PRODUCT PATENTS IN INDIA IN LIGHT OF TRADE RELATED INTELLECTUAL PROPERTY RIGHTS AGREEMENT

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INTRODUCTION

A patent is a grant of a right, privilege or authority over an invention.[1]Generally, patents can be defined as an exclusive right[2] for a limited period, granted to the Patentee. Patents in India are governed by Patents Act, 1970,effective April 20, 1972("Patents Act"), as amended thrice since 1995 by the Patents (Amendment) Act, 1999 ("First Amendment"), the Patents (Amendment) Act, 2002 ("Second Amendment") and Patents (Amendment) Act, 2005 ("Third Amendment") ("Amended Patents Act").India signed the agreement for the establishment of World Trade Organization ("WTO") including the Agreement on Trade Related aspects of Intellectual Property Rights ("TRIPS") on January 1, 1995 because of which it became necessary to amend the Patents Act.Patents Act abolished product patents for chemical products, food, medicine or drug. However, Third Amendment reintroduced the concept of product patents in India. Therefore, it is important to understand *the* i*mplications of inclusion of product patents in India in light of TRIPS.*This paper discusses the benefits as well as drawbacks of inclusion of product patents in India and also provides suggestions to overcomesome of these drawbacks. The scope of this paper is limited to analyze the amendments relating toproduct patents introduced in the Patents Act incompliance with TRIPS.

HISTORY

India's patent regime was governed by Patents and Designs Act, 1911("Old Patents Act"),which had provisions for both product and process patents. However, these provisions created

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[1]FEROZ ALI KHADER,THE LAW OF PATENTS – WITH ASPECIAL FOCUS ON PHARMACEUTICALS IN INDIA 2 (2007)

[2] Excludes others from making, using, selling, importing the patented product or process.

monopoly of foreign companies in Indiaand did not provebeneficial for Indians. Therefore, in 1957, a committee under the chairmanship of Justice N. Rajagopala Ayyangar was appointed to completely revamp theOld Patents Act. Patents Act was largely based on the"Report on the Revision of the Patents Law" submitted in September 1959 ("Ayyangar Report"), as modified by the Report of the Joint Committee of Parliament dated November 1, 1966.With respect to product patents, Ayyangar Report[3] mainly discussed two (2) matters. First matterwas with regard to inventions relating to chemical products, or products produced by chemical processes.Ayyangar Report provided that patentability of these should be confined to the processes by which the products are obtained and to deny patents to the products. The reasons for this recommendation were based on the history of the law relating to patents regarding chemical inventions in Europe, the experience othercountries somewhat similarly situated like India and the disadvantages to an underdeveloped country of permitting product claims for such inventions.

Second matter was with regard to patents for inventions relating to food and medicine.Ayyangar Report recommended that no patents should be granted for claims for articles of food and medicine as such but that processes for producing them should be patentable. Thereason for this is stated to be that the denial of product claims is necessary in order that such important articles of daily use as medicine or food which are vital to the health of the community should be made available to everyone at reasonable prices and that no monopoly should be granted in respect of such articles. It was considered that the refusal of product patents would enlarge the area of competition and thus result in the productionof these articles in sufficient quantity and at thelowest possible cost to the public. However, rendering even the process unpatentable shall not be in public interest.

In accordance with Ayyangar Report, Section 5 in Chapter II of the Patents Act provided that no product patent shall be granted for the substances intended for use, or capable of being used as food or as medicine or drug, or relating to substances prepared or produced by chemical processes.

[3] Part III – "Restrictions on the patentability of inventions: patents for chemical substances, food and medicine etc."

PRODUCT PATENTS AND TRIPS

TRIPS prescribes the minimum standards for the protection, enforcement and harmonizing of intellectual property rights, to be adopted by the member countries of WTO.

Paragraph 1 of Article 27, dealing with subject-matter of Patents, is the major provisionof theTRIPS Agreement. The trade-related intellectual property aspect that for a long time has been perceived as the most serious obstacle against trade in goods was the discriminatory treatment of certain fields of technology as regards patents in particular, the non-availability of patent protection in the chemical and pharmaceutical fields.[4]This Paragraph 1 removed the obstacle and covers both products and processes, in all fields of technology, patentable provided they are new, involve inventive step and capable of industrial application. Member countries are not allowed to discriminate in their patent regimes on the basis of the place of invention, whether products are imported or locally produced and fields of technology such as the pharmaceutical and chemical fields. However, Article 27 provides certain exceptions that can be excluded from patentability.[5]

Article 28.1(a) confers the Patentee with exclusive rights, including, where the subject matter of a patent is a product, to prevent third parties from making, using, offering for sale, selling, or importing the patented product.

Article 65.4 authorizes developing countries members to delay,application of the provisions of product patent protection to areas of technology that they did not protect when the TRIPS Agreement came into force, for ten years from the date of entry into force of the WTO Agreement.However, Article 70.8 established the so-called mailbox systemand provides that

[4]NUNO PIRES DE CARVALHO,THE TRIPS REGIME OF PATENT RIGHTS 245(3d ed. 2010)

[5]Exceptions are: 1. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals.(Article 27.3 (a))

2. Plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, member countries should provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.(Article 27.3 (b))

3. Inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided such exclusion is not made merely because the exploitation is prohibited by their law. (Article 27.2)

where a member country does not make available patent protection for pharmaceutical and agricultural chemical products as of the date of entry into force of the WTO Agreement, that Member shall provide a means by which applications for patents for such inventions can be filed.Further, Article 70.9 provides condition[6] under which WTO member is obligated to grant exclusive marketing rights ("EMR")to a product that is subject of a patent application filed under Article 70.8.

The fourth WTO Ministerial Conference in Doha on November 14, 2001, adopted the Doha Declaration on the TRIPS and Public Health ("Doha Declaration"). The Doha Declaration recognized the gravity of the public health problems affecting many developing and least-developed countries, and the concern about prices of medicines. Doha Declaration recognized various flexibilities under paragraph 4 to paragraph 6[7], the main being right of the members to grant compulsory license.

AMENDMENTS TO PATENTS ACT IN ACCORDANCE WITH PRODUCT PATENT REGIME OF TRIPS

India is a member of WTO since its inception onJanuary 1, 1995 and therefore bound to adopt TRIPS Agreement.

Under Article 65.4, India, being a developing country, had the transition period of 10 years. However, as the Patents Act, did not provide for grant of product patentsin the fields of

6 The condition is that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member country and marketing approval has also been obtained in such other Member country.

7 Flexibilities are: a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

agricultural chemicals and pharmaceuticals and also for grant of EMR, the provisions of Article 70.8 and 70.9 wereapplicable to India. The First Amendment came in 1999, with retrospective effect from January 1, 1995, after WTO Appellate Body recommended India to bring its legal regime in conformity with obligations under Article 70.8 and 70.9 of the TRIPS Agreement, on the complaint filed by USA and European Communities. India started accepting applications for inventions relating to pharmaceutical products and retained the priority of such inventions, until the "mail box" opened in 2005. The amendment also provided for the grant of EMR for such products.[8]

Second Amendmentincludeduniformity of patent term for twenty (20) years[9], amendment of the definition ofinvention[10],amendment of Section 3 to include exclusions permitted by TRIPS Agreement under Article 27, amendment of Section 48[11]to align rights of patentee as per Article 28 of the TRIPS Agreement and inclusion of general principles applicable to working of patented inventions, compulsory licenses and revocation of patents for non-working[12].

Patents Actwas made compliant with the mandate of TRIPSby Third Amendment. Section 5 of the Patents Act was omitted and product patents in the area of pharmaceutical and other chemical inventions are now allowed in India. This is the most prominent and controversial change in the Patents Act. Further, the provisions relating to EMRwere removed. In addition, other important changes relating to product patents included:

8 Addition of Chapter IV A.

9Amendment of Section 53

10 Section 2(1) (j) -"invention" means a new product or process involving an inventive step and capable of industrial application.

11 Section 48. Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee—

(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India:

(b) where the subject matter of the patent is a process the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:

12 Addition of Chapter XVI

1. Addition of definition of "pharmaceutical substance"[13], "new invention"[14],amendment of definition of "inventive step"[15], "Patent"[16]and deletion of definition of "Food" and "Medicine or drug".
2. Clarification that mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance is not an invention that is patentable.[17]
3. Protection of the interests of generic manufacturers through issuance of an automatic compulsory license and non-institution of infringement proceedings against such enterprises. Patent-holder who has been granted product patentsunder mail-box applications is only entitled to receive reasonable royalty from enterprises which have made significant investments and were producing and marketing the concerned product prior to January 1, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent.[18]
4. Making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law shall not constitute infringement of patent rights.[19] These are generally known as bolar provisions.

13 Section 2(1) (ta) - It as any new entity involving one or more inventive steps.

14 Section 2(1) (l) - It means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.

15 Section 2(1) (ja) - "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art

16 Section 2(1)(m) – "patent" means as a patent for any invention granted under the Act.

17 Section 3(d). Explanation to Section 3(d) - 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 substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy.

18Addition of Section 11 A (7)

19Amendment of Section 107A (a)

5. Import of patented products in India from a person duly authorized under the law to produce and sell or distribute the product is not infringement of patent rights.[20] Thisis generally known as parallel imports.
6. Grant of compulsory licensefor manufacture and export of patented pharmaceutical product[21] to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has also been granted by such country or such country has allowed importation of the patented pharmaceutical products from India.[22]

IMPLICATIONS OF INCLUSION OF PRODUCT PATENTS IN INDIA

The reintroductionof product patents motivates for innovation butits negative impacton the drug prices and access to life-saving drugs has been largely debated.

To understand the implications of inclusion of Product Patents in India, analysis has to be done from pre-TRIPS scenario. In early 1950s, the indigenous sector accounted for about 62% of the pharmaceutical market. However, the rise and growth of multinational corporations ("MNCs") and therapeutic revolution changed the dynamics and the market share of the indigenous sector declined to 32% by 1970.[23]Dependency on importsof many essential bulk drugsled to very high prices.This was the direct result of availability of both product and process patents in accordance with Old Patents Act. However, the situation changed in 1970s because of the farsightedness of the Ayyangar Report and enforcement of the Patents Act.It created favorable environment for the Indian companies through abolition of product patent and the entire indigenousmarket became generic.Generic manufacturers used reverse engineering mechanism because process patent-holder was not able to stop them from manufacturing the end product. Medications became

20Amendment of Section 107A (b)

21 Explanation to Section 92A defines 'pharmaceutical products' as any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

22Addition of Section 92A

23SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY - PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES (2005).

cheaper because of lower investment in Research and Development ("R&D") and increased competition in market. In the late 1970s and 1980s, Indian companies started large-scale production of bulk drugs and from 1990s both production and exports grew remarkably fast. The indigenous market share increased from 60% in 1991 to 68% in 1998 and 77% in 2003.[24]Net exports increased from 4.4% in 1988-89 to about 50% in the early 1990s and more than 75% in the early 2000s. The quality and low cost of the generic drugs made India receive worldwide recognition.

Nowa fear exists that the reintroduction of product patent might be unfavorable for the Indian generic pharmaceutical companies. Under the Amended Patents Act, product patent grants right to prevent generic production for 20 years, creating monopoly. Moreover, Indian pharmaceutical industry has been mainly emphasizingon production and not on innovation. The reverse engineering mechanism used by Indian generic manufacturers is different from the mechanism used to arrive at new drugs. The cost involved in researching and introducing a new drug is also huge. Monopoly and R&D cost might lead to non-availability of cheap drugs.

Amended Patents Act fails to fully utilize the public health safeguards available to WTO member states under TRIPS, which were reaffirmed by the Doha Declaration. Still, life-saving drugs can be accessed if compulsory license provisions are implemented generously.Compulsory License provisions should be made applicable to address public health matters, in situations when there is the inefficient supply of generic drugs and to safe guard possible abuse of patent.On March 9, 2012, the Controller of Patents, Mumbai granted first ever compulsory license to Natco Pharma Limited to make sorofenib tosylate, a genric version of Bayer's high-priced patented anti-cancer drug Nexavar.Bayer Corporation appealed against this grant but Intellectual Property Appellate Body ("IPAB")upheld the grant of compulsory license paving the way for reduction in prices of costly life-saving drugs.IPAB's decision was based solely on the public interest. However, there are very recent reports that Bayer Corporation has challenged the IPAB order in the Bombay High Court.

[24] Ibid

There are argumentssupporting the Product Patents as cultivating an innovation culture in Indian pharmaceutical industries. It is true that the Indian companies invested far lesser in R&D than their foreign counterparts.However, even after the Third Amendment, only few major Indian companies have increased the R&D expenditure.The average R&D spending of Indian companies is still very lowwhen compared to their international counterparts and comes to about 4% of the total turnover which is in stark contrast to that of Germany which stands at 9%.[25] However, one benefit of reintroduction of product patents has been that it has opened up opportunities for availability of new products, which Indian companies are unable to produce. MNCs may explore the Indian market for selling its product and might also shift its production base to India becauseof low cost of production.

To prevent ever-greening and grant of frivolous patents, Section 3 (d) disallows Swiss Claims, unless the new form has enhancement of efficacy over the older version. A 'Swiss Claim' is a claim for patent wherein the use of a substance or composition that has already been used for a medical purpose is intended or specified to be used for a new medical purpose. However, the term "enhancement of the known efficacy"is not explained in the Amended Patents Act.The meaning of this term was discussed in detail in case of the Swiss drug company Novartis, which attracted a lot of attention in India and internationally. Supreme Court pronounced its judgement on April 1, 2013, rejecting the Novartis patent application for beta-crystalline form of Imatinib Mesylate, marketed under the names of "Glivec" or Gleevec". SC laid that a subject matter in order to get a patent has to pass the test of Invention and Patentability, both being distinct concepts.SCdiscussed the Patentability under Section 3(d)and held that in case ofmedicines, whose function is to curedisease, the test of efficacy can only be "therapeutic efficacy" and this should receive anarrow and a strict interpretation. SC held that the new form of a knownsubstance has to have significantadvantageous and beneficial propertiesover known substance in order to passthe bar of enhanced therapeutic efficacy.

CONCLUSION

[25]UWE PERLITZ, INDIA'S PHARMACEUTICAL INDUSTRY ON COURSE FOR GLOBALISATION 7 (2008).

The Indian pharmaceutical industry flourished due to reverse engineering. Now, Indian pharmaceutical industry should invest to resort to new and innovative R&D because the gestation period of 35 years is sufficient enough to gather foot hold. The Government of India ("GOI") should encourage pharmaceutical industry to undertake R&D and help them in bringing their R&D level to that of the developed countries.

Further, Indian generic companies have the basic option of collaborating with innovator foreign companies for manufacturing, marketing, distributing and R&D. Collaborations are mutually beneficial for both foreign company and Indian company. Foreign companies receive royalty by supplying technology while manufacturing of the product can happen in India. Marketing is profitable for foreign companies that do not want to invest in marketing infrastructure and for the Indian companies who can market new products which otherwise are not accessible to them on grounds of technology or patents. Licensing agreements helps in collaboration on R&D mainly for development of absolutely new molecules andgain massive success because of the research potential of the Indian companies and infrastructural support of the foreign companies. Another option available to small Indian companies is to merge with large MNCsand share mutual resources.

Indian companies also have the option of manufacturing patented drugs if they are granted compulsorylicense. Additionally, other steps can include the GOI spreading awareness of patents among the industrialists,researchers,students andgeneral public at large.GOI should not compromise with the researchexemptions,bolar provisions and parallel import. Bolar provisions ensure that affordable equivalent generic medicines are brought to market immediately upon the expiry of the product patent and also provide aid to the generic industry to oppose the frivolously granted patents.

To remove ambiguity, GOI should also clarify some very important provisions like definition of "Pharmaceutical Substances" "Inventive Step" and "New Invention".