

Evolution And Future Implications Of Intellectual Property Rights On Indian Pharmaceutical Market

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Abstract: India has been an incredible nation with an unexpected growth in pharmaceutical industry after its change of policy in 1970. It is often said that remarkable growth of pharmaceutical exports is a result of confidence built up in industry due to the progressive adherence to IP commitments. However, the statistic shows that it was only after the abolition of product patent protection in 1970 that the export market developed. This article describes the evolution and future implications of intellectual property rights on Indian pharmaceutical market.

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Introduction

India has been an incredible nation with an unexpected growth in pharmaceutical industry after its change of policy in 1970. It is often said that remarkable growth of pharmaceutical exports is a result of confidence built up in industry due to the progressive adherence to IP commitments¹. However, the statistic shows that it was only after the abolition of product patent protection in 1970 that the export market developed². The distinction between process and product patents in live with international patent practice before 1995 TRIPs agreement has led to the development of a huge generic industry built on reverse engineering brand-name drugs through slightly modified processes³. However, TRIPs obligation has compelled India to provide stronger protection which has led to modifications in its patenting law in 1999, 2002 and 2005. The 2005 Act has been most crucial as it provide protection to products itself. It is critical to look into the impact on pharmaceutical industry with emergence of these new amendments. It is also worth considering the recommended changes which India could have made or can make for its benefit and also importing countries taking into consideration the flexibilities of TRIPs.

Global Status of Indian Pharmaceutical Industry

The media giants like the New York Times coming out with misguiding editorials⁴, possibly aimed at stifling India's strength and powers in science and technology. It is important yet to analyze threadbare whether the new Patent act is a sell-out or a well-planned game plan to isolate India at the WTO. Without reforms, India would not have reached such dizzy heights. It yet does not select Indian companies to seek extra protection on their home turf. Ironically, these pharma majors are also filing patents abroad and are doing roaring business in the very countries where patent laws are strictly in force. It also demeans the

well-established strength of the Indian intellect that is headed for the destination 2020.

There is a concerted move to crush India's science and technology skills. The well-known British think-tank Chatham House ran a seminar entitled, 'Can Indian research changes the paradigm of the global pharmaceutical industry?' After the conference many Indian companies showcased their research. Consequently, streams of foreign R &D heads have been arriving I India to seek partnerships with Indian companies across the whole pharma supply chain including clinical, discovery, herbal research and manufacturing.

Robert Blackwill, former Dean of Harvard University and Ambassador to India said, "There has been a sea change in attitude by the people of India towards patents as they reap the benefits of the knowledge economy. The science and technology prowess of India is cutting edge and she must take her rightful place, along with China at the head of developed economics".

Similarly, in the 229th meeting of the American Chemical Society, the policy makers noted that scientists from India would soon be able to have the most innovative products outclassing he Americans. While a new drug development costs touch \$1.5 billion overseas, it is an established fact that India can produce state-of-the art drugs at a fraction of that amount leveraging on low cost, high quality, speed and large patient profile.

Together with the presence of largest number of US FDA approved plants outside⁵ the USA, producing high quality drugs at lowest cost, India is in an enviable position to take on the best in the world. It is this reality that is causing worries for the policy makers in the West.

The Patent Act, 2005 can in no way influence cost of drugs. The government has taken care that drugs patented before 1995 are not covered by the

patents. These include the drugs in the WHO essential list. With over 20,000 competitors, market forces will keep the prices under control. Rise in prices, if at all, would be more due to illogical policies of the finance ministry and rising duties and taxes than the patent law. In India, 97 per cent of drugs are off patent and are manufactured by a vast number of companies. Besides, physicians will always have the alternative of using older, cheaper but equally effective molecules to treat patients.

The new Patent Act Ordinance, introducing the long awaited product patents. The Ordinance includes several provisions aimed at rationalizing timelines, allowing flexibility and reducing processing time for patent applications. The new Act will boost R&D and will help to bring in foreign direct investment in the industry and contribute to improved healthcare. There are three areas where India will continue to lag behind in ushering in World Class IPR standards. The first is that India should join other leading countries and progressive nations in moving away from pre-grant opposition. The Ordinance as announced will provide representation by third parties and lengthen time for grant of Patent. The second area of concern for the Industry are the exiting CL provisions that go much beyond national emergency and extreme urgent situation, public health crises and anti-trust situations. Broadening the scope of CL can lead to unfair commercial gains to favored companies. The third area of concern for the research based manufacturers is that anew provision has been added in the Ordinance that treats patent holders in respect of mailbox applications on a discriminatory footing in so far as them being denied the rights and privileges from the date of publication retrospectively.

The Patent Amendment opens up vast opportunities for the Indian pharmaceutical firms. Large companies like Ranbaxy, Nicholas Piramal, Dr. Reddy's, Wockhardt, Lupin etc, are investing heavily in R&D and in a few years should be able to launch their own patented molecules all over the world. We also have the largest number of US FDA approved manufacturing facilities outside USA. Therefore, India is poised to emerge as a significant player in the area of generics. There is an apprehension that medicine prices are going to go through the roof in the product patent regime. This is a myth propagated by some sections of the industry. Over 97% of the drugs in the WHO list of essential drugs are already out of patent, and will continue to be available at current prices. And there are several therapeutic equivalents available for the rest. The NPPA will keep on monitoring medicine prices. As such, medicines contribute to only about 15% of healthcare expenditure. The bulk of the expenditure (85%) comes from diagnostic tests, hospitalization, doctor's consultation fees etc.

Therefore, this obsession with medicine prices in India is not warranted.

Significance of IPRs in Pharmaceuticals

One of the most fundamental changes in global trade policy set out by the Uruguay Round of trade negotiations was the commitment by all the World Trade Organization (WTO) Members to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS lays down minimum standards of protection for intellectual property rights (IPR) and their enforcement, which are mandatory for WTO member countries for implementation. However, it allows flexibilities within its overall provisions or articles, to take effective steps to meet the healthcare needs of the member countries, especially Least Developed Countries (LDCs) and developing countries.

The TRIPS Agreement, deals not only with patents, but also with other forms of IPR such as copyright, trademark, industrial designs, geographical indications and others. India has already been having a reasonably strong copyright, trademark and industrial design protection and enforcement, even prior to TRIPS.

Three dominant IPs which play important role in development and commercialization of pharmaceutical industry are patents, trademarks, and trade secrets. Apart from patents, other forms of IPs such as trademarks, copyright, designs and confidential information are also largely relevant to pharmaceutical industry.

Future of Indian Pharmaceutical Industry

India's pharmaceutical industry has the competitive advantage in improving its market share as prescription drugs worth more than US\$ 65 billion are to lose their patents in 2007-08 which shall enable India to become the regional hub in Research & Development (R&D), manufacturing and exporting activities⁶. The new patent regime has provided for structural changes in the industry and encouraged innovation and greater investment in R&D. The Indian Pharmaceutical industry is already on the concretized path of economic prosperity and is all set to benefit substantially through various developments arising out of impact due to TRIPS regime worldwide. It is expected that with the advent of a new patent regime in India, US is also required to provide special focus on modifying US legislation on matters relating to extension / evergreening of patents by US pharma majors which resulted in restricting the growth of the Indian generics manufacturing⁷.

A. New Initiatives and Measures for Protection and Promotion

As a 'Business Protection' measure, the US and Indian pharmaceutical companies are to extend

mutual co-operation in matters relating to dealing with HIV/AIDS pandemic by: (i) advocating and creating awareness; (ii) setting up ART Centers⁸. US has shown positive signals for promoting Indian pharmaceutical industry by: (i) providing \$29.3 million to India for undertaking HIV/AIDS prevention, care and treatment programs; (ii) establishing an Indo-U.S. Corporate Sector Fund for which six pharmaceutical companies have undertaken to contribute \$1.2 million; (iii) providing USFDA approval to 13 generic antiretroviral drugs produced by Indian pharmaceutical companies which may be purchased, for use around the world, as part of the US President's Emergency Plan for HIV/AIDS⁹.

The several initiatives and measures taken by the Indian government for providing the required support, boost and encouragement for Indian pharmaceutical industry include: (i) permitting 100% Foreign Direct Investment (FDI) for manufacture of drugs and pharmaceuticals provided the activity does not attract compulsory licensing or involve use of recombinant DNA technology and specific cell / tissue targeted formulations; (ii) tax incentives under the Income Tax Act, 1961 for in-house R&D; (iii) life saving vaccines exempted from excise duty; (iv) clinical trial of new drugs exempted from excise duty to encourage companies like Cipla; (v) all drugs and materials used in clinical trials to be provided customs and excise duty exemption; (vi) companies in knowledge-based pharmaceutical business to be provided equity support; (vii) customs duty reduced to 5% on 10 anti-AIDS and 14 anti-cancer drugs; and (ix) duty on certain life saving drugs, kits and equipment reduced and such drugs are also exempted from excise duty and countervailing duty¹⁰.

B. New Business Avenues

1. Contract Manufacturing

The global pharmaceutical outsourcing market in areas of Active Pharmaceutical Ingredient (API), research, formulation and manufacturing is estimated at US \$48 billion and with the regulatory changes in European Union coupled with the restricting of its fine chemical industry the competitive Indian pharmaceutical industry is all set to explore and exploit the business potentiality¹¹. US is required to provide the Indian companies the required FDA and other accreditations / approvals for items manufactured in India and exported to other countries. MNC pharmaceutical companies are increasingly outsourcing their manufacturing activities to Contract Manufacturing Organization (CMOs) for achieving efficiencies in: cost, capacity and time-to-market, and also to obtain a specific expertise which is not available with them. MNC pharmaceutical companies are outsourcing their manufacturing to India due to stringent restrictions imposed and greater regulatory

compliances. India has a competitive advantage in contract manufacturing owing to: (i) relatively low-cost of production, (ii) availability of skilled manpower and (iii) availability of raw materials at competitive prices. The Indian pharmaceutical sector manufactures about 400 bulk drugs belonging to several therapeutic segments. Indian Drug Manufacturers Association (IDMA) estimates that there are nearly 20,000 manufacturing units operating in India of which 80% of the companies are into contract manufacturing catering to the domestic and international markets. Many large production houses in the country are becoming USFDA compliant to be benefited from the vast business potentiality. India currently has 75 USFDA approved plants¹². There are several generic manufacturers in the US who are outsourcing their future generic API requirements from independent manufacturers based in countries like India. Some of the MNC's have already established their subsidiaries in India for contract manufacturing operations. Large Indian companies like Ranbaxy-Eli Lilly and Lupin-Cynamid have taken the lead in signing major contract manufacturing agreements. Companies like SmithKline Beecham have also already established its own manufacturing unit in India to cater to its global requirements of over the counter drugs and Wochardt India has also set up its manufacturing unit for its nutritional products and a large part of its production facility is being used to contract manufacture for overseas customers.

2. Contract Research & Development

As per the report of the Chemical Pharmaceutical Generic Association, the Contract Research business in India is valued at \$100-120m in 2005 and growing at a rate of 20-25 per cent each year¹³. India is also a preferred destination for contract Research and Development in pharmaceuticals owing to its proven abilities in the field of Information Technology (IT). The pharmacy research is becoming more IT oriented and the Indian contract research companies have started following the Good Clinical Practice (GCP) guidelines prescribed by USFDA. The other reasons for emergence of India as a favourable destination for such operations include: (i) Contract Research Organizations (CROs) in India offer a wide range of services in the field of drug discovery like chemical synthesis, methodology development in analytical techniques and process up gradation; (ii) availability of a large English speaking population; (iii) availability of highly educated and qualified technical personnel coupled with low employee costs. In 2005 contract research in India was valued at US \$ 100-120m and growing at a rate of 20-25 per cent each year, according to a report by the Chemical Pharmaceutical Generic Association. There are 15 prominent CROs in India now providing efficient R &

D services on a low-cost basis. Contract research and development in India is undertaken in different ways: (i) large MNCs entering into strategic alliances with subsidiaries of global CROs – eg. Quintiles and Covance; (ii) Global CROs and local Indian CROs entering into Joint Venture (JV) agreements – eg. US – based Parexel and Synchron Research Services; (iii) Indian CROs operating independently eg. Siro Clinpharm; and (iv) Subsidiaries of Indian pharmaceutical companies operating as independent entities, eg. Well Quest¹⁴. There are more than ten global MNC pharmaceutical companies operating in India, who had already made India their hub for production of APIs and finished formulations at low costs. Other Indian pharmaceutical companies that undertake contract research on process development for leading MNCs include: Divi's Laboratories Ltd., (DLL), Hyderabad; Regent Drugs, Delhi; Cadila Healthcare, Ahmedabad.

3. Contract Clinical Trials

Clinical trials constitute nearly 70% of the cost associated with the development of a 'New Chemical Entity' involving expenditure in the range of US\$ 350 to 500 million¹⁵. There has been a considerable reduction in time gaps between the introduction of 'innovative drugs' and therapeutically similar innovations¹⁶ resulting in Indian companies getting more focused on conducting clinical trials. Neeman Medical International, a 100% subsidiary of Max group of companies had acquired 2 CROs in US to explore and exploit the vast business potentiality provided to India owing to its new patent regime and other regulatory changes made recently¹⁷. These companies have started undertaking contracts from global MNCs which favor outsourcing of their clinical trials related requirement so that they can concentrate on marketing of the new drug molecule discovered by them. India has emerged as a preferred destination for clinical trials for various reasons including: (i) presence of a large number of medical colleges approved by Medical Council of India (MCI); (ii) availability of more than half a million doctors; (iii) over 16,000 hospitals which can be utilized as ideal centers for clinical trials; (iv) availability of highly qualified and technical manpower; and (v) abundance of diseases which makes it a favorable place for carrying out contract clinical trials activities. There have been several collaborations with Indian companies and foreign companies focused on clinical trials. Indian companies like MEX India Ltd., have established their 100% owned subsidiary NMI BV at Holland and have operating entity NMI worldwide to support the clinical trials enrolment needs of pharmaceutical, biotech and medical service industry. This contract research organization of Indian origin is able to meet the rapidly growing demands of

expeditious enrolment of appropriate patients by locating previously untapped patent populations in key regions of the world. Clinical research practices and clinical trials are consistently conducted by Indian companies in accordance with requirements under International conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Good Clinical Practice (GCP) and Food and Drug Administration (FDA) standards¹⁸.

4. Traditional Knowledge in India

The IP policy issues on Traditional Knowledge (TK) deal with: (i) Defensive protection whereby IP rights are given to customary TK holders under the WIPO administered patent systems: (a) International Patent Classification system and (b) the Patent Cooperation treaty Minimum Documentation; and (ii) Positive protection providing positive rights and empowering TK holders to protect and promote their TK¹⁹. The draft policy objectives and core principles for protection of TK have already been prepared by WIPO²⁰ and it is expected that TK shall soon emerge as a boon to India with the establishment of new patent regime.

'Traditional Knowledge (TK) is essentially culturally oriented or culturally based, and it is integral to the cultural identity of the social group in which it operates and is preserved'²¹. The TK matters relating to India that made news after the advent of new patent regime and raised serious controversies and would have made resulted in unimaginable ramifications and consequences include: (i) USPTO providing for patent on usage of turmeric for its wound healing properties; and (ii) European Patent Office (EPO) providing patent for seeds of Neem which possess fungicide properties since times immemorial. The new patent regime enabled protection of TK in India through enabling legislations²². There are nearly 150,000 recorded ayurvedic, unani and siddha medicines and around 1,500 yoga exercises which originated in India and existing for more than 5,000 years, but yoga exercises are being allowed to be patented in the western countries and India also continues to be a victim of 'bio-piracy' due to lack of sincerity by the western countries in providing adequate IP protection to TK²³. As per World Health Organization (WHO) findings: (i) more than 70% of the people living in India use traditional medicine for primary health care; and (ii) around 42% of the people living in Us and 70% of those living in Canada have used traditional medicines at least once for treatment without being required to compensate for usage of TK²⁴. Several suggestions on protection of TK in India include: (i) providing proper documentation of TK; (ii) registration and innovations under the established patents system; and (iii) development of a sui generis

system²⁵. It is also being felt that proper documentation of TK could help in checking bio-piracy²⁶. The Ayurvedic system of medicine in India has already documented more than 35,000 Ayurvedic formulations in the Traditional Knowledge Digital Library (TKDL) and the details of the same are being converted into Patent Application Format which could be retrieved on the basis of: 9i) Traditional Knowledge Resource classification (TKRC); and (ii) International Patent Classification (IPC) systems²⁷. South Asian countries have agreed to create a digital library of the region's TK and also develop laws to prevent such knowledge being misappropriated through patents by others²⁸.

Conclusion

India is an important emerging market for the pharmaceutical industry, with a large population, significant unmet medical need, and a growing middle class representing large potential pool of consumers for innovative medicines. Nestled within India's statutory patent regime is a provision governing patenting of new forms of known drug substances that is unique among member countries to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). India is an important emerging market for the pharmaceutical industry, its large population, significant unmet medical need, and growing middle class forming a large potential pool of consumers for innovative medicines and medical treatments. Despite the well-established presence of a home-grown generic drug industry, pharmaceutical innovator companies continue to increase their presence in India, a country with rapidly growing economy and large, technologically savvy workforce.

At the same time, Indian patent law has evolved dramatically, particularly in light of India's accession to the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS). Indian patent law has undergone multiple transformations during the last decade in an attempt to comply with TRIPS. Nestled within India's statutory patent regime is a provision unique among TRIPS countries governing patenting of new forms of known substances. This provision raises a substantial statutory bar to patenting new salts or polymorphs of known pharmaceutical substances, and was apparently intended by the Indian Parliament to reign in the practice known as evergreening by pharmaceutical innovator companies.

References:

1. Press statement by the Indian Ministry on December 27, 2004.
2. Sudip Chaudhuri, Industrial policy, Globalization and India's Pharmaceutical Industry, Conference on Post Liberalization Constraints on Macroeconomic Policies'

- organized by IDEAS and UNDP, Mutukadu, Chennai, 27-29 January, 2006.
3. Indian Trips – compliance legislation under fire, Bridges Weekly Trade News Digest, ICTSD.
4. Sarah Hiddleston, Patent Trouble, Frontline, February 23, 2007 at 131.
5. M.D. Nair, From Local to Global – The Growth Path for Indian Pharmaceutical Industry, The Pharma Review, December, 2006 at 37.
6. Rediff India Abroad, good times beacon pharma firms, available at <http://www.rediff.com/money/2007/mar/01bud20.htm> (last visited Sep. 5, 2007).
7. India Brand Equity Foundation (IBEG), India-Fastest Growing Free Market Decomary: Pharma MNC's turn to India for Cost Management, available at http://www.indianembassy.at/content/india/documents/Pharma_MNC.pdf (last visited Sep. 5, 2007).
8. Sapna Agrawal, Indian Companies readying for USFDA, available at <http://wwwl.impactinfosys.com/admin/newspdf/India.pdf> (last accessed march 17, 2007).
9. Kirsty Branes, India Top of the World for Contract Research Business, available at <http://www.drugresearcher.com/news/ng.asp?n=69977-india-china-contract-research> (last visited Sep.5, 2007).
10. Harvey Bale, Patents Protection and Pharmaceutical Innovation, 29 N.Y.U. J. Int'l Law & Policy 95, 1995-96, Page 101.
11. Neeman Medical International, Max India Eyes control of two CROs in US, available at <http://www.neeman-medical.com/max-india-cro-news.aspx>, (last visited sep. 5, 2007).
12. Neeman Medical International, About us, available at <http://www.neeman-medical.com/neemanmedinternational.aspx> (last visited sep. 5, 2007).
13. World Intellectual Property Organization (WIPO), Traditional Knowledge, available at <http://www.wipo.int/tk/en/tk/> (last visited sep.6,2007).
14. World Intellectual Property Organization (WIPO), Traditional Knowledge, available at http://www.wipo.int/tk/en/consultations/draft_provisions/doc/tk-provisions.doc (last visited sep.6,2007).
15. Dr. Elizabeth Varkey, Traditional knowledge – The changing scenario in india available at, www.law.ed.ac.uk/ahrc/files/67_varkeytraditionalknowledgeinindia03.pdf (last visited sep.6, 2007).
16. The Geographical Indication of Goods (registration and Protection) Act, 1999 focuses on protection of the goods using geographical indications and the TK in such goods produced and sold can now be registered and protected.
17. BBC News, India hits back in 'bio-piracy' battle, available at http://news.bbc.co.uk/1/hi/world/south_asia/4506382.stm (last visited sep.6, 2007).
18. Traditional Knowledge digital Library, March 13, 2005, available at http://dhanvantriayurveda.tribe.net/thread/1872d2b2-2771-42db-ba49-670a5471_cbe7 (last visited Sep.6, 2007).