COMPETITION COMMISSION OF INDIA

Case No. 41/2012

Dated: 05/03/2013

IN THE MATTER OF:

Manoj Hirasingh Pardeshi … Informant

Through

Ms. Savita Singh, Ms. Veena Johari and Ms. Kajal Bhardwaj, Advocates

And

Gilead Sciences Inc., USA … Opposite Party

ORDER UNDER SECTION 26(2) OF THE COMPETITION ACT, 2002

The information was filed by Manoj Hirasingh Pardeshi ('the informant') under section 19(1) of the Competition Act, 2002 ('the Act'), against Gilead Science Inc., USA ('the OP') for alleged contravention of provisions of sections 3 and 4 of the Act.

2. The informant claimed to be treatment activist, working towards universal access to first line, second line and third line treatment for HIV and other opportunistic infections and providing treatment literacy to people living with HIV and affected communities. The OP is a USA based pharmaceutical company engaged in the business of manufacturing drugs. Medicines Patent Pool (MPP) (not a party in the present case) is

a Swiss non-profit foundation based in Geneva created with an objective of forming a patent pool for medicines. Tenofovir (TDF), emtricitabine (FTC), cobicistat (COBI), elvitegravir (EVG) and a combination of these four products called 'Quad' are Antiretroviral (ARV) drugs used for treatment of HIV infection. The Active Pharmaceutical Ingredient (API) is the raw material used for production of drugs. The informant submitted that the OP was presently manufacturing TDF and FTC in USA and other countries whereas EVG, COBI and Quad are in the development stage and yet to be approved for use in HIV treatment.

3. The informant stated that as per WHO data globally by the end of 2009, the number of people living with HIV was around 33.3 million. The National AIDS Control Organisation, India (NACO) in its annual report 2010-11 stated that India had the third largest number of people living with HIV/AIDS.

4. The treatment for HIV infection is known as Antiretroviral Therapy (ART) and is to be taken life-long. The treatment prolongs and extends the life of the person affected by 20 to 25 years and improves the quality of life. The treatment is segmented into three levels: first line, second line and third line. The first line treatment is given to a person whose CD4 count reaches about 300-350 and/ or when there are opportunistic infections. The second line treatment is given to those on whom the first line treatment does not show desired results or who have developed resistance to the first line treatment. The World Health Organisation (WHO) has set guidelines for the first line, second line and third line ARV treatment. TDF has been recommended by the WHO as the first line

treatment and as replacement of another first line ARV medicine stavudine. Another first line ARV medicine is FTC. TDF is also used for second line treatment.

5. In 2006, the OP entered into non-exclusive voluntary license agreements ('LA-2006') with about 10 companies including Medchem, Alkem, Aurbindo, Hetero, Matrix etc. for production and distribution of TDF and other ARV medicines. The informant contended that purportedly the license agreement stipulated that the licensees would pay royalty @ 3 to 5 % on the sale of the finished product. The OP permitted the licensees to:

a. sell TDF, FTC and a combination of TDF and FTC (sold by the OP under the brand names Viread, Emtriva and Truvada respectively) in India and export to about 99 countries;
b. seek the Active Pharmaceutical Ingredient (API) from, or sell API to other OP licensees only; and
c. seek API from the OP's own API supplier.

6. On 12.07.2011, the OP entered into a license agreement (LA-2011) with MPP to pool licenses and give sub-licenses to pharmaceutical manufacturers worldwide including India. Subsequently, LA-2011 was amended to include South Sudan in the appendix to the agreement and covenants regarding not to sue and other clarifications. LA-2011 allowed MPP to sub-license the production and distribution of five ARV drugs (TDF, FTC, EVG, COBI and Quad) by way of tripartite agreement among the OP, MPP and the Indian pharmaceutical companies.

7. In view of LA-2011, MPP entered into tripartite agreements ('tripartite agreement') with two Indian pharmaceutical companies namely, Aurobindo Pharma Ltd. and Emcure Pharmaceuticals. The informant alleged that the clauses of the tripartite agreement were anti-competitive and in contravention of the provisions of the Act. The clause 4 of the tripartite agreement provided for the payment terms i.e. royalty at 3% and 5% for different drugs and their combinations. It was mentioned by the informant that the OP made two product patent applications i.e. in 1997 for TDF and in 2004 for TDF and its compositions, at Indian Patent Office which were vehemently opposed by Indian pharmaceutical companies.

8. The informant stated that the OP wrongly claimed in the appendix to LA-2011 that it had been granted patents i.e. 2174/DEL/98 and 01316/CHENP/2004 whereas the website of Indian Patent Office showed that the former application was not yet published and the latter did not exist. The informant alleged that the appendix neither stated that the application was with respect to a process or a product or a divisional application nor did it state that the product patent application was rejected.

9. The informant pleaded the following three types of agreements were in contravention of the provisions of the Act:

a. Voluntary non-exclusive agreements entered into by the OP directly with Indian Pharmaceutical companies since 2006 for production and distribution of TDF and FTC medicines and their combinations.
b. Licence agreement of the OP with MPP which allowed MPP to have sub-licences with Indian pharmaceutical companies.

c. The sub-license tripartite agreement among the OP, MPP and the Indian pharmaceutical companies. (all three agreements collectively referred to as 'license agreements')

10. Referring to various clauses of the license agreements, the informant had alleged *inter alia* as under:

a. The license agreements limited the production and supply as they restricted the purchase and sale of API only from the OP or the OP approved licensees.

b. Restrictions on purchase of API also controlled price of API which could make production of drugs expensive and unaffordable. The license agreements also restricted new combinations of the drugs using same API, as the licenses were for fixed dosages and fixed combinations.

c. The said license agreements were among OP, MPP and Indian Pharmaceutical companies so that the OP could have an exclusive supply agreement for API.

d. The license agreements were in the nature of exclusive supply agreements as they restricted the purchasers, in the course of manufacturing and production process of the said medicines, from acquiring or otherwise dealing, in any manner, with any other supplier of API other than the OP or its licensees.

e. The license agreements were anti-competitive as they contained an 'exclusive distribution' provision which limited, restricted and withheld supply of the drugs in question to any area outside the list of countries mentioned in the Appendix thereto.

f. Indian pharmaceutical companies would not be able to supply drugs produced under the license agreements to any other country or territory not covered in the Appendix.

g. Many developing countries were left out of the licence agreements which were potential markets for Indian pharmaceutical companies. This curtailed the freedom of licensees to compete in the market, and restricted the market coverage for the pharmaceutical companies in India, and had an adverse impact on international competition and prices of medicines.

h. The license agreements were like 'tie-in' arrangements as they required Indian pharmaceutical companies to purchase API for the drugs in question and their combinations within the territory from the OP and its licensed distributors and agents only.

i. Patent pooling was a restrictive practice as it locked the technology and production in a few hands by entering into agreements to pool patents, thereby making it difficult for those companies outside the pool to compete.

j. The license agreements entailed unreasonable conditions on non-patented drugs, restricted competition in the market by dividing the markets among pharmaceutical companies that would otherwise compete using different technologies.

k. The license agreements that the licensees were to enter into with the re-sellers were also to be scrutinised and approved by the OP and the agreements could be terminated at the behest of the OP.

l. The license agreements limited the innovation and technical development of Indian pharmaceutical companies as these agreements provided for one time

know-how transfer from the OP to Indian pharmaceutical companies and the OP had no obligation to reveal any kind of improvements to Indian pharmaceutical companies.

m. The license agreements provided that royalty be paid and continued to be paid even though there was no patent granted on the drugs. The royalty was to be paid by Indian pharmaceutical companies to the OP and it would pay a fixed amount to MPP for tripartite agreement. The payment of royalty where there was no product patent in India on the drugs was alleged to be unreasonable.

n. The license agreements also restricted the use of drugs only for HIV and in the case of TDF for hepatitis-B also. Hence, if there was a new use of the known medicine, it could not be sold or produced by the licensee for such new use.

o. API license was bundled with the product as such a generic manufacturer would be unable to produce a TDF product under the license using API produced by entities not licensed by the OP.

11. The informant *inter alia* prayed that the inquiry be conducted into the non-exclusive voluntary license agreements entered into by the OP with Indian pharmaceutical companies since 2006 till date; the agreement with MPP and the tripartite agreement among the OP, MPP and Indian pharmaceutical companies for contravention of sections 3 and 4 of the Act. The informant also prayed for interim relief that the OP be restrained from carrying out any act under all the license agreements till the conclusion of the inquiry.

12. After hearing the counsels for the informant, the Commission considered it necessary to call NACO and National Institute of Pharmaceutical Research (NIPER) for preliminary conference so as to have a broader view of HIV drugs and their availability in India. The representatives of NACO and NIPER made a presentation on ARV drugs before the Commission. Dr. B.B. Rewari represented NACO and Dr. Anil Kumar Angrish represented NIPER. From the presentations, it was gathered that the ARV treatment in India is provided either through the public sector programme or by private practitioners. It was informed that approximately six lakh patients were being treated under the national AIDS control programme run by the Government with the help of WHO whereas the number of patients going to private practitioners were miniscule. It was also stated that NACO uses only WHO pre-qualified drugs for the national AIDS control programme.

13. NACO informed the Commission that in the treatment, one pill containing minimum three ARV drugs combination is given to a patient. The ART was a combination of the following inhibitors: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non- Nucleoside Reverse Transcriptase Inhibitors (NNRTI), Protease Inhibitors (PI) and Fusion Inhibitors(FI). The first line ART regimen followed in India consisted of Zidovudine/ Lamivudine/ Nevirapine or Stavudine (Tenofovir)/ Lamivudine/ Nevirapine. The second line ART regimen followed in India consisted of TDF (Tenofovir) (300mg) + 3TC (Lamivudine) (300mg) in fixed dose combination or ATV/r (Cap. Atazanavir 300mg. + tab. Ritonavir 100mg). The Indian market for ARV drugs was dominated by generic products manufactured by Indian pharmaceutical companies. From the presentations, it was gathered that there are 12 Indian companies who manufactured

WHO pre-qualified ARV drugs and approximately 9 foreign companies also manufactured WHO prequalified ARV drugs.

14. It was further stated that NACO procured ARV drugs for around Rs. 300-500 crore annually for its national AIDS control programme. The top four Indian companies manufacturing ARV drugs were Cipla (52%), Emcure (32%), Genix (8%) and Ranbaxy (5%). It was also observed that the market was experiencing constant growth of approximately 12% over the last three years.

15. It was also informed that the following patent applications of different companies were rejected by the Indian Patent office:

a. Gilead Sciences (tenofovir – can be used as both first line and second line treatment);
b. Tibotec pharmaceuticals (darunavir – second line treatment drug) (rejected in September 2009).
c. Bristol-Myers Squibb (atazanavir bisulphate);
d. Abbott (lopinavir/ ritonavir) (rejected in January 2011).

16. After considering the information available and the submissions of the counsel for the informant, application of sections 3 and 4 of the Act was examined in context of the available facts. Section 3 (1) of the Act *inter alia* provides that no enterprise or association of enterprise etc. can enter into an agreement in respect of production, supply, distribution etc. or provision of services, which causes or is likely to cause an appreciable adverse effect on competition in India.

17. Sub-section (4) of section 3 of the Act *inter alia* provides that any agreement amongst enterprises or persons at different stages or levels of 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 tie-in arrangement; exclusive supply agreement; exclusive distribution agreement; refusal to deal and resale price maintenance would be an agreement in contravention of section 3(1) if such agreement causes or is likely to cause appreciable adverse effect on competition in India. The OP first entered into the voluntary license agreement LA-2006 with the Indian pharmaceutical companies and allowed them to manufacture and sell the drugs as per terms and conditions of the agreement. However, it was not clear whether LA-2006 was still effective or continued to have any continuing effect post 20.05.2009 as the substantive provisions of the Act came into force on this date, whereas LA-2006 was signed prior in time. Therefore, the agreement between the OP and the Indian pharmaceutical companies could not be examined for the agreement was entered into much prior to the enforcement of the provisions of the Act. The second agreement was between the OP and MPP i.e. LA-2011 which allowed MPP to sub-license the manufacture and sale of the drugs to Indian pharmaceutical companies. This agreement will not fall within the ambit of section 3(4) of the Act since MPP is nowhere in the production chain. The last agreement i.e. the tripartite agreement falls within the contours of section 3(4) of the Act vis-à-vis the OP and the Indian pharmaceutical companies who are placed in different stages of the production chain and therefore, appreciable adverse effect on competition needs to be examined keeping in view the factors in section 19(3) of the Act.

18. Section 19(3) of the Act which lists the factors to be considered for appreciable adverse effect on competition reads as under:

"(3) 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."

19. HIV treatment was beyond the reach of common man even in highly advanced countries, since the cost of annual HIV treatment was exorbitant. As HIV was spreading very fast, US President's Emergency Plan for AIDS Relief (PEPFAR) and Clinton Foundation, Bill and Melinda Gate Foundation came together. With the intervention of these organizations and due to intervention of Medicine Patent Pool, the companies having patents over the HIV treatment medicines were compelled to share their technology and to reduce the price. Cipla had taken the lead and announced in March, 2001 to cut the price of most profitable ARV drugs from $11000 per patient per year to $ 350 per patient per year. Cipla nearly toppled the original manufacturers, who had monopolized ARV drug market. With the advent of time, all other companies were forced to reduce the price and presently the cost of one day's drug per patient is hardly Rs.10-15 in India. Although the originator companies for ARV drugs had held this market, but after Cipla announced the manufacture of generic version of ARV drugs,

India dominated the generic ARV drug market. The generic version of ARV drugs from India are used by US President's Emergency Plan for AIDS Relief, Clinton Foundation, Bill and Melinda Gates Foundation, Government of South Africa and Governments of different countries from Africa. These drugs are manufactured as WHO pre-qualified products. While about 21 Indian companies are manufacturing and marketing these WHO pre-qualified products, there are around 12 foreign companies manufacturing WHO pre-qualified products.

20. As per information available in public domain and verified from NACO, Indian companies presently are manufacturing most of the generic drugs and India is known as pharmacy of the world. The first line ARV Regimen drugs freely available in India and used are as under:-

First Line ART Regimens		
Regimen	National ART Regimen	Preference
Regimen I	Zidovudine + Lamivudine + Nevirapine	Preferred regimen for patients with Hb >9 gm/dl
Regimen I(a)	Tenofovir + Lamivudine + Nevirapine	For patients with Hb < 9gm/dl
Regimen II	Zidovudine + Lamivudine + Efavirenz	Preferred for patients on anti-tuberculosis treatment, if Hb > 9 gm/dl
Regimen II (a)	Tenofovir + Lamivudine + Efavirenz	For patients on anti-tuberculosis treatment and Hb < 9 gm/dl

The Second line ARV Regimen Drugs are as under:-

Second Line ARV Drugs		
Second Line ARVs	**Dosage**	**Dosing schedule**
TDF + 3TC	Fixed dose combination of TDF 300 mg + 3TC 300 mg	0-0-1 (One tablet in the night)
ATV/r	Cap. Atazanavir 300 mg	0-0-1 (One capsule in the night)
	Tab Ritonavir 100 mg	0-0-1 (One tablet in the night)
TDF: Tenofovir; 3TC: Lamivudine; ATV/r: Ritonavir boosted Atazanavir		

21. Presently, a vast majority of people in low and middle income countries are being provided generic ARV drugs produced by Indian manufacturers unhampered by patent and other intellectual property restrictions. The Patent Act,1970 was amended by India in 2005 to allow product patents on medicines, in line with WTO agreement on Trade Related Aspects of Intellectual Property Rights. However, this did not affect the production and supply of generic ARV drugs. In 2006, India accounted for more than 80% of the donor funded developing countries market. In 2008, India accounted for 87% of ARV purchase volume throughout the donor funded developing countries market. The proportion of ARVs produced by Indian manufacturers is even higher within certain market niches. In 2008, India produced generic drugs accounted for 91% of paediatric ARV volume and 89% of adult NRTI (Nucleoside Reverse Transcriptase Inhibitors) and NNRTI (Non Nucleoside Reverse Transcriptase Inhibitors) purchases.

22. Although, in India about 16 lakh people are considered HIV affected but around only 5,00,000 people are taking treatment under NACO Programme, where treatment is provided free of cost. A very small portion of the patients suffering from HIV go to private practitioners. Even the private practitioners may prescribe either the generic version of ARV or the patented version of the drugs. Therefore, the market for patented drugs for HIV treatment is negligible as compared to the market for generic formulations as approved by WHO. There are 21 companies manufacturing 152 brands of ARV generic drugs in India. These pharmaceutical companies were getting international contracts for supply of ARV drugs. For example, Hetero drugs won $ 20 million order from South Africa and Aurobindo Pharmaceutical in 2011-12 made a gross turnover of Rs.43387.3 million and experienced a growth of 13.4% only in ARV sales. Thus, it can be easily stated that the market for the OP's patented drugs being manufactured on license basis was too small to have appreciable adverse effect on the competition.

23. The ARV drugs market had been growing consistently and more and more brands/ drugs were being launched by Indian pharmaceutical companies which not only benefit the Indian consumers but also the international consumers. The industry had been experiencing constant improvement and changes in the production of the ARV drugs and chances are that the alleged tripartite agreement will only help the market grow because of the OP sharing the technical know-how of third line drugs with other companies. Moreover, in India, the third line ARV drugs have not taken off. NACO has not entered into the territory of third line treatment as presently no patient has reached the stage where third line treatment may be required to be prescribed and it restricts itself more to the first line treatment with very few patients being given second line treatment. Even if the contention of the informant is accepted that the license agreements were anti-

competitive, still there would be no appreciable adverse effect on competition since only the private practitioners who recommend the drugs in question, and cater only to a miniscule number of patients as compared to the national AIDS control programme. Therefore, in the opinion of the Commission, no appreciable adverse effect on competition would be there due to the alleged agreements and no contravention under section 3(4) of the Act was made out.

24. As abuse of dominance was also alleged, the applicability of section 4 of the Act was examined. It was noted that the informant discussed five ARV drugs namely TDF, FTC, EVG, COBI and Quad and their availability in the market, however, it was learnt that there were many other drugs present in the market including Zidovudine, Lamivudine, Nevirapine, Indinavir, Nelfinavir etc. It was also noted that these drugs were sold in different combinations under different brand names by the pharmaceutical companies. As stated above, there were more than 150 brands manufactured by more than 20 companies in India. The specific end use for which ARV drugs are manufactured in India (mostly generic form) includes not only the five drugs named by the informant but also the other drugs approved by WHO and used for treating HIV/AIDS. These drugs can be interchanged or substituted with each other and can be used in different combinations for treating HIV/ AIDS. Therefore, the relevant product market in the present matter was the production/ manufacture of ARV drugs. The relevant geographic market for our consideration has to be whole of India since the conditions were homogenous throughout the country. Thus, the relevant market under section 2(r) of the Act was the production/ manufacture of ARV drugs in India.

25. The explanation to section 4 of the Act defines dominant position to mean a position of strength enjoyed by an enterprise in the relevant market in India which enables it to

operate independent of competitive forces prevailing in the relevant market or affect its competitors or consumers or the relevant market in its favour. On examining the dominant position of the OP, it was seen that the OP had no legal existence in India and did not engage in any business in India. Further, the relevant market was fragmented with many players engaging in the activity of production/ manufacture of ARV drugs in India. Accordingly, the OP was not a dominant player in the relevant market in India and therefore, no abuse as envisaged under section 4 of the Act could exist.

26. In the light of aforesaid discussion, the Commission finds that no *prima facie* case was made out against the opposite party under section 3 or section 4 of the Act for referring the matter to DG for investigation. It was a fit case for closure under section 26(2) of the Act.

The Secretary is directed to inform all concerned, accordingly.

Sd/-	Sd/-	Sd/-
(H.C.Gupta)	(Geeta Gouri)	(Anurag Goel)
Member	Member	Member
Sd/-		Sd/-
(M.L.Tayal)		(Justice S.N.Dhingra) (retd.)
Member		Member

Sd/-
(Ashok Chawla)
Chairperson