Presentation on IPR matters – with special reference to The Patents' Ordinance and The Rules

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Competition Provisions in TRIPS

- Art 40 – 1.Some licencing practices or conditions pertaining to IPRs can adversely affect trade and Trfr of Tech.
- 2. Members can legislate on what consti - tutes abuse of IPRs affecting Competition e.g. exclusive grantback or coercive package licencing etc

Competition and Patents

- Patents are a legal exception to Free Competition. This limited monopoly is accepted provided there is a balance in patent holders' rights and their societal obligations
- Checks on abuse of monopoly such as CL, Government use provisions, price control etc

Highlights of the Ordinance

- International obligations under TRIPS completed
- Product Patent in Pharmaceuticals, Food and Agro-chemicals
- Chapter IV A dealing with EMRs dropped.
- All pending applications for EMR to be considered applications for examination of the Patent Application

Highlights of the Act

- Pre-Grant Representation by way of Opposition allowed on two grounds namely patentability and non-disclosure of geographical source of biological material and traditional knowledge.
- Existing production of drugs which would be covered by Mail-Box patents to continue till the date of grant of patent.
- Parallel imports from any authorized source allowed

Pre-Grant Opposition (PrGO)

- PrGO was strengthened by an all party JPC and passed by Parliament unanimously in 2002. What was the sudden necessity to drop it - Particularly so when it was TRIPs compatible?
- “Representation by way of opposition” is a very weak substitute for a full fledged right of Pre-Grant Opposition.
- Chances of ‘ever-greening’ and issuance of undeserving patents high.
- Procedure of ‘Representation’ and publication is not consumer friendly.

Continued availability of drugs affected by Mail – Box Patents

- We appreciate the provision that the existing production of drugs affected by Mail Box Patents can continue up to the date of grant of Patent.
- But this will not solve the problem. The Government should allow continuation of such production by providing a statutory royalty to the patent holder.

Local working

- Flexibilities provided in TRIPs have not been utilized. Local working necessary for transfer of technology as well as for keeping the price down.
- How can a country of a billion plus population depend upon imports by MNCs?
- Hon'ble Minister assured about this in his press briefing. But we do not find it anywhere.

Patentability

- “mere new use” is an unnecessary narrowing of the definition. (Sec 3 d)
- Polymers, metabolites and other minor changes are not specifically made non-patentable. This will give rise to costly litigation which MNCs can afford but we cannot.
- Micro-organisms occurring in nature, gene sequences, micro-biological processes should not be allowed to be patented.

Compulsory Licences

- Procedure under Sections 87 and 88 are too elaborate and lengthy.
- Sec 92 A – not available in countries with no patent law or where the drug in question has not been patented. Re-drafting of the Section is required.
- Government's powers to take over patents have limitations.
- Royalty question kept vague.

Concerns

- Main concern continues to be weakness in our Patents' Law and a tilt in favour of the Patent Holder who are going to remain MNCs in the foreseeable future.
- Prices of patented medicines and access to medicine will continue to be a problem particularly because of low purchasing power in India (One third being below the poverty line and there being no social security.

Price Control of Patented Drug Prices

- The present Provisions in DPCO for patented drugs are not adequate because competition in this area is severely restricted. (Import Price plus 50%). If a patented medicine is manufactured in India then it can be brought under price control.
- But DPCO is under ECA, which is not a proper vehicle to deal with internationally patented products.
- We require a law to check prices of Patented drugs on lines of Canada, Japan, UK etc

Post 2005 scenario (India)

The domestic industry **will be affected adversely**. Our industry will have to depend upon **contract manufacturing, outsourcing, contract clinical trials etc.** A poor substitute for a well developed industry.

- Likely tough competition in the world market between generic drug manufacturers and the erstwhile patent holding MNCs wanting to continue their hold on the market,
- Also **competition within the country (India)** for generic drug market between the local and overseas manufacturers will rise.

Drug prices - **Post 2005 scenario (India)**

- Drug prices of the patented product will certainly be high. In nearby Pakistan and Indonesia the prices are 5 to 10 times the Indian price.
- The talk ‘prices will not rise’ is most misleading, to say the least.
- Prices of second best and others will also go up in sympathy.

Drug Prices (Contd)
Post 2005 scenario

- Experience the world over that cost of patented medicines is high. Examples - Ciprofloxcin 10s Rupees 29 in India (generic price), 424 in Pakistan (patented price) and 393 in Indonesia (patented price)
  - Ziduvudine Rs 58 (India) 313.47 (Pakistan) and 393 (Indonesia)
  - Simuvestatin Rs 25(India), 283 (Pak), 187 (Indonesia).

Drug Prices (Contd) Post 2005 scenario

- Example – Ciprofloxacin. Bayer reduced price by 70% at the height of Anthrax scare in 2001 under threat of US Govt. granting CL. Year 2001 was the 18th year of the patent on Ciprofloxacin (Expired 2003). **Does it not mean that by selling at three times the right price all these years, they overcharged the American people?**
- The truth is that the MNCs charge **'WHAT THE MARKET CAN BEAR'** and **not 'WHAT IS REASONABLE'**

Experience of USA - From "The Truth About Drug Companies" by Marcia Angell, Prof Harward University

- Top U.S. drug makers spend 2.5 times more on marketing than R&D. Then, why blame R&D for prices?
- At least a third of the new drugs are discovered by Public funded institutions and Universities. (Example – Texol by NIH sold to Bristol Myers for $20,000
- Me-too drugs – minor variations. 6 Cholesterol reducing drugs, 9 ACE inhibitors for BP etc. Nobody sure which one is better. Companies are bringing out variations. The original drug usually a University research. The new drug is priced highest.

Access to Drugs (India)

- Access to medicines particularly the high cost patented drugs would go down in the post 2005 India. Even the price of the 2nd best alternative drug (generic) would also go up in sympathy with the price of the patented drug.
- Doctors are likely to prescribe the best medicine (mostly patented) even in case of less serious patients who can be cured by lower potency (generic) drugs to enhance their reputation. Cost is no consideration.
- The problem in India is very crucial because there is no social security system. The majority of our population is unprotected from the vagaries of life.

R&D.
Options on Funding

- Government (public) funding.
- Public-Private joint funding.
- Government buying inventions and paying royalty – i) at a Fixed Royalty, or at a Royalty dependent on sale or popularity of the drug or 'rated quality of life improvement ((Aidon Hollis 2004)'.
- Government buying the required drug patent through auction system and places it in public domain (Kremer 1998)

Patent Harmonization

- We are not against patent harmonization as being tried by WIPO through PCT, PLT, SPLT etc BUT
  - In the interest of developing countries the pace of harmonization should be slowed down,
  - Acceptance of International Search and Examination results should be optional ;
  - Enforcement harmonization should be put on hold till SPLT is not agreed to by all,
  - FTAs or Regional Agreements which go beyond TRIPs, should not be accepted.

Data Exclusivity-TRIPS Article 39.3

- "Members when requiring, as a condition for 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, Member countries shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use."

How the demand is going beyond TRIPs?

Under 39(3),

- **Members are free to decide what test data should be submitted to National Health Authorities for giving Marketing Approval. The MNC demand restricts this.**
- **There is no compulsion on Members to require companies to file this or that data. The MNC demand takes away these sovereign rights.**
- **Members can rely on marketing approvals from other countries re. test data and other published data - considered in public domain. The MNC demand is that they should not rely on this data. This is unacceptable.**

Comparison with Indian Sch. Y requirements

- Article 39.3 of TRIPS is not triggered if no submission of undisclosed data is required as a condition of approving a pharmaceutical product.
- The Indian law does not require 'the submission of undisclosed test or other data' or 'unfair commercial use'.

Data Exclusivity - Other arguments

- Any monopoly would raise prices to unacceptable levels. Having accepted patent monopoly, there is no logic in extending monopoly in the name of Market Exclusivity or Data Exclusivity.
- Rise in prices of critical drugs is unacceptable as public policy.
- Data Exclusivity and R&D are not connected. It is a canard spread by MNCs to allure developing countries to accept their demands re. Data Exclusivity.

Data Exclusivity - Arguments continued…

- During the final phase of Uruguay Round, the draft texts submitted by USA was rejected and a consensus article on protection of data (present 39.3) was accepted. Not satisfied by that, USA now want to go back on TRIPS and are trying to get their demand of Data Exclusivity implemented by all Member States through bilateral negotiations.
- Why should developing countries accept it?

Conclusion - Ordinance

- **Growth of domestic industry may suffer. Technology Transfer is not taking place to the desired extent.**
- **R&D: Should be encouraged. Government funding, joint sector funding and International funding may be organized for R&D for diseases of tropical and developing countries.**
- Prices are bound to rise. The Government should ensure that the prices of drugs are reasonable and that the medicines are affordable for the public.

Conclusion - Ordinance

The Government should take these realities in consideration and correct the weaknesses pointed out above when the Ordinance comes up before the Parliament.

The most ideal step would be to refer the Ordinance (Bill) to a especially constituted Joint Select committee of the Parliament for scrutiny.

Conclusion – Other Points

- Price control upon Patented drugs required because competition in this area is severely restricted.
- Patent Harmonization should not be accepted. At least it should be slowed down.
- Data Exclusivity – Our existing law is TRIPS compatible. Nothing further is required.
- (End. Thank You)