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MNC patent monopoly and takeover of generics in India

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New Delhi, 20 Dec (K. M. Gopakumar) - A new study reveals that multinational pharmaceutical companies are exploiting their product monopoly to charge high prices under India's product patent law as well as gradually taking over the domestic generic sector.

The study titled "Multinationals and Monopolies; Pharmaceutical Industry in India after TRIPS" is authored by a well-known researcher on the Indian pharmaceutical industry, Prof. Sudip Chaudhari of the Indian Institute of Management based in the city of Kolkata.

The study examines the behaviour of multinational companies (MNCs) in the Indian pharmaceutical market during the period following the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), especially from the date of introduction of the product patent regime on 1 January 2005.

(India introduced a series of policy measures during the 1970s in order to provide an enabling environment for its national pharmaceutical industry. The Patent Act of 1970 which prohibited product patent protection, was one of the important steps. India reintroduced product patent protection in 2005 in order to comply with the TRIPS Agreement. Price control on medicines, compulsory obligation on MNCs for the local production of bulk drugs, prohibition of MNCs from the production of certain products etc. were some of the policy measures introduced in the 1970s. However, when India underwent economic liberalisation in the 1990s, all these policy measures, which provided the enabling environment for the domestic generic pharmaceutical industry, were withdrawn.)

The study concludes that, "the days of product monopolies and high prices are back in India". MNCs have started importing and marketing of new-patented medicines at exorbitant prices especially for life-threatening diseases like cancer and at the same time lagging behind in investments in India.

Further, MNCs are also expanding and increasing their aggregate market share in the generic sector, not only organically but also through mergers and acquisitions (M&A) and strategic alliances. Thus, the broad conclusion of the study is that MNCs are trying to take India back into the old days of product monopoly and high prices.

The conclusions of the study are based on analyses carried out in three areas viz. market structure and prices of patented products, the growing imports of finished products, and the rise of MNC dominance in the market.

MARKET STRUCTURE AND PRICES OF PATENTED MEDICINES

According to the study, from 1995-2010, there were 180 new chemical entities (NCE) and new biological entities (NBE) (hereafter termed "medicines") in India in terms of value. In the period 1995-2010, the US Food and Drugs Administration provided marketing approvals for 413 NCEs, excluding NBEs.

According to the study, out of these 180 new medicines, MNCs are marketing 92 in India and enjoy a monopoly over 34 medicines. These 34 medicines account for 31% of their sales of 92 medicines. The monopoly status is based on the actual monopoly in the market (single source

producer) and not based on the patent status in India. Out of 92 products, 53 products account for more than 50% of the sales of 92 products.

A break-up of the 180 medicines in terms of the patent history shows that patents for 62 drugs have expired in the United States of America (USA) and another 67 drug patents were granted prior to 1995. A further 51 drug patents were granted in the USA after 1995, i.e. after the implementation of the TRIPS Agreement. As mentioned above, the study does not analyse the patent status of these 180 medicines in India.

The study also found that MNCs enjoy monopoly on 8 medicines even after the expiry of patents for molecules of these medicines in the USA. Thus, the study also points to the existence of other entry barriers, which can prevent the generic entry even after the expiry of patents, such as complex manufacturing process etc.

Thirty-four medicines that enjoy marketing monopoly in India fall into the following therapeutic areas: Anti-cancer (11); cardiac (7); anti-infectives (5); analgise (3); Neurological (4); Diabetic (3); ophthal/otologicals (1).

The study provides the exorbitant prices on the 34 monopoly medicines. Six highly priced medicines are (price is provider per unit): A 50 ml injection of Roche's anti-cancer drug trastumuzab (brand name: Herceptin) costs USD2,585.76 (Rs 135,200); Merck's cetuximab (Erbitux) USD1,683.93 (Rs 87,920); Bristol-Myers-Squibb's ixabepilone (Ixempra) USD1,271.18 (Rs 66,430); Pfizer's pegaptanib (Macugen) USD867.48 (Rs 45,350); Sanofi-Aventis' rasburicase (Fasturtec) USD861.27 (Rs 45,000); Roche's bevicizumab (Avastin) USD711.49 (Rs 37,180).

The broad range of price for the other 28 medicines are (price per unit): 6 products costing between Rs 10,000 and Rs 15,000 (USD191 to 287); 8 products between Rs 1,000 and Rs 10,000 (USD19 and 191) another 6 products between Rs 100 and Rs 1,000 (USD 2 to 19) and only 8 products with prices below Rs 100 (USD2).

The study also shows that there is no effective differential pricing. It found that in certain categories, competition may take place among different molecules (medicines) in certain therapeutic categories like cardiac and anti-diabetic.

The study cites the potential competition among the molecules cerivasation, dronedrone, saxagplin, and stagplain. Such competition may potentially reduce the impact of high prices. However, the study notes that little such competition exists for medicines for life-threatening diseases in the absence of effective substitution.

The study also discusses the possibilities of policy response in the light of exorbitant prices of new medicines. It examines the viability of both price control and compulsory licensing.

On price control, it states that "Price control is not forbidden under TRIPS or any other agreement of the WTO. The Draft National Pharmaceuticals Policy, 2006 (p. 15) recommended mandatory price negotiations of patented drugs before granting marketing approval and stressed the importance of studying the experiences of Canada, Australia, France and other countries believed to have a good system".

Comparing price control with compulsory license, it says: Price control "if properly implemented makes drugs more affordable but does not provide any room for the generic companies. (Compulsory license) not only makes the prices more affordable through competition. It also ensures some space to the generic companies, which is vital for their long term sustenance".

Further, it states that "the policy option which is much more potent and sustainable in the longer run is compulsory licensing ... the exorbitant price provides a very good rationale for compulsory license".

The study also found that use of TRIPS flexibilities contributed to the competition in the market. It found that monopoly exists only on 50% of the post-1995 products introduced in the market. The study says that incorporation of two TRIPS flexibilities might have contributed to this fact, viz. section 11A (7) and Section 3(d) of India's Patents Act.

[Section 11A (7) allows the Indian generic industry to continue the production of generic medicines, which they have started on or before 31 December 2004. Section 3(d) denies patent protection to a known substance in the absence of significant improvement on efficacy.]

IMPORTATION OF MEDICINES

The study finds that there is a sharp increase in the importation of formulations by MNCs in the post-TRIPS period between 1995-2010. Even though there is an export surplus, "importation has grown at a faster rate than exports leading to a decrease in formulations trade surplus".

The value of import of formulations has expanded from USD69.5 million to USD1,096.1 million between 1995 and 2010 and shows a compound annual rate of growth (CARG) of 20%. During the same period, exports have grown at 17% CARG.

The study states that 65% of the formulation imports in 2010 came from five countries viz. Switzerland, USA, UK, Germany and France. Out of these five countries, Switzerland alone accounts for a third of these imports.

Further, it also reveals that import of formulations by 7 major MNCs viz. Abbott, Aventis, GSK, Pfizer, Novartis, Merck and Wyeth have grown in recent years. Between 1997-2010, the import of formulations from these seven companies have grown from around USD20 million to USD120 million.

MNCs that are not operating in India are entering into marketing alliances with Indian generic companies to sell their products. Indian companies such as Elder, USV, Emcure, Cdaila Healthcare, Piramal, Ranbaxy are acting as authorised agents for imported formulations.

The study also points out the weakness of the current price control framework to address the high prices of imported formulations.

On price control, it states: "If the current provisions of the Drugs Price Control Order (DPCO) are to be strictly followed, the National Pharmaceutical Pricing Authority (NPPA) cannot ask for the details of the imported cost of drugs. In fact an attempt by NPPA to do so has failed - the concerned MNC went to the court to prevent NPPA from asking for cost data. NPPA is required to accept whatever costs the importers declare. Thus, importing high priced drugs is one way of avoiding price control. It is important to change the provisions of DPCO to find out whether the costs and prices claimed by the importers are reasonable".

Further, the study points out that the dependence on importation has increased foreign exchange spending of MNCs.

"Whereas the foreign exchange deficit of the MNCs has gone up from USD20.52 million in 1994 to USD205.05 million in 2010, i.e. at 15% per annum (CARG), foreign exchange surplus of the top Indian companies increased at 29% per annum during the same period. Between 1994 and 2010, MNC export earnings increased by only 5% per annum (compared to 22% by the Indian companies), but dividend remittances increased by 16% per annum. Export intensity, i.e. exports as a percentage of sales has remained stagnant for the MNCs at around 4% in 2010 compared to about 50% for the Indian companies".

During the same period, Indian companies' foreign exchange earnings have grown from USD40.07 million to USD2,392.58 million.

The study also exposes the myth of MNC investment. While there is a sharp increase in the

investment on plant and machineries by Indian companies between 1995 and 2010, MNCs' investment has stagnated. "By 2010, MNC investments accounted for only 5% of the investments of Indian companies of Rs 137,652.5 million."

Further, the study sums up MNCs' approach to local manufacturing in India by stating that, "the manufacturing activities of the MNCs after economic liberalization are reminiscent of the 1950s and 1960s when the official policy was quite liberal but the MNCs were reluctant to undertake manufacturing".

RISING ROLE OF MNCS IN THE INDIAN MARKET

According to the study, MNCs are trying to grow aggressively in the generic segment and thus changing the traditional approach of relying only on the patented drugs and developed country market. However, MNCs are now trying to capture the generic market too.

"So far as India is concerned, the most obvious reflection of such changes in strategy is taking over of Indian companies by MNCs and strategic alliances between MNCs and Indian companies."

Indian companies such as Dr. Reddy's, Aurobindo, Cadila Healthcare and Torrent have entered into supply agreements with MNCs such as GSK, Astrazeneca and Abbot. Dr Reddy's, for example, will supply about 100 branded formulations to GSK for marketing in different emerging markets across Latin America, Africa, Middle-East and Asia-Pacific excluding India."

The study states that "the post-TRIPS environment and the strategy being adopted by the MNCs suggest that they are on the way to dominating the industry again" using the following three ways. "First, unlike in the earlier period, the MNCs are aggressively pursuing growth in the generic segments. Second, they will enjoy monopoly power in the patented drugs market. Third, they have the financial capacity to take over more Indian companies."

The study points out that the recent acquisition of Indian generics has really helped MNCs to increase their aggregate share in the Indian pharmaceutical market.

It says "the share of the MNCs in the domestic formulations market has dramatically increased from less than 20% in March 2008 to 28% in December 2010 with the taking over of Ranbaxy by Daiichi Sankyo in June 2008; Dabur Pharma by Fresenius Kabi Oncology in August 2008; Shantha Biotechs by Sanofi-Aventis in July 2009; and the domestic formulations business of Piramal Healthcare by Abbott in May 2010."

Further, "The Abbott group comprising Abbott, Piramal Healthcare and Solvay Pharma is now the largest company in India with a market share of 6.2% ahead of the second largest Cipla (5.7%). Abbott was the 30th largest company in the domestic formulations market in March 2008 with a market share of only 1.1%".

Lastly, the tendency of MNCs to step up their equity stake in their Indian arms has actually accelerated in the last few years. Novartis has increased foreign equity from 50.93% in 2005 to 76.42% in 2010, Pfizer from 40% to 70.75%, Abbott from 61.7% to 68.94%, and Aventis from 50.1% to 60.4%.

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