. The industry saw that many of its practices being challenge and susceptible to the practices falling under MRTP. Some interesting cases have come up before the courts and tribunals during the MRTP regime. Although not all cases led to rationale outcomes, sometime the courts juggling with the application of certain provisions, it essentially remains the fact that economic analysis was not always an important ingredient in arriving at conclusions. Even though it relied on factual assertions, the case laws tend to adopt a structural approach. However, the courts when it came to interpretation of the Act went for the purposive interpretation. The cases mentioned here bear the testimony to the same. In some interesting cases the followed as an outcome of MRTP on price regulation, the courts have held that the restriction so imposed on the drugs and pharmaceutical products, fail to qualify the term so used as 'reasonably necessary'**.** It also opined that the new system of obtaining NOC/LOC will prove to be a detriment to the consumers as it will deny them the use of new pharmaceuticals and drugs and thus will be hit by the provisions of section 33(1)(b). Also the Tribunal failed to see, how the system as claimed will be affecting in the rise in unemployment in the sector. In another case the tribunal noted that higher price was coupled with falling sales leading to the maintenance of the price at an unreasonable level and high ratio of the profits to the share capital. In this connection, the Court was of the opinion that while the sale is dependent on the demand of the product in the market, the production of the product in turn depends on various factors. It was found that the price prevalent at the relevant period of time was stated to conform to the prices fixed by DPCO. Thus the charge of monopolistic trade practices was not maintainable.

On the issue of free sample distribution which raises anticompetitive concerns, the court held that since the drug so concerned has to be prescribed by the registered practitioner, the court believed that samples of drugs are to be tested first and then medicated. It was also agreed by the Tribunal that, *since marketing is one of the essential concomitant of sale, considerable cost is also incurred in the same.* In many ways, this decision has tacitly justified the issuing of free samples by drug companies to physicians, one of the methods in drug promotion. On the issue of price fixing among retailer and wholesaler, the Tribunal looked into the provision so encapsulated in the MRTP act, section 33(1) (d) and said that it deals with an agreement between the sellers or an agreement between the buyers. The impact of this decision is on those types of vertical agreements like resale price maintenance where fixing margins on recommended prices could lead to price escalation thereby reducing competition.

Another case on restrictive price maintenance, the Tribunal was of the opinion that since the prices are mentioned as maximum retail prices, it is obvious that the retailers are authorized to sell the drug less than what has been prescribed in the list. On the issue of boycott of the life saving drugs brought about by the active connivance and encouragement of the errant parties is a restrictive trade practice as it causes to consumers and general public considerable suffering because of non-availability of the medicines, commission rejected the argument of the charged parties that the boycott was only a non-

co-operation movement. The boycott was held to be a clear restrictive trade practice. In a case related to irregularities in issuance of tender, the court was of the opinion that the terms of the invitation of the tender are not subject to judicial scrutiny. The government always has a free hand in setting the terms of the tender. In a case that revealed the jurisdictional conflict between NPPA as a price regulator and MRTP as a Commission deciding on reasonability of prices and its impact on competition, the court asserted by the respondents in that case issues of pricing are considered by the NPPA that commission should look into pricing only when it has implications for competition. While the case was dismissed on grounds of the accused company having negligible market share, the issue of jurisdiction was not set any ratio. In a case related to excessive pricing, it was held that excessive pricing or pricing pattern having no relationship with the cost of the input is not anti-competitive if such a trade practice does not have the effect of preventing, distorting or restricting competition in the market.

The reforms of 1991 brought in the necessity of a new law dealing with issues concerning competition. The Raghavan committee report noted that most countries had modern legislations for preserving competition. It also noted that the existing MRTP was grossly ineffective to deal with new situations. The Indian competition Act, 2002 is clear to the extent that it is the effect of the monopoly that is the target of regulation and prohibition. The Act prohibits or regulates three type of activities:

- *Anticompetitive agreement (section 3)*
- *Abuse of Dominant Position (Section 4)*
- *Regulation of Combination (section 5 and 6)*

Since the Act was to a large extent a response to economic reforms and globalisation process and hence to maintain a standard law dealing with type of practices regarded as raising competition concerns is also responsible for the new law. After a long wait, on 15 May, 2009, the Ministry of Corporate Affairs notified certain sections of the Competition Act, 2002 by powers vested in it under section 1(2). Sections 3 and 4 are operational from the 20th day of May, 2009.

It is pertinent to note that the CCI may inquire into any alleged contravention of the provisions contained in subsection (1) of section 3 or sub-section (1) of section 4 either on its own motion or on receipt of any information, in such manner and] accompanied by such fee as may be determined by regulations, from any person, consumer or their association or trade association; or a reference made to it by the Central Government or a State Government or a statutory authority.

The study has examined various issues in the Competition Act and its application to the pharmaceutical industry in India. In case of pharmaceuticals, the following questions may be pertinent in defining relevant market under the definition given in the Act. The physical characteristics test would require the commission to consider the drugs have the same dosage and delivery forms such as injectable, liquid, capsule, tablets, or topical; the end use test suggests and inquiry if drugs have the same frequency of dosage, such as once -a- day or extended release; whether drugs have the same strength of dosage, distinguishing, for example, 10mg and 30mg tablets;

Consideration of the price of goods or services would require an inquiry if the drugs are branded or generic; price constraints through price controls and negotiations may be considered as a constraint on supra normal pricing. However, price negotiations can add to the deceptive element since it does not fully constrain the alleged monopolist from pricing. Currently, since most drugs (except 74 drugs) from the National Essential Drug List are not under price controls, it would mean that price control may also not be an essential consideration.

The distinction between prescription drugs and OTC drugs may have substantial difference in assessing relevant markets. In case of prescription drugs, since information asymmetries are greater, it would require that such an important constraint on consumer choice be taken into consideration. Further, whether drugs are currently marketed or are in development; whether drugs treat the same disease, condition, or indication; whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same “mechanism of action”); whether drugs have the same specific chemical compounds. The commission may thus inquire into a variety of factors. Generally, in case of pharmaceuticals, ATC classification is considered as standard for understanding the class of therapeutics. As seen above, ATC is classified into five levels. ATC 3-4 level classification is considered to be the most relevant in defining the relevant product market in case of pharmaceuticals.

It may be noted that the SSNIP test may not be of much help in defining relevant markets. It is so because cross elasticity in demand in very low in case of prescription drugs. Hence this test must be used with caution in the pharmaceutical context. Further, the question is if *cellophane fallacy* applies in case of pharmaceuticals. It is interesting to note the consequences of the application of *Cellophane Fallacy* in determining the scope of relevant product market in case of pharmaceuticals. *Cellophane fallacy* is inapplicable when there are excellent substitutes. In most cases, it is difficult to envision a situation where doctors would prescribe alternate medicines to cure a disease. Interchangeability is highly impossible given that patient needs can be addressed only through particular drugs. In a prescription market situation, it is evident that there does not exist a high cross-elasticity of demand. At a high enough price, interchangeability with poor substitutes may not look good to doctors who prescribe the medicine. Thus the *Cellophane fallacy* does not apply in case of pharmaceuticals. Pharmaceutical companies also compete in marketing drugs. Several different market participants are involved today in purchasing pharmaceuticals, which may complicate market definition analyses.

Generally, in pharmaceutical case, *sans* intervention by state governments, geographic markets are national markets. In the Indian context, it is unlikely that drug procurement can sufficiently alter conditions in the relevant market. However drug procurement by state authorities may constrain the demand for pharmaceutical products. But this is more often than not the case with government procurement in India. Supply side constraints imposed by transportation costs and local requirement relating to manufacturing and sale. In terms of consumer preferences, not much of a difference may be found in terms of Thus in the context of pharmaceuticals the relevant geographic market would mean national markets unless there is huge variation in prices due to local procurement schemes by the government.

Section 3(1) prohibits anticompetitive agreements. It is pertinent to note that the Commission must follow factors specified under section 19(3) are compulsory. However, it creates a confusing situation if all agreements under section 3 must undergo this scrutiny. It is so because certain horizontal hardcore cartel agreements are per se void. In such situations it is evident that factors under section 19(3) need not be taken into consideration. More importantly, terms used in the factors specified in section 19(3) require an economic analysis, where only further regulations can clear the haze.

In its application to the pharmaceutical sector section 3(3) can prove helpful in dealing with hardcore agreements more specifically in the supply chain. Mass boycott of products, medicos agreeing to prescribe or not to prescribe a particular brand etc… are within the purview of section 3(3) prohibitions. Some agreements under section 3(3) are *per se* void if they are in the nature of hardcore cartels and do not require any factors to be considered under section 19(3). It is pertinent to note that section 3(3) can be used in effectively deterring collusive practices in drug procurement. While there is no direct evidence of bid rigging practices in Indian drug procurement, it must be noted that there is less effective competition prevailing in bidding of speciality drugs. They can be in the nature of market allocating agreements. Section 3(3) however, does not prohibit combinations which are in the nature of acquisitions, merger or conglomerates. They are governed by sections 5 and 6 of the Act. It is pertinent to note that joint ventures are kept out of the application of section 3 provided such joint venture agreements increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services. It is pertinent to note that many market / R&D agreements in the nature of joint ventures are routinely entered in pharmaceutical will be kept out of the purview if such agreements if such agreement increases efficiency. However, there is no clear definitional understanding of what accounts to efficiency and hence one may retort to section 19(3) for guidance.

Vertical restraints can be challenges under section 3(4) of the Act. As noted in this study the pharmaceutical supply chain is beset with practices that can be regarded as vertical restraints. Certain tie practices, especially combinational theraphies can be validly challenged. However, this must not be confused with fixed dose combination (FDCs) which are directed to single patient required different doses of different medicines. However, tie-in practices which require a retailer or consumer to purchase some other good along with the one demanded falls within the mischief of this section. Price discounts and other forms of exclusive arrangements are also caught within section 3(4). However, much is yet to be desired from the guidelines that the CCI will come forth with.

It is pertinent to note that section 3(5) partially excludes the operation of agreements concerning intellectual property rights as antithesis to competition. Again, much is yet to be desired from the guidelines as to what practices are prohibited. It must be specifically noted that certain anti competitive practices which lead to the prohibition of protection of the existing trade and industry, development of new industrial activities, promotion of export, availability of the product at affordable price, can

be successfully challenged under the Patents Act, 1970. A compulsory license may be issued for after such allegations are satisfactorily proved before the patent controller. The Patents Act also allows issuance of compulsory license where prevention of unreasonable terms–such as grant-back requirements, packaging, prevention of challenges–in voluntary licences, exploitation of the market based only on import etc. led to anticompetitive fallouts. However, there is no necessity of the rule of reason analysis to be applied in case of the patent law. Suffice it would be to prove that such provisions do exist in the agreements. It must also be noted that for a successful application under the patents act, there is no consideration for an inquiry in to the relevant market. This illustrates that compulsory licensing provisions under patent laws are in the nature of public interest provisions and not based on stricter competition law analysis. As stated above, the regulation from the CCI will have to clarify the caps and thresholds that would be kept for regarding agreements to fall within the mischief of this section. The EU block exemptions on technology transfer may only provide an illustrative guide. However, the competition commission is bestowed with full powers to reasonably fix the thresholds. However, it is evident that section 19(3) factors will have to be considered.

Exception to exclusion under section 3 category also pertains to entering into anticompetitive agreements for the purpose of export market. Section 3(5) also allows for the right of any person to export goods from India to the extent to which the agreement relates exclusively to the production, supply, distribution or control of goods or provision of services for such export.

Dominance, per se is not illegal but its abuse is. The vexed question which is to be answered is "determination of dominant position'. Cases analyzed in the context of US and EU jurisdictions amply assert that willingness of the courts to understand that law does not make mere size of a corporation, however impressive, or the existence of unfettered power on its part, an offence, when accompanied by unlawful conduct in the exercise of its power. It may be noted that the competition laws of all jurisdictions do not contain a general prohibition on the abuse of dominance or on the misuse of market power. Some laws only prohibit specified conducts by undertakings in a dominant position or having a substantial degree of market power.

Section 4 (1) of the Indian Competition Act states, "No Enterprise shall abuse its dominant position". There are however certain differences in these basic provisions. While the Indian law prohibits abuse of dominant position by enterprises in general, the certain countries may have provisions in the law that prohibits the "abusive exploitation of a dominant position". Needless to say dominance has been traditionally defined in terms of market share of the enterprise or group of enterprises concerned. However, a number of other factors play a role in determining the influence of an enterprise or a group of enterprises in the market. These include, besides market share, the size and resources of the enterprise; size and importance of competitors; economic power of the enterprise; vertical integration; dependence of consumers on the enterprise; extent of entry and exit barriers in the market; countervailing buying power; market structure and size of the market; source of dominant position viz. whether obtained due to statute etc.; social costs and obligations and contribution of enterprise enjoying dominant position to economic development. The Commission is also authorized to take into account any other factor which it may consider relevant for the determination of dominance.

There are primarily three stages in determining whether an enterprise has abused its dominant position. The first stage is defining the relevant market. As noted above, the analysis in case of pharmaceutical products in complex. The second is determining whether the concerned undertaking/enterprise/firm is in a dominant position/ has a substantial degree of market power/ has monopoly power in that relevant market. The third stage is the determination of whether the undertaking in a dominant position/ having substantial market power/monopoly power has engaged in conducts specifically prohibited by the statute or amounting to abuse of dominant position/monopoly or attempt to monopolize under the applicable law.

Explanation to section 4 define dominance as "a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to— (i) operate independently of competitive forces prevailing in the relevant market; or (ii) affect its competitors or consumers or the relevant market in its favour". It is pertinent to note that the act does not distinguish between passive or active market power. An effect based test would allow the application of this section if the enterprise has become dominant due to existence of passive market power. The Act clearly states that there shall be an abuse of dominant position if an enterprise or a group directly or indirectly, imposes unfair or discriminatory condition in purchase or sale of goods or service; or price in purchase or sale (including predatory price) of goods or service. Predatory pricing is also included. It is pertinent to note that the Commission take note of unfair prices in case of pharmaceuticals also. Nothing

in Act mandates the Commission not to intervene in price regulation only because of the existence if NPPA or issue compulsory license because of the existence of provisions for compulsory license under patents act, 1970. In cases of unfair pricing the recourse taken by the South African commission may be considered.

Pharmaceuticals suffer from the problem of excessive pricing and predatory pricing cases are very rare except where patents are about to expire and brand manufacturer wanting to preserve his long held monopoly. In case of application of the essential facilities doctrine, the Act deals with EFD under section 4 and Section' however the treatment is different. Our Supreme Court has imposed ceratin obligations which are similar to EFD. The court held that writ can't be issued in the matter of contractual obligation. Moreover no writs can be issued if the rights are of a private character. The court recently held in ABL Industries that writ can be passed in contract matters if one the parties is Govt. and it's *essential* for the govt. to work fairly. Furthermore, Indian law has institutionalized the entire concept of Essential Facilities through certain Acts. As applied to the pharmaceutical sector, the EFD can prove helpful in accessing patented knowledge. The remedy is generally in the nature of compulsory licensing.

It is pertinent to noted that section 4 analysis requires under section 19(4) the Commission shall, while inquiring whether an enterprise enjoys a dominant position or not under section 4, have due regard to all or any of the factors mentioned therein.

Three important factors can be understood to have positive implication for section 4 analysis. What are social costs is not defined. Again, section 4 may warrant development dimension to the understanding of dominant position. However, most importantly the commission may consider any factor that is relevant for an abuse of dominant inquiry within the scope of section 19(4).

Section 5 prescribes the thresholds under which combinations shall be examined. While the threshold prescribed have a potential to include many medium and big size acquisitions in the Indian pharmaceutical market, it is important to note that section 5 and 6 provisions have not been notified. Section 6 states that "No person or enterprise shall enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void". Section 6 mandates a pre combination review notice to be given to the commission within 30 days of the decision of the companies to enter into a combination. Section 20(4) requires that for the purposes of determining whether a combination would have the effect of or is likely to have an appreciable adverse effect on competition in the relevant market, the Commission shall have due regard to all or any of the factors mentioned there in.

Without provisions relating to combinations being notified, it would be difficult to put on hold acquisitions that might have adverse effect on competition in India. It is important to note that the tests developed in comparative jurisdictions can only provide a guide in the absence of specific regulations issued by the CCI. What is important for review of combinations is also an assessment of impact of combination on innovation markets. It is pertinent to note that acquisitions which involve takeover of generic companies may lead to change in priorities of generic companies. Overall effective competition in generic markets may thus be reduced.

Section 49(3) Chapter VII dealing with Competition Advocacy bestows powers to the CCI to conduct advocacy on competition issues. However, this in itself does not explain the need for role of advocacy in the pharmaceutical sector. There is a need for advocacy because the Competition Act in India is itself new and its possible application requires a thorough understanding of the systems that are already in place. It should be noted that not all government functionaries consider competition elements in formulating policies relating to pharmaceuticals. The classic example in this case is the Draft National Pharmaceutical Policy of 2006 issued by the Department of pharmaceuticals which does not mention the use of competition law as an instrument to abate excessive pricing by pharmaceutical companies; Pharmaceutical sector, as it stands, is a highly regulated sector and various regulatory authorities govern different aspects of the industry; The pharmaceutical industry heavily relies on the patent system where possibilities of abuse of patents stand a higher chance. This is specifically because legal monopolies through patents are market interventions to cure market failures in innovation. Abuse adding to it may aggravate concerns for competition; there is high amount of scrutiny in the pharmaceutical sector globally. Incidences of pharmaceutical companies abusing patents and dominant position prevail widely. This is also confirmed by the recently concluded EU Pharmaceutical sector Inquiry (July 2009). Hence there is a need for a muliti-pronged strategy for creating awareness about competition issues on ex ante basis. Since there are different actors in the

Pharmaceutical industry and healthcare markets, strategies can be specifically with reference to various actors have been suggested.

The following table provides for specific recommendations as part of this study:

Practices in Pharmaceutical Markets

Issue	Recommendation
Price discounts among wholesalers and retailers	Sensitize wholesalers and retailers about competition compliance as amounting to vertical restraint
Group boycotts by physician association or retailers	Sensitize wholesalers and retailers about competition compliance as amounting to horizontal restriction
Resale price maintenance	Sensitize wholesalers and retailers about competition compliance as amounting to vertical restraint
Perverse incentives	Department of Pharmaceuticals to be recommended to frame guidelines for drug promotion in the light of voluntary measures taken up by the industry having failed
Drug Promotion	Sensitize industry associations and physician associations about impact of anticompetitive drug promotion on consumer preferences and take suitable measures in case of non-compliance
Drug Procurement	Closely examine the efficient drug procurement models such as Tamil Nadu model (TNMSC) and Suggest that all government drug procurement to emulate such models. Monitor competition in speciality drugs
Direct to Consumer Advertising	Seek for a monitoring mechanism to completely ban DTCA of all prescription drugs

Mergers, Acquisitions and Alliances in the Indian Pharmaceutical Industry

Issue	Recommendation
Merger provisions to be notified	The Government of India should immediately notify the merger provisions
Guidelines	Frame adequate guidelines with a view to prohibit combinations that foreclose competition in generic markets for ensuring sustained generic supply
Post merger	Keep strict vigil on acquisitions allowed so that generic company strategies remains unchanged, especially in relation to challenging invalid patents

Innovation Polices :

Issue	Recommendation
PUPFIP Bill	Request the DBT to consider the anticompetitive impact of publicly funded patents on prices and suggest withdrawal of a normative based framework

Patent Law Issues:

Issue	Recommendation
Maintain higher standards of patentability and Proper	Patent Office/ Department of Industrial policy promotion

application of patentability criterion under section 3(d)	(DIPP), Ministry of Commerce should be in informed about anticompetitive nature of questionable patents
Challenge pharmaceutical patents that are questionable under standards of patentability prescribed under Indian Law through pre and post grant oppositions and through invalidity proceedings	Generic firms and health groups must be sensitised about patent oppositions
Create firm guidelines based on appeals court judgments	DIPP should be advised to frame guidelines and patent offices must implement them in letter and spirit
Avoid granting *exparte* temporary injunctions in case of alleged patent infringement	Judicial officers must be sensitised about the anticompetitive impact of granting temporary injunctions when validity of patent is called in question.
Guidelines should clarify the time framework for issue of compulsory licenses under patent laws	DIPP and patent offices must be advised for creating an effective and deterrent compulsory licensing mechanism
Seek compulsory license after expiry of three year period where patented drug prices are high or patent is not locally worked- by following criteria led down under patents Act.	Generic firms and health groups should be informed about such a mechanism
Seek notification for emergency provisions	Ministry of health to be advised that emergency provisions can lead to effectiveness in issuance of compulsory licenses where prices are high

Drug Price Regulation in India: NPPA Price Controls and *Ex Ante Price Competition*

Issue	**Recommendation**
Expand the purview or price control of scheduled drugs where competition is inadequate due to exercise of passive market power	NPPA must be recommended
Monitoring of all patented prices	CCI should coordinate with NPPA to monitor prices and seek measures where prices are exploitative
Price negotiation of patented drugs	CII may advise Department of Pharmaceuticals should reconsider this strategy
Price monitoring and control of non-scheduled, including newly patented drugs	CCI may recommend direct price control where prices are exploitative to the NPPA

Drug Regulation and Competition

Issue	**Recommendation**
2008 amendments to the Drugs and Cosmetics Act	Reconsider definition of "spurious" so as not to conflate it with enforcement of trademarks or other forms of intellectual property rights
Schedule M	Recommend a study of impact of standardization (schedule M) on small scale industries in India
Approval of biological generic drugs	The DCGI must be recommended to ensure that while safety of bio-generics is paramount, competition concerns about early entry of bio-generics must be taken into consideration
Data protection	Maintain Status-quo on the official position not to grant the same
Patent linkage	Advice the DCGI not to consider claims on patents while

	granting marketing approvals if requested by originator companies, especially in the light of judicial decisions.

Consumer Drug Information

Issue	Recommendation
Adequate consumer drug information	Loopholes in existing legal and regulatory mechanisms identified in this study to be remedied by advocating for appropriate changes

Laws governing the supply Chain

Issue	**Recommendation**
Drug substitution	Recommend to the GOI that pharmacies must be allowed to substitute generic drugs for originator or branded drugs
Physician prescription	Medical Council to be advised to bring changes in the law to ensure that generic substitution is mandated for prescription drugs in case of availability
Drug Advertising	CCI to recommend the Advertising Council of India to conduct a study of effect of Direct to Consumer Advertising on Consumer Preference and it relationship to Prices
Drug Promotion Code	Seek effective implementation of the code by industry associations and advice the health ministry and DoP to frame adequate guidelines

Intellectual Property Rights and Competition Law

Issue	**Recommendation**
Section 3(5) of the Competition Act	Issue recommendatory guidelines based on consideration made in this study. It should be noted that guidelines and cases in comparative jurisdictions should only be persuasive
Abuse of dominance through patent abuse	Pricing practices can be challenged. CCI may frame guidelines in this regard
Issue of innovation markets	CCI should frame adequate guidelines to ensure that innovation markets are not concentrated due to combinations
Essential facilities doctrine	CCI may conduct a study on the use of essential facilities doctrine in accessing patented knowledge

In conclusion, it can be said that while the pharmaceutical industry is highly regulated and prices are currently one of the lowest in India, information asymmetries and exercise of passive market power does lead to anticompetitive outcomes. With the advent of the product patent regime, generic entry and prices of drugs are a major concern. It is expected that as per the current framework the CCI may actively play a role in ensuring healthy and competitive markets from a health care perspective which will go a long way in fulfillment of the objectives laid in the Competition Act, 2002.

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Company	Biotech patents						Pharma patents						Total
			Utility patents			Design patents			Utility patents			Design patents	
	Number	Percentage	Product	Process	Product and process		Number	Percentage	Product	Process	Product and process		
Alembic	0		–	–	–	–	5	1	–	4	1	–	5
Aurobindo Pharma	0		–	–	–	–	9	2	–	6	3	–	9
Bharat Biotech International	2	11	–	–	2	–	0		–	–	–	–	2
Bharat Serums and Vaccines	0		–	–	–	–	3	1	–	–	3	–	3
Biocon	6	32	1	4	1	–	13	3	4	6	3	–	19
Cadila Healthcare	0		–	–	–	–	4	1	–	1	2	1	4
Cadila Laboratories	0		–	–	–	–	1		–	–	1	–	1
Cadila Pharmaceuticals	0		–	–	–	–	1		–	–	1	–	1
Chemintel India	0		–	–	–	–	3	1	–	2	1	–	3
Cipla	0		–	–	–	–	4	1	–	3	1	–	4
Dabur India	0		–	–	–	–	6	1	–	3	3	–	6
Dadur Pharma	0		–	–	–	–	1		–	–	1	–	1
Dabur Research Foundation	0		–	–	–	–	31	7	7	8	16	–	31
Dr. Reddy's Laboratories	0		–	–	–	–	34	8	6	11	17	–	34
Dr. Reddy's Research Foundation	0		–	–	–	–	44	10	4	4	36	–	44
Emcure Pharmaceuticals	0		–	–	–	–	1		–	1	–	–	1
Fermenta Biotech	0		–	–	–	–	1		–	–	1	–	1
Fortune Bio–tech	0		–	–	–	–	1		–	1	–	–	1
Gangagen Biotechnologies	3	16	–	–	3	–	0		–	–	–	–	3
Glenmark Pharmaceuticals	0		–	–	–	–	7	2	1	2	4	–	7
Indian Herbs and Research Supply Company	0		–	–	–	–	8	2	2	2	4	–	8
Indus Biotech	0		–	–	–	–	2		1	1	–	–	2
Ipca Laboratories	0		–	–	–	–	1		–	1	–	–	1
J. B. Chemicals and Pharmaceuticals	0		–	–	–	–	4	1	2	–	2	–	4
Jai Surgicals	0		–	–	–	–	1		1	–	–	–	1
Jubilant Organosys	0		–	–	–	–	5	1	–	5	–	–	5
Kopran	0		–	–	–	–	1		–	1	–	–	1
Kopran Research Laboratories	0		–	–	–	–	2		–	–	2	–	2
Lekar Pharma	0		–	–	–	–	1		1	–	–	–	1
Lupin	0		–	–	–	–	4	1	–	3	1	–	4
Lupin Labs	0		–	–	–	–	13	3	2	9	2	–	13
Max India	0		–	–	–	–	3	1	–	3	–	–	3
Natco Pharma	0		–	–	–	–	1		–	1	–	–	1
Natural Remedies	0		–	–	–	–	1		–	–	1	–	1
Nicholas Piramal India	0		–	–	–	–	4	1	–	2	2	–	4
Orchid Chemicals and Pharmaceuticals	0		–	–	–	–	22	5	–	14	8	–	22
Panacea Biotec	0		–	–	–	–	16	4	5	1	10	–	16
Proalgen Biotech	1	5	–	–	1	–	0		–	–	–	–	1

(*Contd.*)

Source: Sriramkumar Sundaramoorthy et. al. 2009.

Table 1. (*Contd.*)

Company	Biotech patents						Pharma patents						
			Utility patents			Design patents			Utility patents			Design patents	Total
	Number	Percentage	Product	Process	Product and process		Number	Percentage	Product	Process	Product and process		
Ranbaxy Laboratories	0		–	–	–	–	84	20	13	53	18	–	84
Reddy US Therapeutics	3	16	–	3	–	–	9	2	9	0	–	–	12
Reliance Life Sciences	4	21	1	2	–	1	0		–	–	–	–	4
RPG Life Sciences	0		–	–	–	–	3	1	1	2	–	–	3
Sahajanand Biotech	0		–	–	–	–	2		2	–	–	–	2
Sami Labs	0		–	–	–	–	12	3	1	8	3	–	12
Shasun Chemicals and Drugs	0		–	–	–	–	1		–	–	1	–	1
Strides	0		–	–	–	–	2		–	1	1	–	2
Strides Arcolab	0		–	–	–	–	1		–	–	1	–	1
Strides Research and Specialty Chemicals	0		–	–	–	–	1		–	1	–	–	1
Sun Pharmaceutial Advanced Research Centre	0		–	–	–	–	1		1	–	–	–	1
Sun Pharmaceutical Industries	0						10	2	2	5	3	–	10
Suven Life Sciences	0		–	–	–	–	1		–	–	1	–	1
Themis Medicare	0		–	–	–	–	2		–	–	2	–	2
Torrent Pharmaceuticals	0		–	–	–	–	10	2	1	2	7	–	10
Tsar Health	0		–	–	–	–	2		–	–	2	–	2
USV	0		–	–	–	–	9	2	–	4	5	–	9
Wockhardt	0		–	–	–	–	14	3	1	2	11	–	14
Wockhardt Europe	0		–	–	–	–	3	1	–	2	1	–	3
Subtotal	19	100	2	9	7	1	425	100	67	175	182	1	
Total					19						425		444

Annexure II

Collection of Three News Items on Drug Promotion in India

By Shabnam Minwalla

The Times of India

Date: 11th 12th and 18th September, 2003

Pharma firms dictate what doctors prescribe: Study

How does a doctor decide which drugs to prescribe to his patients? If an ongoing study is any indication, the capsules and creams may be chosen less for their curative powers than their lucrative side-effects. For, in the profit-oriented world of pharmaceuticals, doctors are routinely wooed with gifts ranging from mobile phones to sponsored weddings. These details emerged from a study on the 'Promotional Practices of Pharmaceutical Firms in India', conducted by the Forum for Medical Ethics in collaboration with the Drug Controller General of India and the World Health Organisation (WHO).

Over six months, a team of researchers conducted more than 100 in-depth interviews with pharmaceutical companies, doctors, chemists and medical representatives in Mumbai and came up with disturbing findings. "Drugs are often promoted through dubious, even unethical practices,'' said Dr Nobhojit Roy of the Forum for Medical Ethics, which released the preliminary findings at a seminar last week. "This extends from sponsored conferences in five-stars to high-value gifts like motorcycles and cars. There are even cases where pharma companies have helped doctors set up small nursing homes.''

Such stories have long been whispered in the medical world, but have rarely been investigated. This, despite the fact that inappropriate prescriptions could lead to dangerous side effects, medical complications and needless expenses for patients. "We've all heard about doctors being sent for free trips to Singapore and that kind of thing, but there's little documentation on the subject,'' said Sunil Nandraj of WHO India.

"We see this as an exploratory study that has given clues to various trends.'' It emerged, for example, that many Mumbai chemists demand payments from pharma companies to stock new products, while most doctors expect at least a pen or a diary from visiting med-reps. "Consultants are rewarded more handsomely than GPs, while big prescribers are also favoured,'' said Dr Roy, while pointing out that this was likely to influence doctors and their prescription patterns.

"Medical associations have actually told pharma companies, 'If you don't sponsor our conference we will boycott your drugs.' '' Interestingly, nobody— not the government or medical and pharmaceutical representatives— bothered to counter these damning accusations.

"We know such practices are in vogue, but cannot do much because our legislation is silent on drug promotion,'' said deputy drug controller Dr M. Venkateswarlu, pointing out that competition is acute in a market exploding with almost 60,000 branded formulations.

Added Dr R.K. Sanghvi of the Indian Drug Manufacturers' Association, "Breakthrough drugs that enter the market early are promoted through scientific information. But 'me too' drugs and irrational formulations have to be pushed vigorously, resulting in excessive sampling, lavish conferences and obscene gifts. I recently heard of a pharmaceutical company sponsoring the wedding of a doctor's daughter. And it is a matter of time before they give the dowry as well.'' Concurred Dr Ketan Parikh of the Association of Medical Consultants, who observed that pharma companies were footing even birthday party bills, "Medical education is so corrupt and expensive today that you can hardly expect doctors to be saints.''

Admittedly, the Medical Council of India has laid down a code of conduct. But given that the doctors and pharma companies have established a cozy relationship and patients rarely realise that they are pawns in a larger game, it will clearly take more than self-regulation to tackle the problem.

Is your doctor a bunny, wolf, sheep or dodo?

Classifying people as bunnies, wolves, sheep and dodos may sound like a flaky party game. But it's also serious business. "Medical representatives are sometimes trained to slot doctors into four groups," says Dr Peter Mansfield, founder of Healthy Skepticism. "So bunnies are doctors who care most about their patients, wolves care most about money, sheep want to keep up with other doctors, while dodos are those who are burnt out. Once the doctor's motivation is clear, it's much easier to sell a new drug. This is just one strategy used by global pharmaceutical companies to promote their products—be they capsules for TB or pills for shyness. For, the world's most profitable industry routinely resorts to skewed information, seminars in Seychelles and psychological tricks to push formulations to doctors. "As a result, patients often get drugs that are less effective, have more side-effects or are more expensive," says Dr Mansfield, an Australian general practitioner, who for 20 years has been trying to create global awareness about the reality behind the lab-coated facade. "That is why our motto is, 'Improving health by reducing harm from misleading drug promotion."

Dr Mansfield first came into conflict with pharmaceutical companies as a medical student in Bangladesh in 1981. He was appalled to find a rash of irrational, even harmful, drugs in the market—including an anabolic steroid being advertised as an appetite stimulant for children. "I didn't have to be a senior doctor to know this was bad," recalls Dr Mansfield, who organised a group of subscribers to bomb the offending pharma company with indignant letters. "We took on a crazy tonic marketed in Thailand by Pfizer, which had ingredients like ox-bile extract, and a Bayer's tonic in Pakistan, which was essentially a light beer with arsenic and strychnine. We actually got a dozen products withdrawn in the '80s." Today, however, Dr Mansfield admits that he is dealing with a more sophisticated industry, which goes to great lengths to convince doctors about the benefits of new and expensive drugs. "Instead of going through research papers, most doctors are happy to believe that a new drug that is popular and recommended by experts is the best option," says the activist, who was in the city to attend a seminar on drug promotion in India.

The problem with this reasoning, however, is that experts often toe the party line, and new drugs often mean unexpected side-effects. "Studies in the US and France have found that only three per cent of new drugs are big advances in medicine," says Dr Mansfield, explaining why gifts and parties with scantily-clad dancing girls are necessary marketing tools. "Social science evidence indicates that even small gifts work. So, while ethical codes in the US, for example, specify a $100 ceiling, I believe in a 'no- gift' policy. Most doctors across the planet accept gifts innocently, but it's time they woke up from 'The Truman Show' and understood the reality."

After years of indifference, this message has found a receptive audience. Healthy Skepticism is launching an on-line project called AdWatch, which dissects pharma ads. While Dr Mansfield is suddenly flooded with invitations to speak at medical seminars, "There's a new wave of interest," he says, adding that the situation has become too appalling to ignore. "Now we are trying to stay on the surfboard."

Many doctors rely on skewed data

In the 24 years since Dr Arshad Gulam Mohammad graduated from medical college, much more has changed than merely the price of Crocin. About 50 per cent of the drugs he prescribes were not taught in his college pharmacology class.

"It's a constantly changing scenario,'' said the surgeon, pointing out that new pills, potions and surgical equipment flood the market every year. This is a predicament faced by doctors around the world. For example, a study in the UK found that senior doctors haven't formally studied 85 per cent of the drugs they prescribe to patients. In India, with its 60,000 branded formulations, the challenge is even greater.

How do doctors keep up with new medicines? And how do they decide whether a recent entrant is worth the hefty price tag or find out about undesirable side effects? A study on drug promotion in India, being conducted by the Forumfor Medical Ethics, indicates that most doctors not only accept sizable gifts from pharmaceutical companies, but also swallow skewed scientific information. "It's only possible to understand the benefits and dangers of news drugs by reading recent textbooks, research and prestigious journals,'' said Dr Mohammad. "These sources are untainted by the profit motive.'' But in reality, few Mumbai doctors bother to search the Internet or read medical journals.

"Most rely on medical representatives, intuition and sponsored conferences at which participants are more interested in drinking than learning,'' said Dr V.Murlidhar of SionHospital,who was involved with the Forum study. Added Dr K. Weerasuriya of WHO, "Understanding indications, contra-indications and side-effects of drugs is crucial. Inadequate or biased information leads to poor and even dangerous usage.''

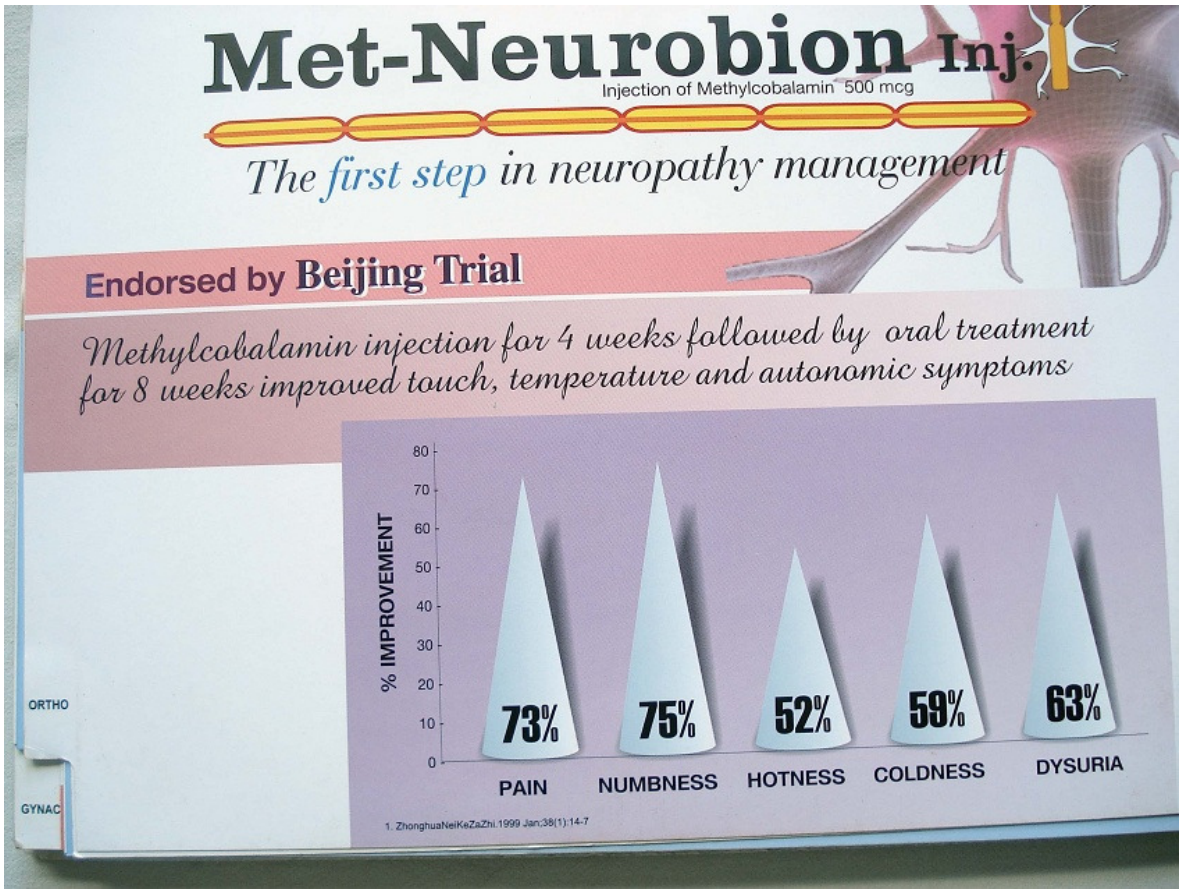
Most doctors unquestioningly accept savvy sales pitches, people in the profession admit. "About 95 per cent of the information supplied to doctors comes directly or indirectly from the industry,'' said Dr R.K.Sanghvi of the Indian Drugs Manufacturers' Association, admitting that handpicked speakers at conferences and sponsored articles in journals can make even pedestrian products sound like miracle cures. Even more central is the role of medical representatives who, rather than serving as dispensers of scientific information, have been reduced to spies and salesmen. They routinely strike deals with chemists to find out what local doctors prescribe, and then make their calls armed with this information and gifts. "I keep hearing about training programmes for MRs, but haven't attended a single in my 23-year long career,'' said Amitava Guha, a Kolkata-based medical representative. He said that drug information is often communicated to doctors with the help of tools like cartoons and brightly coloured pop-up books.

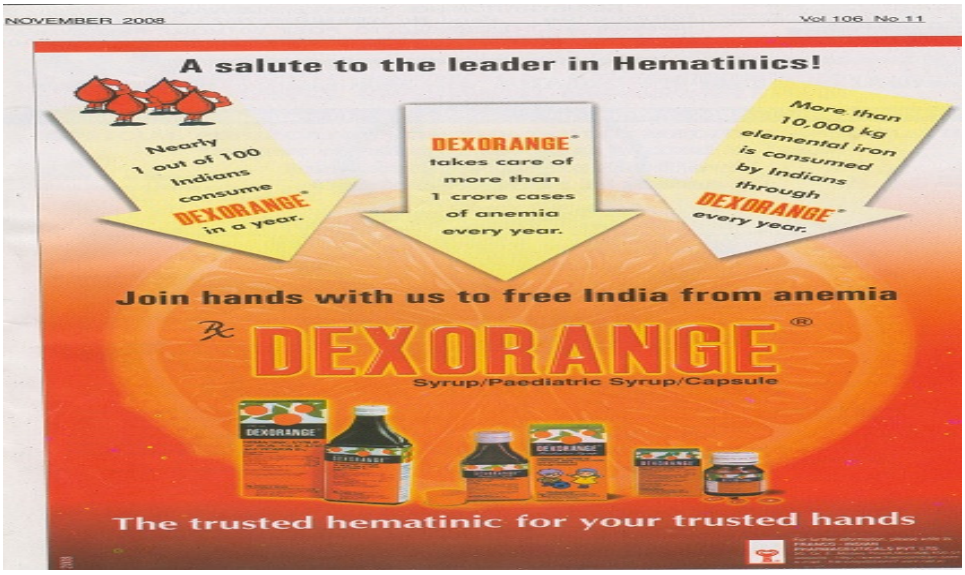
How are these gimmicks and biased facts being countered? The Australian government, for example, has appointed a team to visit doctors and furnish them with independent information—a project that convinced many doctors to switch from aspirin to paracetamol in arthritic cases, and resulted in a sharp fall in gastric ulcers. Other countries are emphasising the importance of continuing medical education. "In India we see the MBBS and MD as exit level exams,'' said Dr Murlidhar. "But it's time we realised they are just entry level exams. Only doctors who learn through their lives will be able to see through the sales pitches and biases.''

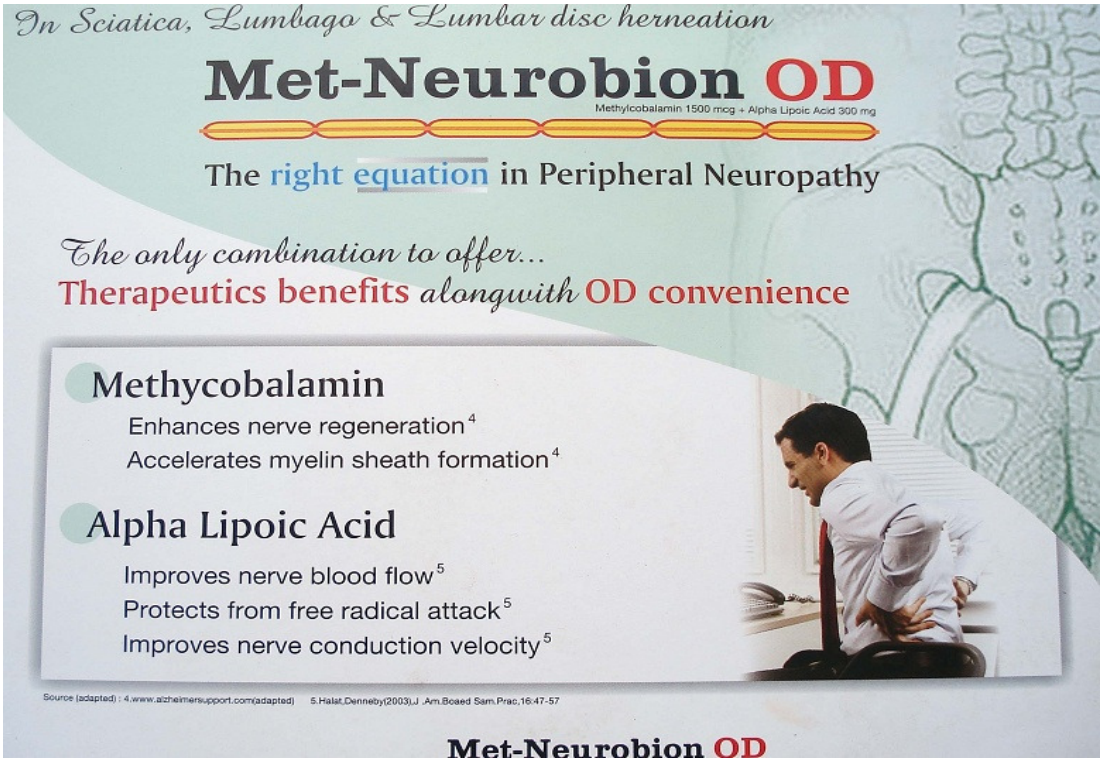
Source: The Times of India, 2003

Annexure III

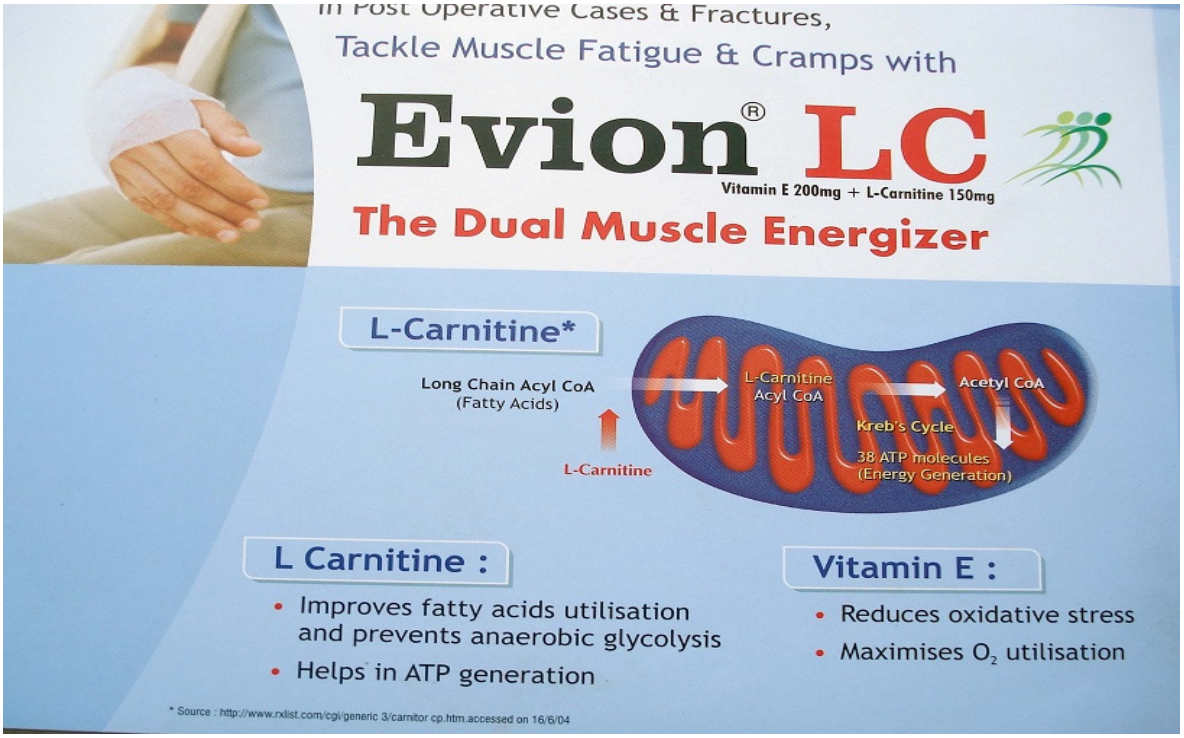
Collection of drug promotion materials (Guha 2009)






In Sciatica, Lumbago & Lumbar disc herneation
Met-Neurobion OD
Methylcobalamin 1500 mcg + Alpha Lipoic Acid 300 mg
The right equation in Peripheral Neuropathy
The only combination to offer...
Therapeutics benefits alongwith OD convenience
Methycobalamin
Enhances nerve regeneration[4]
Accelerates myelin sheath formation[4]
Alpha Lipoic Acid
Improves nerve blood flow[5]
Protects from free radical attack[5]
Improves nerve conduction velocity[5]
Source (adapted) : 4.www.alzheimersupport.com(adapted) 5.Halat,Denneby(2003),J .Am.Boaed Sam.Prac,16:47-57
Met-Neurobion OD

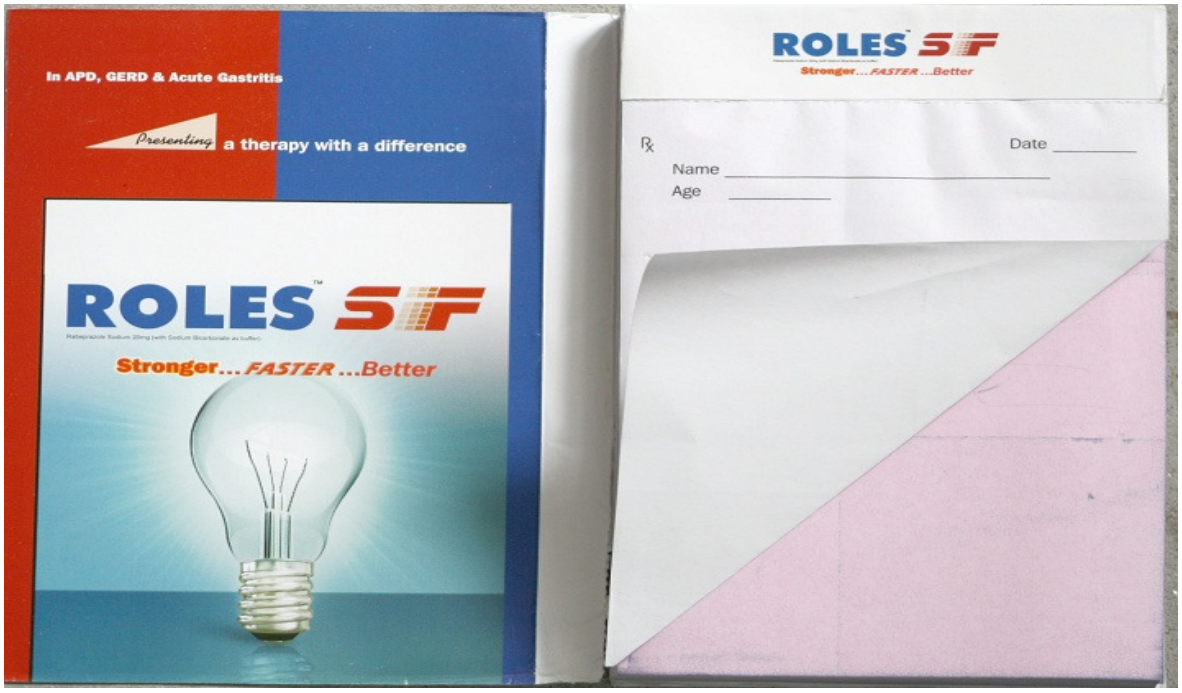

Rx
Meganeuron OD Plus
Methylcobalamin, Alpha Lipoic Acid; Folic Acid, Biotin, Benfotiamine, Vit. B6 Capsule
Mega Composition with OD Plus Benefits
Improves nerve conduction velocity[1]
Greater improvement in vibration perception threshold[1,2]
Reduces neuropathic pain and improves paraesthesiae[1,2]
Improves neuropathic symptoms[3]
Two-fold antioxidant action
Diabetic Peripheral Neuropathy
Post Herpetic Neuralgia
Nerve Compression Disorders
Degenerative Nerve Disorders (Parkinson's & Alzheimer's Disease)
Post - Stroke
Also Available
Meganeuron Injection
Prompt relief from
Tingling Numbness Pain
Vitamin B12 deficiency
Meganeuron
1. Alcohol and alcoholism 2006; 41 (6) :636-42
2.Cochrane Database Syst Rev. 2008 Jul 16;(3):CD004573
3. Expert Opin Investig Drugs. 2008 Jun;17(6):953-64


In Post Operative Cases & Fractures,
Tackle Muscle Fatigue & Cramps with
Evion® LC
Vitamin E 200mg + L-Carnitine 150mg
The Dual Muscle Energizer
L-Carnitine*
Long Chain Acyl CoA
(Fatty Acids)
L-Carnitine
L-Carnitine
Acyl CoA
Acetyl CoA
Kreb's Cycle
38 ATP molecules
(Energy Generation)
L Carnitine :
• Improves fatty acids utilisation and prevents anaerobic glycolysis
• Helps in ATP generation
Vitamin E :
• Reduces oxidative stress
• Maximises O_2 utilisation
* Source : http://www.rxlist.com/cgi/generic 3/carnitor cp.htm.accessed on 16/6/04


TELDAY pregeb M
GENNEXT
Details
1. What is "GenNext"?
GenNext is a reward scheme valid for Rx containing the following brands:
TELDAY
TELDAY-R
TELDAY H
pregeb M
2. How do I earn Rewards?
Each brand Rx for one patient gives you 10 Reward points.
You need to collect minimum 500 points between 1st Feb and 30th April'07
These Reward Points are to be redeemed for GIFTS
3. Can I have multiple Rx of these brands in one Rx?
Yes, you can. A single Rx for a patient can get you maximum of 20 points if you have prescribed all 2 brands in that Rx. You will earn points as many times a brand is prescribed.
4. What else do I require to do?
First and foremost the Letter of Acceptance attached in this file has to be duly signed, indicating your option of gift for which you are contesting. (This would not prevent you from getting the gift based on the reward points that you have earned at the end of contest, even if it is lesser than for what you contested for:- Eg: If you have indicated, 2500 points in the LOA and if you have earned only 1000 points, certainly you would be receiving the gifts for 1000 points)


GenNext
Requesting for your continuous prescription support
Ipod shuffle CLIP OR HDFC Bank Card
2500 reward points
Nokia 6233 OR Apple Ipod Nano 4 GB
5000 reward points
Tata Sky TV Dish
1500 reward points
Nokia Bluetooth Headset
OR Titan Steel Watches
1000 reward points
Gold Plated Cross Pen
OR Transcend Flash Drive
500 reward points
AZUC
torrent
Disclaimer : Gifts shown above are only indicative


For the use of a Registered Medical Practitioner, Hospital or Laboratory only
ROLES SF
Rabeprazole Sodium 20mg (with Sodium Bicarbonate as buffer)
Mega Draw
One 1st Prize
Plasma TV
Two 2nd Prizes
i Phone
Three 3rd Prizes
Home Theater System
Ten 4th Prizes
DVD Player
Assured Gift-
Premium Bedsheet
* The visuals depicted are just tentative and the actual brand/model/make may change without any prior information
* This scheme is valid till December, 2008.
* Ranbaxy reserves the right to modify/alter/change/cancel/withdraw any or all of the conditions of the draw at any point of time
* The decision of Ranbaxy regarding the Mega Draw shall be final & binding.
*Conditions Apply
RANBAXY STANCARE
RANBAXY REXCEL


In APD, GERD & Acute Gastritis
Presenting a therapy with a difference
ROLES SF
Stronger... FASTER ...Better
ROLES SF
Stronger... FASTER ...Better
Rx
Date
Name
Age


LUCKY DRAW
Winners Samsung RT 25 Refrigerator
1 Dr P K Gupta Gaya
2 Dr Manoj Jain Agra
3 Dr Shaji S Varkala
4 Dr T Sudhakar Kurnool
Winners Sony Cyber Shot Camera
1 Dr T V Ramaiah Mandapeta
2 Dr R K Shahi Gorakhpur
3 Dr S N Roy Ghatakpur
4 Dr C P Sukumar Chennai
5 Dr C Chandrasekhar Madurai
6 Dr B K Das Cuttack
7 Dr C H Karia Jnangarh
8 Dr Jayant G Shah Surat
9 Dr Mahavir Godara Jodhpur
10 Dr S T Bhutia Gangtok
Winners Silver Coins
1 Dr Ajay Kumar Adimali
2 Dr Manoj Jain Agra
3 Dr Rakesh Singhal Agra
4 Dr A S Gunani Ahmedabad
5 Dr B S Patel Ahmedabad
6 Dr Bhupendra Shah Ahmedabad
7 Dr Atul Vasani Ahmedabad
8 Dr Dinesh Patel Ahmedabad
9 Dr Dipak Patel Ahmedabad
10 Dr Manoj Jani Ahmedabad
11 Dr Prashant Shah Ahmedabad
12 Dr Jitendra Patel Ahmedabad
13 Dr Kh Mehta Ahmedabad
14 Dr Mahesh Patel Ahmedabad
15 Dr Nimesh Trivedi Ahmedabad
16 Dr A Pode Ahmednagar
17 Dr P Shinde Ahmednagar
18 Dr R D Thakare Ahmednagar
19 Dr M V S N Raju Akividu
20 Dr Premakumar Alathur
21 Dr Rajendran Alathur
22 Dr Sadasivan Alathur
23 Dr Rajeev Singhal Aligarh
24 Dr Naresh Jaiswal Alwar
25 Dr C L Meena Alwar
26 Dr Rafeeq Alwaye
27 Dr Sanjay Sirsath Amalner
28 Dr Ashwini Sood Ambala
29 Dr Awani Chowdhry Ambala
30 Dr R K Aneja Ambala
31 Dr Akhtar Khatri Ankleshwar
32 Dr Jeevanandam Arni
33 Dr P Mazumdar Badhula
34 Dr Venugopala Reddy Bagalur
35 Dr Kamla Dalal Bahadurgarh
36 Dr Vivek Verma Bahraich
37 Dr R PSharma Bally
38 Dr T Somasekhar Bangalore
39 Dr Dinakar Bangalore
40 Dr K A Rajeshwari Bangalore
41 Dr Kalyan Saha Bara
42 Dr Neyaz Ahmad Sheikh Baramulla
43 Dr Kirti Patel Bardoli
44 Dr I K Patel Baroda
45 Dr N K Chatterjee Baruipur
46 Dr B. Veer Belapur
47 Dr B M Hiremath Belgaum
48 Dr Dhiraj Kowarkar Belgaum
49 Dr R G Kulkarni Belgaum
50 Dr Shantala Bellary
51 Dr Epari Narayan Rao Berhampu
52 Dr Manoj Sethi Berhampu
53 Dr PBharathi Berhampu
54 Dr M Mahipal Bhainsa
55 Dr D D Arya Bharatpur
56 Dr S N Sharma Bharatpur
57 Dr D U Patel Bharuch
58 Dr N D Pitudaria Bharuch
59 Dr Paresh Solaki Bhavnaga
60 Dr Vijayprakash Patel Bhiwandi

Annexure IV

Drug Expenditure by Govt.

States	Drugs & Med.* (Mln)	Health Exp. (Rs. Mln)	% of Drugs to Health
Andhra Pradesh	1270.45	13142.40	9.67
Assam	153.01	3269.08	4.68
Bihar	220.31	7134.84	3.09
Chattisgarh	250.26	2258.71	11.08
Gujarat	269.38	7154.79	3.77
Haryana	309.61	3147.09	9.84
Karnataka	778.39	9863.31	7.89
Kerala	1242.06	7293.15	17.03
Maharastra	2030.59	17837.95	11.38
Madhya Pradesh	792.19	6668.93	11.88
Orissa	213.02	4213.57	5.06
Punjab	91.63	6182.64	1.48
Rajasthan	904.50	9731.16	9.29
Tamil Nadu	1809.72	11843.28	15.28
Uttar Pradesh	710.42	13557.88	5.24
West Bengal	579.84	13194.83	4.39
Central Govt.*	7264.92	59770.00	12.15
All-India*	18890.38	1962636.86	9.63

Source : Budget Documents, Respective States & Central Govt.
*** Many states report drug expenditure under the category of Materials and Supplies.**

Source: Sakthivel Selvaraj (2009)

Annexure V

High Drug Price – Retail & Tender Price

Disease conditions	Therapeutic drug	Formulation	Strength and No.	Retail Price (Rs.)	TNMSC price (Rs.)	Price difference (%)
Cancer	Cyclophsphamide	Endoxan-N	50mg;10	36.35	13.218	275
Cancer	Fluorouracil	Fluracil	5ml	11.67	1.001	1166
Child and infectious disease	Chloramphenicol	Chloromycetin	250mg;10	30.76	4.4	699
Child health	Phenytoin Sodium	Dilantin	100mg;10	131.55	9.75	1349
COPD and Asthma	Betamethasone	Walacort	0.5mg; 10	3.55	1.043	340
COPD and asthma	Salbutamol	Asthalin	4mg;10	5.21	0.522	998
CVD	Verapamil	Veramil	40mg;10	5.02	4.392	114
CVD	Atenolol	Aten	50mg;14	25.75	1.2	2146
Diabetics	Insulin NPH	Actrapid	10ml	129.28	86.85	149
Diabetics	Glibenclamide	Daonil	5mg;10	6.60	0.454	1454
Injuries	Bupivaccine HCl	Sensorcaine	0.5%;20ml	34.34	15.5	222
Injuries	Ketamine	Ketalar	50mg;10ml vial	89.50	15.15	591
Japanese encephalitis	Ceftriaxone	Lyceft	1g;vial	90.00	16.11	559
Lymphatic Filariasis	Diethylcarbamazine	Banocide	50mg;10	3.88	0.707	549
Malaria	Chloroquine	Melubrin	250mg;10	4.36	2.233	195
Maternal health	Carboprost	Prostodin	1amp	80.13	68.5	117
Maternal health	Ferros Sulphate	Ferrochelate-Z	150mg;10	19.94	0.495	4028
Mental health	Chlorpromazine	Chlorpromazine-NP	25mg;10	5.95	1.81	329
Mental health	Alprazolam	Alprocontin	0.5mg;10	22.55	0.442	5102
Tuberculosis	Rifampicin	Rifacilin	150mg;100	99.68	66.6	150
Tuberculosis	Pyrazinamide	PZA-Ciba	500mg;10	42.46	5.188	818
Others	Rantidine	Consec	150mg; 10	7.51	2.205	341
Others	Dopamine	Dopinga	5ml	25.00	6.05	413
Others	Ciprofloxacin	Ciplox	200mg;100ml	27.00	6.41	421
Others	Paracetamol	Calpol	500mg;10	8.78	1.24	708
Others	Diclofenac Sodium	Diclonac	50mg;10	11.03	0.686	1608
Others	Diazepam	Calmpose	5mg;10	13.70	0.4	3425
Others	Dexamethosone Sodium Phosphate	Decdan	2ml	10.36	0.222	4667
Others	Cetrizine	Alerid	10mg;10	31.50	0.561	5615

Source:For Retail Price—Monthly Index of Medical Specialities, India, August, 2004
For TNMSC Price—Tamil Nadu Medical Services Corporation (TNMSC). Available from URL: http://www.tnmsc.com/system.html

Source: Saktivel Selvaraj (2009)