INDIA'S PATENT LAW: A TUSSLE BETWEEN DEVELOPMENT AND PROFITS

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Introduction

The objectives of India's draft National Pharmaceutical Policy, 2006 are to ensure accessibility and availability of drugs at reasonable prices and to promote further research and development. Such policies are core of every health policy in almost every country in the world. Various countries are developing mechanisms to provide low priced and innovative drugs to its citizens.[1] There is direct connection between drug prices and availability of generics. Preliminary study of pharmaceutical sector by European Commission in 2008 revealed the significant decrease in drug prices after the entry of generic drug companies into the market.[2] Both the objective of reasonable price and innovation need to be balanced to achieve overall policy goals. Research and development of drugs is highly capital intensive and uncertain because it is based on trial and error with very low success rate.[3] On an average it takes twelve to fifteen years for a new drug to develop and commercialize.[4] Only five out of five thousand go up to the human testing level and near one out of five is applicable for human usage.[5] Due to the exorbitant cost of R&D pharmaceutical companies want to gain as much revenue as they can earn from the few blockbuster drugs and use patent strategy as a tool to maximize their revenue.

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[1] Kesseaheim A S, *intellectual property policy in the pharmaceutical sciences: the effect of inappropriate patents and market exclusivity extensions on the health care systems*, the AAPS journal, 9 (3) (2007) E306-11; Grabowski H, *patents innovation and access to new pharmaceuticals,* journal of international economic law, 5 (4) (2002) 849-860

[2] Caves RE, patent *expiration, entry and competition in the US pharmaceutical industry,* Brookings Papers: microeconomics,1991,p.1-66, http://www.brookings.edu/~/media/projects/bpea/1991%20micro/1991_bpeamicro_caves.pdf (5 may 2013)

[3] Morton S and Fiona M, *barriers to entry, brand advertising and the generic entry in the US pharmaceutical industry,* International Journal of Industrial Organization, 18 (7) (2000) 1085-1104

[4] Madhani P M, *In enhancing enterprise competitiveness strategy, operations and finance*, edited by U Dhar, P Gupta and R K Jain (Allied publishers, New Delhi),2007, p.253-271

[5] *Fact sheet: new drug development process*, California biomedical research association, www.ca-biomed.org/pdf/media-kit/fact-sheets/CBRAdrugdevelop.pdf (5 January 2013)

The Indian pharmaceutical industry has emerged as major provider for health care products and caters the pharmaceutical needs of 95% population in India.[6] These industries are prominent supplier of generic medicines at affordable price for the poor population in the world and fondly referred as pharmacy of the poorer world. There has been a paradigm shift in the policies and programmes governing this section which has transformed the once non-existent Indian pharmaceutical industry into $6bn industry.[7]

The Indian Patent (Amendment) Act, 2005 marked the beginning of new patent regime aimed at protecting the Intellectual Property Rights of patent holders. The Act was in fulfilment of India's commitment to World Trade Organization (WTO) on matters relating to agreements on Trade Related Aspects of Intellectual Property Rights (TRIPs).[8] However, the multinational companies (MNCs) in pharmaceutical business in India developed apprehension about the sincerity and intensions of India in implementing provisions of newly amended Act in true letter and spirit of the TRIPs agreement.

The TRIPs agreement and its interpretation

Article 27 (1) of TRIPs agreement provides that;

- Patents shall be available for any inventions, whether product or process, in all fields of technology
- Patent rights shall be enjoyable without discrimination in the field of technology.

The TRIPs agreement does not specify what an invention is. National laws can define this concept according to the standards generally applied, that is, the test of novelty, inventiveness and industrial application. It is also required that patents be available and patents rights enjoyable without discrimination irrespective of the place of invention, whether the products are imported or produced locally. There is no obligation under the TRIPs to adopt an expansive concept of invention. While implementing Article 27(1) of the TRIPs agreement,

[6] FICCI report for national manufacturing competitiveness council (NMCC)competitiveness of the Indian pharmaceutical industry in the new product regime, March 2005, available at: http://www.ficci.com/studies/pharma.pdf, accessed on May 26 2008

[7] id

[8] WTO,Agreement on Trade Related Aspects of Intellectual Property Rights, Annex c, available at: http://www.wto.org/english/docs_e/legal_e/27-trips.doc

each country should carefully consider the economic, legal and ethical aspects involved in the patenting of living materials or certain types thereof.[9]

Section 2(8) of Patents and Designs Act, 1911, of Bangladesh defines invention in the following words; *"Any manner of new manufacture and includes an improvement over an allied invention"*. Unlike the Patents Act, 1970 in India, 1911 Act does not specify the requirement of being useful in the definition of invention. But the courts have always held the view that patentable invention, apart from being a new manufacture, must also be useful.[10] An *"Invention is the act or operation of finding out something new; the process of contributing and producing something not previously known or existing, by the exercise of independent investigation and experiment".* [11]

Some countries may decide not to confer protection on second uses of known medicinal products, the patentability of which has been accepted in most industrialised countries.[12]

Indian Patent Act

The Indian Patents (Amendment) Act, 2005 defines what a new invention is. Section 2 (1) (l) defines

"New invention 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 had not fallen in public domain or that it does not form part of the state of the art"[13]

Section 2(1)(ja) defines

"Inventive step, or 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 the person skilled in the art".

The definition of invention and inventive step makes it clear that any existing knowledge or thing cannot be patented. Therefore, discoveries are excluded from patenting, subject to

[9] K.D. Raju, Interpretation of Section3(d) of the Indian Patents Act,2005: Case study of Novartis
[10] Bishwanath Prasad Radheshaym v. Hindustan Metal Industries, AIR 1982 SC 1444
[11] Smith v. Nicoles,88 U.S.(21 wall.) 112 22 LED. 566; Hollister v. Benedict Burnham Manufacturing co. (1885), 113 U.S. 59,5 S.ct 717, 28, Led. 901
[12] supra
[13] http://www.ipindia.nic.in/ipr/patent/patent-2005.pdf

section 3, unlike the practice of granting patents for discovery in the United States. Section 3(d) stipulates the condition to be fulfilled for patenting of an invention. The efficacy criterion is discussed elaborately in this section.

"The mere discovery of a new form of an unknown substance which does not results in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of unknown process, machine or apparatus unless such known process results in a new product or employs at least new reactant".

In Scherer technologies Inc, application for a liquid fill composition for a soft capsule dosage was asked to be patented. The Intellectual Property Appellant Board held that an inventive step can only be acknowledged if an unexpected effect or advantage is proven by evidence. In order to prove unexpected effect or enhanced efficacy of the claimed invention the applicant must disclose in the specification comparative test showing evidence of an unexpected effect or advantage of the user specific amount over the prior art. Therefore, the claimed composition is not patentable under section 3(d) of Indian Patents Act, 1970.[14]

In the common parlance, the expression discovery refers to "the act, process or an instance or gaining knowledge of or ascertaining the existence of something previously unknown or unrecognized".[15] A discovery essentially refers to finding out something which already exists in nature but was previously unknown. Therefore, it is unlike an invention which refers to a new product or process involving inventive steps and capable of industrial application. [16]

In Aventis Pharmaceuticals inc. Ltd, where a calcium dietary supplement, that was already invented and patented in the United States was re-invented in the form of chewable dosage, the creators were seeking patent. It was held by the Intellectual Property Appellant Board that it would have been obvious to the person skilled in the art to make such composition without any technical effect. Hence the claims do not meet the requirement of Section 2(1)(ja) of Indian Patents Act, 1970.[17]

[14] Application No. 1993/DELNP/2004, Delhi Patent Office, 2004
[15] The Webster's third international dictionary of the English language
[16] Section 2 (1)(j) of the Patents Act, 1970; Swarup Kumar, *intellectual property watch*, June 2007
[17] Application No. 1021/CHENP/2006,Chennai Patent Office, 2009.

In 2002, India amended its patent law to provide the TRIPs mandated 20 year patent term for all invention, to be applied to pharmaceutical patents at the conclusion of transition period. The amendment also includes new compulsory license provisions. These provisions permit a compulsory license application three year after a patent is granted if the "reasonable requirement of the public" regarding invention have not been satisfied, invention is not available in reasonably affordable price, or the invention is not been "worked" or produced in India.[18] The law also provide for immediate compulsory licensing in case of Governmental notification of public health crisis or public non-commercial use or where the product will be exported to countries with insufficient manufacturing capacity to address public health problem.[19] The compulsory license provisions of Indian law are, by far, the broadest of all worlds' patent system.[20] As such they raise substantial concern among multinational pharmaceutical companies; to date' however, no c ompulsory licenses have been sought or issued under new law. The critical step in India's implementation of its TRIPs commitment came in January 2005 with the end of transition period and the required amendment of its law to provide patent protection for pharmaceutical products. According to Indian industry and Government representatives India now is taking "calibrated approach" to intellectual property protection that seeks to take in account concern for public health, access to medicines and the interest of the domestic industry.[21]

Ongoing patent law controversy

Despite the substantial patent law changes since Indian entry into the WTO, there are still gaps and provisions that raise objections from multinational pharmaceutical companies. First and foremost, multinational companies seek a law to protect the clinical trial and other data use to obtain marketing approval of new pharmaceutical products. Second, they raise concern

[18] India Patents Act, 2005, Section 84
Domestic "working" requirements are controversial; the US challenged at the WTO such a requirement in Brazil's patent law, however, the dispute was terminated based on Brazilian agreement to provide advanced notice to where it intended to issue an advanced compulsory license based on the fact that the patent was not domestically worked. (USTR 2006)
[19] India Patents Act, 2005, Section 92-A
[20] Mueller 2007, 107-9
[21] U.S. India business council 2007; Reddy 2007 v.

about patenting standards and particularly the patent exclusion for derivative pharmaceutical products. [22]

Data protection

Drug regulators in most countries require the submission of safety and efficacy data before a pharmaceutical can be approved for marketing. This data can be extremely expensive to amass. The fully capitalized cost to develop a new drug reportedly averages more than $800 million with much of the cost attributable to the conduct of clinical trials.[23] TRIPs require that such data be kept confidential and that it be protected against "unfair commercial use".[24] However, because TRIPs does not define the critical tern included in this requirement, the precise nature of the obligation arguably is unclear. The United States, European Union and many Multinational Pharmaceutical firms interpret TRIPs to require "data exclusivity", meaning the data submitted to a marketing authority cannot be relied upon a basis for approving a generic drug for a particular period (ranging from five years in US to up to 10 years in European Union countries). Others note that some European countries interpret TRIPs to protect test data only against misappropriation or other circumstances in which it is unfairly obtained.[25]

The appropriate level of protection for test data has been intensely debated in India for years. A Government committee recommended a calibrated approach that would account for the minimum requirement envisaged by TRIPs and the national interest in access to medicine through promotion of domestic generics industry. Under this approach, pharmaceutical test data would receive only minimal protection during a transition period (of unspecified duration). Regulation could rely on the originating company's data to approve generic drugs but legal protection would be available for misappropriated data. After the transition period, five years of data exclusivity would be provided for pharmaceuticals which safeguards to ensure public health. Interestingly, the committee also recommended the data submitted to regulators to obtain approval for traditional medicines (a sector dominated by domestic

[22] Katherine Connor Linton and Nicolas Corrado, *A calibrated approach: Pharmaceutical FDI and evolution of Indian patent Law, web version August 2007, United States International Trade Commission journal of international trade and economics*
[23] DiMasi, Hansen and Grabowski 2003, 151
[24] TRIPs Article 39.2 and 39.3
[25] Thomas 2006 CRS-18

companies) receive five years of protection immediately, without any transition period.[26] The committee realised that not providing data exclusivity for pharmaceuticals could adversely impact FDI and discourage the launch of new products in India.[27]

Exclusion of derivatives

Another controversial aspect of Indian Patents Act is the exclusion from patentability for derivates of known substances, unless it can be shown that they are significantly more efficacious than the original substance.[28] This exclusion was meant to preclude "ever greening"- the practise of extending the terms of patent through related patent on modified forms of the same drug, new drug delivery system or new uses.[29] The types of efficacy needed to show that a derivative is patentable, the ability of patent examiners to evaluate medical efficacy data, and the standards governing the patent examiner data evaluation are all unclear.

The Government of India charged a technical expert group with determining whether this exclusion from patentability was TRIPs compatible. This expert group issued an opinion in December 2006, concluding that it was not, but later withdrew it due to "technical inaccuracies".[30]

The Novartis case [Novartis v. Union of India]

The Novartis case began in the year 1997 with patent application filed by Novartis AG for the b-crystalline of Imatinib Mesylate, brand name Glivec, which is slightly different version of their 1993 patent, a vital anti leukaemia drug, filed before the Chennai Patent office. The petition claimed that the Novartis invented the beta crystalline salt form of the free base emanative. In 2003, Glivec was granted exclusive marketing rights in the Indian market. Meanwhile Novartis obtained orders preventing some of the generic manufacturers from generic equivalents of Glivec. It is worth mentioning that the generic companies were selling their versions of Glivec at $177 to $266 while Novartis used to sell it for $2666 per patient per year. Pre grant oppositions were filed by the Indian pharmaceutical companies and by an order dated January 2006, the assistant controller and design, Chennai patent office, rejected

[26] Reddy 2007, v
[27] Reddy 2007, 32
[28] India Patents Acts Section 3(d)
[29] Mueller 2007, 72
[30] Nair, 2007

the application under the restriction placed on granting of patents under section 3(d) of the Patents Act 2005. Novartis, in response to the rejection of the application, challenged the constitutionality of section 3(d) before the high court judicature at Madras. This challenge was based on primarily two grounds namely:

1) Section 3(d) is unconstitutional as it places restrictions on the granting of a patent that violates article 27.1 of the TRIPs agreement.

2) The worlds 'enhanced efficacy' and 'significantly differ in the properties with regard to efficacy' are not defined that they confer unguided power in the patent controller who can decide the application on case by case basis. Hence the section 3(d) is arbitrary, illogical and vague and offends the equality guaranteed in the article 14 of the Constitution of India.[31]

The respondent on the other hand vehemently argued that the section 3(d) is TRIPs complaint and this court is not the right forum to raise the issue rather than the WTO settlement body. The respondent in this case also argued that under the TRIPs agreement, members are free to adopt law within the framework of the TRIPs agreement and are equally free to adopt and implement their national policies such as right to health to its citizens. The Hon'ble High Court of Madras decided mainly on the jurisdiction issued and said that it lacked jurisdiction to entertain the issue. Court concluded on the basis of general principle, which states that non compliance with an international obligation does not provides parties with a right to challenge a domestic statute unless the international instrument grants such rights.[32]

Implications of the Novartis case

The perceived inadequacies in Indian Patent Laws describe above and the order given in the Novartis case, appear to have impacted multinational pharmaceutical companies evaluation of the investment environment. In India, Novartis has stated that it constructed its new research institute in Singapore rather than India because of its concern about patents protection. Also, Novartis has announced the creation of a Shanghai Research Institute because of its perception that, unlike India, China has a system in place to improve intellectual property protection. Because of intellectual property insecurity the Novartis

[31] Equality before law (Article 14 Constitution of India)- the state shall not deny to any person equality before the law or equal protection of the laws within the territory of India.
[32] supra

research and development collaborations in India are limited to supportive work rather than development of new medicines.[33]

More generally a survey conducted by Ernst and Young and *the economist*, more than 62% of multinational pharmaceutical companies surveyed in India considers threat to intellectual property the most serious business risk, and 63% believes that there company risk losing intellectual property rights when trying to integrate with local suppliers and third party service providers.[34] Not just multinational companies are impacted by the intellectual property concerns but a majority of multinational companies and Asian firms surveyed cited deterrent to investment.[35]

Conclusion

Earlier when India's patent system was not in compliance with the TRIPs, there was a risk of a healthy patent protection provisions in India. But now the conditions have changed. India is now a member of TRIPs agreement and our patent system is fully compliant with TRIPs. Further, India, being a developing country, where most of its population is leading its life without basic amenities of food, clothing, shelter and medication has to rely on generic medicines to cater to the needs of its citizens. Though this decision would affect the foreign drug manufacturers for further investments and is likely to have repercussions in attracting foreign investments. But this decision prevents companies only from obtaining modifications on patents it does not bar patent protection on instrumental investments.[36] Moreover, effort on innovation must be lead by domestic companies rather than relying completely on foreign companies. The Indian companies can emerge as leading companies if they are encouraged to focus on Research and Development and innovation rather than solely running behind the generics. Presently India's share on R&D is merely 2.1% of global spending, that is relatively very less than other countries like China and US that spend 12% and 33.6% respectively.[37]

[33] Business world India 2007
[34] Shared expertise forum 2005
[35] Pricewaterhousecoopers 2007, 11
[36] Lex witness magazine*: The conclusion of Novartis saga*
[37] *Research and development a concept paper,* available at: https://www.deloitte.com/assets/Dcom-India/Local%20Assets/Documents/Whitepaper_on_RD_expenditure.pdf