ISSN 2350-109X
www.indianscholar.co.in

Indian Scholar

An International Multidisciplinary Research e-Journal

PHARMACEUTICAL INDUSTRY UNDER THE TRIPS PATENT REGIME

Prof.(Dr.) Sanjay Sindhu
Professor,
Department of Laws,
Himachal Pradesh University,
Shimla,(HP)

Nandan Sharma
Assistant professor
Shoolini University
Solan, HP India

Abstract

An analysis of the impact of TRIPS Agreement on pharmaceutical industries of the developing countries should be examined in the light of North-South debate on the pharmaceutical industry. North South debate on pharmaceutical industry pertaining to Intellectual Property Rights is primarily focused on two issues viz; the change of the patent system and the substitution of generic drugs for brand name drugs. The patent system as conceived in Paris Convention is not at all acceptable for the developing countries especially with regard to their pharmaceutical industry.[1]The existing international patent system (product patent for pharmaceuticals) is considered to be a major constraint for the establishment of national pharmaceutical industries in the developing countries.

INTRODUCTION

The MNC'S are aggressive campaigners for the compulsory product patent protection for pharmaceuticals because it can be effectively used as a barrier to prevent others from entering into market and thus protect their absolute monopoly interest. According to them, a product patent is an incentive and a reward for innovation. The developing states have a different view and are not ready to grant product patent protection for drugs. They see the product patent on drugs as retarding and hampering the development and establishment of national industry by facilitating an import monopoly. They prefer a process patenting protection instead of a product patent as it creates only limited monopoly. As of now, many developing countries succumbed

[1] Michael R Gadbaw, J. Timothy Richard, (Ed.), *Intellectual Property Rights Global Consensus, Global Conflict*, (1988), p.167

under pressure of developed countries through TRIPS. The main point of controversy was the substitution of generic drugs for brand name drugs. A brand name has always played a primary role in the pharmaceutical marketing and is considered as being a source of market power in pharmaceutical industry. Handsome money is spent for establishing brand names in order to capture and maintain market because of product competition. Brand names help companies to maintain their monopoly even after expiry of patent rights. Brand names of drugs account for two-thirds of the total world sales of pharmaceuticals.[2] Thus, predominance of brand names leads to higher drug prices.

The main reason for the controversy lies in the basic difference of the developed and developing states regarding the objectives of the pharmaceutical industry. The developed countries are more concerned about the safety and quality of drugs and give much importance to the research and innovation of the drugs. Price control and cost effectiveness are given secondary preference. The developing states major concerns are reduction of cost of drugs and making available good quality generic drugs at affordable price to all.

TRIPS AND ITS IMPLICATIONS

1. Wider Patentability

One of the major changes brought by TRIPS was the expansion of patentability. According to the agreement, patent shall be available for inventions whether product or processes. The provision allows patenting of any new invention provided it involves inventive step, and is capable of industrial application.[3]The provision has curtailed the benefit of process patenting enjoyed by pharma industries. The developed countries opted for strong patent protection in order to build up their national pharmaceutical industry without caring about the problems like affordability and access to medicines being faced by developing and least developed countries. Some major shortcomings of product patent regime according to developing countries includes; firstly, that it discourages R&D investment on existing products thus blocking the social objectives of Science and Technology. Secondly, it prevents the development of processes conducive to the environment and socio economic conditions.[4]

2. Term of Patent Protection

TRIPS provided for a universal duration of patent protection i.e. 20 years for all patents. There is no rationality behind such a long duration. The higher cost of R&D and delay in returns are said to be the justification for long duration of patents. These justifications for long duration of patent protection is questioned on two grounds-a short product time cycle in high technology area and short duration for remuneration of investment in a global market.[5]

---

2 Based on Hathi Committee recommendations, the Drug Policy announced in 1987, India Banned marketing of five drugs viz,;Analgin, Aspirin, Chlorpromazine, Ferrous sulphote, Piperazine and its salt under brand names. P.H Rao, "Generic and Brand Name controversy: A sample Survey in Dr. Ekbal (Ed.), *A Decade after Hathi Committee,* (1988), p. 240

3 Article 27 (1), TRIPS Agreement

4 B.S. Chimni, TRIPS for self-reliance: Problem with TRIPS Text, in Proceeding of colloquium in Foreign Trade, GATT and Third World Development, NWGPL, (1991), p. 57

5 BiswajitDhar and Niranjan Rao, "Trade Relatedness of Intellectual Property Rights: Finding the Real Connections," paper presented in The American University, (April 24-25), 1995

ISSN 2350-109X
www.indianscholar.co.in
Indian Scholar
An International Multidisciplinary Research e-Journal

3. Reversal of Burden of Proof

TRIPS stipulated a new rule of burden of proof. According to the TRIPS, the onus of proof is on the defendant for the purpose of civil proceedings.[6] As per TRIPS Agreement, the judicial authorities shall have the authorities to order the defendant to prove that the process to obtain an identical product is different from patented process.[7]Emphasis is on the identical product. This provision blocks any chance of developing a substitute for the patented product and it also gives an effective arm to the patentee to block any such attempt by threatening or initiating legal proceedings. Thus it could negatively affect the innovation activities in small and medium sized enterprises due to risk of facing legal action and high litigation cost. In other words, this provision affects the competitor's effort to develop an alternative process.

4. Importing is Tantamount to Working of Patent

One of the basic objectives of patent protection is to ensure the social and economic benefits of granting state. In order to achieve this purpose and to curb the abuse of patent right by maintaining an import monopoly, many states put the working requirement of patent as one of the requirements to grant patent rights.[8] This is the only concrete obligation upon patent holder. TRIPS provision takes away this obligation and creates an obligation free patent regime. Under the TRIPS Agreement, the patent holder is not under an obligation to work his patent locally. He has been given an exclusive right to import the patented product.[9] This provision is capable of converting the developing states into a market for finished products of the developed states.

5. Domestic Production

Compulsory product patent for drugs and pharmaceuticals would have far reaching consequences on domestic industry. Once product patent is granted, patent protection for usage, dosage and conventional forms exists even after the expiry of patent of basic drug. Product patent protection may extend even to the generic drugs by patenting the process or by patenting the usage, form or combination.[10] The process patent in post TRIPS period is almost equivalent to product patent with the help of reversal of burden of proof provision. The flow of generic drugs is less in strong patent regime with dominance of MNC's. This is mainly due to lesser ability of domestic industries to produce new drugs and dominance of MNC's.

6. High Price

Another detrimental impact of excessive monopoly under the TRIPS regime is the shooting up of prices. This price hike will not affect the old (off patent) drugs but consumers may suffer high prices as far as new patent drugs are concerned. The general price level of drugs in the long run will depend on the market share of the patented drugs.[11]After the amendment to the Patent Act,

---

6 Article 33, TRIPS Agreement
7 Article 34(1), TRIPS Agreement
8 Sections 83, 84, 86, 89, 97, 100, 101, 102, Patent Act 1970
9 Articles 27(1) and 28, TRIPS Agreement
10 B.K. Keayla, TRIPS Patent System: Analysis and Implications, Centre for study of Global Trade System and Development, New Delhi, (1997), p. 13
11 GhayurAlam, "Impact of Proposed changes in IPR in India's Pharmaceutical Industry," prepared for Indian Council for Research on International Economic Relations, and UN Development programme , (1996), p. 31

many new drugs are being launched by MNC's. In case of importation of drugs by MNC's, the prices are bound to rise. The prices have shown a rise in almost all the countries which entered product patent era. Thus, there are many good reasons to establish that new patent regime is making right to health and access to medicine a costly affair.

7. Effects on R&D

In the post TRIPS era there are only three ways to produce new drugs viz invention of new drugs, obtaining licenses from the patentee and compulsory licensing. R&D investment should be augmented in order to produce new drugs and obtain patent on it. R&D investment of the Indian Pharmaceutical Industry is very low. It spends only 2 percent of its turnover on R&D while developed countries spend our 10-15 percent.[12] R&D thrust of Indian Pharmaceutical Industry is on the process of development. Small size and low profitability may be reasons for this. On US $600 an average, million is required to develop a new drug.[13] However it is difficult to estimate exact estimate of Indian R&D. If it is 10 percent of international level, then it is about US $ 60 million (Rs 200 crores).[14]It will be a difficult task for developing countries especially Indian Pharmaceutical Industry to raise its R&D contribution to such level. There is only limited scope for process development in the post TRIPS era. Strong patent protection is not going to boost Indian Pharmaceutical R & D investments. Research in new drug delivery system new processes, new drug research and licensing to multinational companies can address this issue to some extent. Collaboration of the Indian Pharmaceutical Industries with MNC's is the only key to success in post TRIPS era.

8. Effects on Export and Import

Indian exports of drugs and pharmaceuticals have been hampered by the strict patent protection claims. Under the new patent regime Indian pharmaceutical industry can export only generic drugs in the post TRIPS era.[15] The production of new drugs would depend on the mercy of MNC's. But, there is every chance of increase in the export of generic drugs. The demand for generic drugs has been increasing in developed countries since 1980s.[16] The estimated demand of generic drugs is at present US $20 billion and expected to go up to US $ 40 billion in 2005.[17] Many Indian firms are prepared to exploit this boom and a few of them have engaged in marketing operations either through acquiring small generic firms or through joint ventures. Firms like Ranbaxy, Lupin, NATCO, Dr. Reddy's lab, Cipla etc. have set up ventures in USA, China, Russia, Canada, Nigeria and Thailand.[18] But the competition is cut throat in the international generic drugs market. Indian Pharmaceutical Industry faces a tough competition from China. China dumps drugs in the international market at half price when compared to Indian drugs.[19] Other competitors are South Korea, Thailand and Europe. Import of drugs

---

12 Y.H. Ghorpure, "Turmoil in Pharma Sector," Chemical Weekly Annual, (1997), p. 172
13 *Ibid*
14 *Ibid*
15 Supra note 11 at 27
16 D. Brain Reilly, "Drug makers," Fortune, (1991), p. 60
17 Id at 29
18 *Ibid*
19 Supra note 16

showed an upward trend after implementation of TRIPS provisions. The drug policy has already removed many barriers of importation and only 8 categories of drugs have been put under restrictions. New right of patent holder under Article 28 of TRIPS i.e. importation is tantamount to working of patent has removed competition from local market. Many MNC's have entered tie ups with Indian companies. MNC's are not only looking at India for contract manufacturing but also for research and development including Contract Research and Manufacturing (CRM), particularly in the conduct of clinical trials to sales and marketing, information technology, finance, accounting and other services.[20]Pharmaceutical MNCs are looking to implement new and effective business models in India and improve the health of patients.

WEAKNESSES OF INDIAN PHARMACEUTICAL INDUSTRY

Some of the weaknesses being suffered by Pharma industry include low per capita expenditure on health care in rural areas, lack of capabilities, lack of regulatory infrastructure and inadequate overseas marketing infrastructure. Lack of drug inspectors both at centre and state level in the FDA's and lack of resources with the Central Drug Standards and Control Organization (CDSCO) under the Ministry of Health for timely clearance of new drug clinical trials is faced with inadequacies.[21]Ever greening strategy of MNCs to protect market due to expiry of patents, entry of United States and other key markets into a number of FTA's with different countries with intent to compete Indian exports is another threat to the growing competition and entry barriers in export markets. There is a stiff competition from China on cost leading the Indian Bulk drug Industry to a stage of closure due to subsidizing power and financial burden. As a result no company in India is manufacturing antibiotics like Penicillin and Erythromycin etc. A total drugs worth about $192 billion has gone off patent during 2012-2015 ($56 billion in 2015, 40 billion in 2014 and $ 29 billion in 2013).[22] Some of the key drugs that will go off patent this year are Plavix (Sanofi & Bristol – Myers Squibb), Seroquel (Astra Zeneca), Diovan (Novartis), Singulair (Merck), Actos (Takeda) and Lexapro (Forest Labs.).[23] The combined worldwide sales of these six products itself is staggering $34.6 billion.

There are apprehensions that pharmaceutical MNC's that are acquiring control over domestic firms through acquisitions may lead to reduction in supply of vaccines, injectable, particularly for cancer and active pharmaceutical ingredients and specialized oncology verticles.[24]Increasing dependency on block buster patented medicines and its imports, unorganized market for medical disposables and lack of regulations in medical disposables and surgical items are the weakness of Indian Pharmaceutical Industry to cope in future.

INVESTMENT POLICY

The approval of 100% FDI in the pharmaceutical sector under the automatic route for Greenfield investments in new projects and Brown field i.e. the existing pharma companies are allowed approval only through FIPB (Foreign Investment Promotion Board) under the supervision of

---

20 Supra note 11 at 31
21 Supra note 12 at 175
22 www.moneycontrol.com/news/brokeragerecos-sector-report/quick-review Pharma sector-48-associates 7.192 77. html (Visited on 25/07/016)
23 *Ibid*
24 *Ibid*

DIPP (Department of Industrial Policy and Promotion).[25]This has made India as one of the emerging markets for direct investment in Pharmaceutical sector. Industrial Licenses are not required in India for the manufacture of the drugs and pharmaceutical products. Manufacturers are free to produce any drug duly approved by the Drug Control General of India. India received US $ 2 billion of FDI in the Pharma sector during April 2012 and June 2013. From November 2011 to July 2013 as many as 74 Pharma sector proposals were approved by FIPB.[26]Investments in India in R & D have grown from US $ 52.5 million in 2000 to US $ 646.5[27]million in 2010. Some of the investments in this sector are as follows: GlaxoSmithKline Plc. plans to invest Rs. 864 crore to set up a new factory in India, which is expected to be operational by 2017. Cadila Pharmaceutical Ltd. (CPL) plans to invest Rs 100 Crore on expansion, up-gradation and modernization of its manufacturing unit. HLL Biotech Ltd. (HBL) has entered into a long term supply and technology license agreement with the Institute of Immunology, Zagreb, (IMZ) Croatia for the manufacture of measles vaccines in India.[28]Under the partnership agreement IMZ will transfer the technology to manufacture bulk measles vaccines to HBL. Ranbaxy Laboratories Ltd. have received an approval from the Central Drugs Standard Control Organization (CDSCO) to manufacture and market a new drug for the treatment of malaria in adults. Cipla has acquired a majority stake in Uganda based Quality Chemical Industries Ltd. (QCIL).[29]Dr. Reddy's laboratories have received approval from USFDA for its Azacitidine injection used for treatment of some types of cancer and disorders that effect the bone marrow. Indian Pharma manufactures invested 29000 crores in setting up of new manufacturing plants. Orchid chemicals and pharmaceuticals entered into a partnership with Europe based Allecra Therapeutics to develop antibiotics to treat multi drug resistant bacterial infections.[30]Ranbaxy pharmaceutical has entered into an in licensing agreement with alembic. Pharmaceuticals to exclusively market disvenlafaxine base extended release tablets in US. The drug is used for treatment of major depressive disorder. Biocon has entered into an agreement with Mylan for the global development and commercialization of Biocon's generic insulin analog product, which has a global market of US$ 11.5 billion.[31]ZydusCadila has received tentative approval for Doxepin HCL tablets from US drug authorities. Cadila will launch the drug in 2020 after original drug maker's patent expires. Aurbindo Pharma Ltd. has received US Food and Drug Administration (USFDA) approval to manufacture and market TamsulosinHydrochlorine capsules and Clindamycin Plamitate Hydrochloride for oral solution.[32]Sun pharma has received a tentative approval from the US Food and Drug Administration (USFDA) for a generic version of

---

25 Indian Brand Equity Foundation, "Indian Pharmaceutical Industry," published in May (2013),http.www.ibef.org/industry/Pharmaceutical-india.aspx (Visited on 18/11/2015)

26 *Ibid*

27 *Ibid*

28 *Ibid*

29 Rajnish Kumar Rai, "Effect of the TRIMS – Mandated Intellectual Property Rights on Foreign Direct Investment in Developing Countries: A Case Study of the Indian Pharmaceutical Industry," Journal of World Intellectual Property, (2009), (Vol. 11), p. 405

30 Swapan Kumar Bhattacharya, "Reconciling Third Patents (Amendment) Act with the TRIPS Agreement of WTO: Does it Increase India's Global Competitiveness," Prankrishna Pal, (Ed.) *Intellectual Property Rights in India; General Issues and Implications,* (2004), p. 121

31 *Ibid*

32 *Ibid*

Januvia. The drug is expected to be launched in 2022. Thus, various large multinational pharmaceutical companies have shown interest to enter into partnerships, tie ups and acquisitions with Indian pharmaceutical companies to gain sizeable share in domestic market.

CONCLUSION

The above discussion clearly exposes that there are diverse opinions regarding implications of the new Intellectual Property Rights regime on India's pharmaceutical sector. MNC's will stand to gain significantly by way of introducing new products in the Indian domestic market. Prices of life saving drugs are expected to shoot upwards being injurious to developing economies like ours. Thus, future belongs to the knowledge based innovation pharma companies.During the last few years, Indian intellectual property office have undergone major improvements in terms of up gradation of intellectual property legislation, infrastructure facilities, human resources, the processing of intellectual property applications, computerization, databases, quality services to stakeholders transparency in functioning and free access to intellectual property -data through a dynamic website.

Overtime, it is expected that research expenses will increase and new product pipelines will run relatively dry (restricted to in-licensing and generic products), even as both branding and extent of marketing and distribution network will turn critical for success in the domestic market. Various promotional and investment schemes being run by Government may prove as a catalyst to fuel innovation in pharmaceutical sector in India.