New Patent Regime in India: Challenges and Future of the Pharmaceutical Industry

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NEW PATENT REGIME IN INDIA - CHALLENGES AND FUTURE OF THE PHARMACEUTICAL INDUSTRY

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TABLE OF CONTENTS

Introduction..................................................................................................................1
I. The Indian Pharmaceutical Industry – An Overview...........................................4
II. New Patent Regime in India.................................................................5
    A. Background of Patent Regime in India ......................................5
    B. Key Provisions Relating to TRIPS Compliance................7
III. Challenges for the Indian Pharmaceutical Industry..............................................8
    A. Novartis Sues India .................................................................8
    B. Revival of Yoga and Impact of Baba Ramdev 13
    C. Generic Pharmaceutical Manufacturing .............................................13
    D. Drug Prices and Access to Medicines for the Poor ................14
    E. Competition from China...........................................................15
IV. Future of Indian Pharmaceutical Industry........................................................16
    A. New Initiatives and Measures for Protection and Promotion..17
    B. New Business Avenues.........................................................18
        1. Contract Manufacturing......................................................18
        2. Contract Research & Development........................................19
        3. Contract Clinical Trials......................................................21
        4. Traditional Knowledge in India...........................................22
Conclusion..................................................................................................................24

INTRODUCTION

The Indian Patents (Amendment) Act, 2005 (The Act)1 introduced product patents in India and marked the beginning of a new patent regime aimed at protecting the intellectual property rights of patent holders. The Act was in fulfillment of India’s commitment to World Trade Organization (WTO) on matters relating to Agreement on

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Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)\(^2\). The Multi National Corporations (MNC) in pharmaceutical business in India developed serious apprehensions on the sincerity and intentions of India in implementing provisions of The Act in the true letter and spirit of TRIPS Agreement and Novartis sued India before the Hon’ble High Court of Judicature at Madras\(^3\). Mr. R.A.Mashelkar\(^4\) had to resign on the charges of plagiarism\(^5\) after submission of “The Report of The Technical Expert Group on Patent Law Issues”\(^6\) to the Government of India in December 2006, which was subsequently filed by Novartis in support of its case pending adjudication in the Indian


\(^3\) Novartis AG v. Union of India and others. Writ Petition WP 24749 of 2006 filed before High Court, Madras had raised several issues relating to violation of TRIPS Agreement by India. A copy of the Report of the Technical Expert Group on Patent Law Issues has also been subsequently filed as a document in support of recommendations made by the committee appointed by Government of India, on provisions in Indian Patents (amendment) Act, 2005 relating to violation of TRIPS provisions. The recent outcome of this case on rejecting the contentious issues raised by Novartis on constitutionality of section 3(d) of The Act is considered to be having far reaching consequences on the Pharmaceutical Industry in India.

\(^4\) He is currently the President of Indian National Science Academy (INSA). He was the Director General of Council of Scientific and Industrial Research (CSIR) and has the rare distinction of being elected as Fellow of Royal Society (FRS), London. He was also elected Foreign Fellow of US National Academy of Engineering in 2003 and so far 23 universities of international repute have honored him with honorary doctorates. He successfully challenged the patent granted by USPTO for usage of turmeric for wound healing purposes and also the patent on Basmati rice. He established India's first Traditional Knowledge Digital Library resulting in providing the required initiative for change of the International Patent Classification System so that traditional knowledge is recognized and rewarded. He was also the Chairman of the Standing Committee on Information Technology of World Intellectual Property Organization (WIPO). He was awarded the highest civilian awards by the President of India: Padmashri (1991) and with Padmabhushan (2000), available at http://www.csir.res.in/csir/external/heads/aboutcsir/leaders/DG/essence.htm, (last visited on Sep. 4, 2007).

\(^5\) Rediff News, Livid Mashelkar quits patents panel, available at http://www.rediff.com/money/2007/mar/17patent.htm (last visited Sep. 4, 2007). He was very much disturbed with the personalized attacks after submission of report of the Technical Expert Group and stated in his letter to the Secretary, Govt. of India that he was “deeply pained by the fact that doubts, explicit or implicit, have been expressed about my integrity, competence and motives”.

\(^6\) Report of the Technical Expert Group on Patent Law Issues, December 2006, available at http://www.patentoffice.nic.in/pr/patent/mashelkar_committee_report.doc (last visited Sep. 4, 2007). The recommendations made by the Technical Expert Group are: (i) it would not be TRIPS compliant to limit granting of patents for pharmaceutical substance to ‘New Chemical Entities’ only; and (ii) Excluding micro-organisms per se would tantamount to violation of TRIPS Agreement and strict guidelines need to be formulated for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility.
court. US has started funding training programs in India which are focused on strengthening enforcement and patent examination in matters relating to Intellectual Property Rights (IPR) protection. The new patent regime was partly instrumental in the promotion of Baba Ramdev who has spearheaded the revival and resurgence of Yoga and states “It is your birth right to persist disease free, healthy, fit, slim, looking beautiful and younger, in complete peace of mind and get back robust health, better than your age”. The new patent regime has posed several challenges for the Indian Pharmaceutical Industry and also concretized the path to prosperity through: (i) new initiatives and measures for protection of existing business: and (ii) promotion of new business avenues including: Contract manufacturing; Contract R & D; Contract Clinical

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7 The White House, Fact Sheet- United States and India: Strategic Partnership, available at http://www.whitehouse.gov/news/releases/2006/03/20060302-13.html (last visited Sep. 6, 2007). Mr. George W. Bush, US President states: “We have an ambitious agenda with India. Our agenda is practical. It builds on a relationship that has never been better. India is a global leader, as well as a good friend. ... My trip will remind everybody about the strengthening of an important strategic partnership. We’ll work together in practical ways to promote a hopeful future for citizens in both our nations.”

8 Divya Yog Mandir (Trust): Pillars of DMYT and Patanjali Yogpeeth (Trust) – SWAMI RAMDEVJI, available at http://www.divyayoga.com/swamiRamdevJi.htm, (last visited Sep. 6, 2007). Swami Ramdevji is popularly known as “Baba Ramdev”. He has now become a household name in India and also for Indians living in other countries as more than 250 million people watch him regularly on the most prominent Indian TV channels for deriving benefit from Yoga. There are more than 2 million people who derive benefit from the vibrating science of Yoga which helps in building a prosperous, advanced, disease free and subtle new India. He has been practicing celibacy since his childhood and considered to be a renowned scholar in the fields of Sanskrit Grammar, Ayurveda and Vedic Philosophy. He has taught Ashtadhyayee, Mahabhashya, Upnishads alongwith six systems of Indian Philosophy. He has established Divya Yog Mandir in 1995 at Kankhal, Hardwar, Uttaranchal, India and cures about two lac patients per month with his spiritual energy in his Yoga Camps. He has also established Patanjali Yogpeeth, a focused institution for scientific research and treatment through Yog, Spiritualism, and Ayurved which benefits more than 2 million patients with various ailments including HIV/AIDS and Cancer.

9 MedicineNet.com, Definition of Yoga, available at http://www.medterms.com/script/main/art.asp?articlekey=10811 (last visited Sep. 4, 2007) Definition of Yoga: “A way of life that includes ethical precepts, dietary prescriptions, and physical exercise. Its practitioners believe that their discipline has the capacity to alter mental and bodily responses normally thought to be far beyond a person's ability to modulate them. During the past 80 years, health professionals in India and the West have begun to investigate the therapeutic potential of yoga. To date, thousands of research studies have been undertaken and have shown that with the practice of yogic meditation a person can, indeed, learn to control such physiologic parameters as blood pressure, heart rate, respiratory function, metabolic rate, skin resistance, brain waves, body temperature, and many other bodily functions.”

Trials; and development of Traditional Knowledge (TK) based market through rejuvenation of Yoga and Ayurveda.

I. THE INDIAN PHARMACEUTICAL INDUSTRY – AN OVERVIEW

The Indian Pharmaceutical sector has emerged as a prominent provider for healthcare products catering to more than 95% pharmaceutical needs of the country\textsuperscript{11} with a population of 1.1 billion. There has been a paradigm shift in the policies and programs governing Indian pharmaceutical industry resulting in this industry, almost non existent till 1970, transforming to a US $ 6 billion industry growing at a Compound Annual Growth Rate (CAGR) of 13.7\%\textsuperscript{12}. It currently ranks 4\textsuperscript{th} and 13\textsuperscript{th} in terms of global volume and value, respectively, in global pharmaceutical business\textsuperscript{13}. India’s pharmaceutical exports constitute almost 40\% of total production of pharmaceuticals in India and valued at over US $ 3.5 billions of which formulations and bulk drugs constitute 55\% and 45\% respectively\textsuperscript{14}. The export revenue now contributes almost half of the total revenue for the top 3-pharma majors: Dr Reddy’s, Ranbaxy and Cipla\textsuperscript{15}. Indian pharmaceutical industry has over 20000 manufacturing units of which around 260 are in the organized sector\textsuperscript{16}. The Indian pharmaceutical industry has progressed significantly by moving from traditional business models and exploring and adapting to emerging new business models including: Contract research (drug discovery & clinical

\textsuperscript{12} ibid
\textsuperscript{13} ibid
\textsuperscript{14} ibid
\textsuperscript{15} ibid
\textsuperscript{16} ibid
trials); Contract manufacturing; and Co-marketing alliances. The Indian pharmaceutical companies have gained the desired competence in their manufacturing capabilities and have also started fulfilling the Current Good Manufacturing Practices (cGMP) compliance requirements stipulated by International regulatory agencies like United States Food and Drug Administration (USFDA) and Medicine Control Council (MCC).

II. NEW PATENT REGIME IN INDIA

A. Background of Patent Regime in India


17 id 3  
18 id at 6  
The Patent and Designs Act, 1911 introduced during the colonial rule was reviewed and enacted The Indian Patents Act, 1970 which provided for process patents and acted as an essential tool in laying a strong foundation for growth and development of pharmaceutical industry in independent India. The important provisions contained in this Act were: (i) permitting process patents of chemicals which included pharmaceuticals; (ii) reducing the term of patent for process patents in pharmaceuticals to 7 years from date of application of patent and 5 years from date of grant of patents, whereas for all other matters the patent was for a fixed period of 14 years; and (iii) introduction of provision relating to expeditious licensing mechanism.

During the period 1995 to 2005, India carried out 3 amendments to its patent laws and transitioned from process patent regime to product patent regime and became TRIPS Compliant. The 1st amendment of The Patents Act, 1970 was carried out in 1999 whereby “Mail-box” provisions were introduced to provide a means by which product patent applications could be filed with effective from January 1, 1995. The 2nd amendment in 2002 provided for incorporation of all substantive provisions except for providing patents to products. The important provisions incorporated include: (i) redefining patentable subject matter; (ii) extension of patent term to 20 years; and (iii) amending compulsory licensing system. The 3rd amendment in 2005 provided for product patents which marked the beginning of new patents regime in India.

24 Chapter IVA of The Patents (Amendment) Act, 1999 provides grant of Exclusive Marketing Rights (EMR) for a period of 5 years if the product in these applications is granted patent by any of the WTO member countries.
B. Key Provisions Relating to TRIPS Compliance

The TRIPS consistent Indian patent law addressed three important issues relating to patent of products: (i) adoption of definition of “pharmaceutical substance”; (ii) exclusion of “mere discovery of a new form of known substance” and “new use for a known substance”; and (iii) protecting the interests of those who are already producing the products which may be granted patent protection in the new regime. The Act introduced: (i) new definition of the term ‘new invention’; (ii) restrictions in the scope of patentability; (iii) provisions relating to Bolar Exemption; and (iv) provisions on parallel imports.

“Now, it is made explicit in the amended Act that patents would not be available on the following grounds: (i) the mere discovery of a known substance which does not result in the enhancement of the known efficacy of that substance, (ii) the mere discovery of any new property or new use for a known substance, and (iii) the mere use.

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26 §(2)(l) "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 has not fallen in public domain or that it does not form part of the state of the art”,
27 §(3)(d) “the mere discovery of a new form of a known substance which does not result 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 a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
Explanation.—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 substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”
28 §107A(a). "Certain acts not to be considered as infringement.-For the purposes of this Act,- (a) any act of making, constructing, using or selling a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India that regulates the manufacture, construction, use or sale of any product;
29 §107A(b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.”.
of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant.”  

III. CHALLENGES FOR THE INDIAN PHARMACEUTICAL INDUSTRY

A. Novartis Sues India

“The product patent regime is no longer the challenge - it is a reality that the Indian pharma industry has accepted and the exact nature and scope of patentable inventions in the field of pharmaceutical arts will become clear only when the amended law is put to use, and possibly reviewed by the Courts of Law and hopefully the textual law will acquire more clarity in the days to come when the Judges opine on the meanings of contents in contained in the amended provisions”.

The letter and spirit in which India transitioned into the new patent regime has been put to litmus test by Novartis which sued India with the institution of a writ petition before the High Court of Judicature at Madras. Several countries praised India’s

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33 See supra text at 3. In the writ petition Novartis challenged the constitutionality of § 3(d) of The Act and sought annulment of the same by issuance of writ of declaration and also praying for granting of patent. It also prayed for allowing its patent application No. 1602/MAS/98 rejected by the Controller General of Patents and Designs, Chennai on Jan. 25, 2006 for ‘beta crystalline form of imatinib mesylate’ sold under the brand name Gleevac/Glivec which provided Exclusive Marketing Rights (EMR) to Novartis since Nov. 10, 2003.

Novartis filed its case with Indian court at Chennai and sought patentability of its product Gleevec filed under EMR provisions on the grounds alleging: (i) illegality in procedure adopted and also the text of § 3(d) of The Act which was in violation of Article 27(1)\footnote{WTO, \textit{TRIPS: Patentable Subject Matter,} “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”, \url{available at http://www.wto.org/english/docs_e/legal_e/27-trips.doc}, \url{(last visited Sep. 4, 2007)}} and 27(2)\footnote{WTO, \textit{TRIPS: Patentable Subject Matter,} “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect \textit{ordre public} or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”, \url{available at http://www.wto.org/english/docs_e/legal_e/27-trips.doc}, \url{(last visited Sep. 4, 2007)}} of TRIPS Agreement; (ii) arbitrariness by the Controller General of Patents & Designs, Chennai and ignoring rationality underlying Articles 253\footnote{Constitution of India, Article 253. “Legislation for giving effect to international agreements: Notwithstanding anything in the foregoing provisions of this Chapter, Parliament has power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country or countries or any decision made at any international conference, association or other body, \url{available at http://lawmin.nic.in/legislative/Art243-395%20(89-184pp).doc}, \url{(last visited Sep. 5, 2007)}} and 51(c)\footnote{Constitution of India, Article 51( c ) “Promotion of international peace and security.—The State shall endeavor to foster respect for international law and treaty obligations in the dealings of organized peoples with one another”, \url{available at http://lawmin.nic.in/legislative/Art1-242%20(1-88).doc}, \url{(last visited Sep. 5, 2007)}} of the Indian Constitution whereby national laws are required to be harmonized with International treaties; (iii) provision relating to discovery of “new form’ contained in § 3(d) is illogical and against the concept of patents which encourages innovation and intervention by rewarding the person associated with such acts beneficial for society; (iv) deliberate incorporation of §3 (d) after approval of its product Gleevec under the earlier prevailing EMR provisions resulted in disturbing the level playing field laid under The Act in compliance with conditionality under TRIPS Agreement.
The Technical Expert Group on Patent Law Issues with Mr. Mashelkar as its Chairman (Mashelkar Committee) submitted its report to the Government of India on its terms of reference\(^{39}\) which favored incremental modifications / innovations for qualifying for the grant of patent as New Chemical Entities (NCE)\(^{40}\). Several NGOs opposed the case filed by Novartis and urged the doctors and medical professionals to boycott its products in India\(^{41}\). The Indian court rejected the plea of Novartis on patent of Gleevac\(^{42}\). The serious apprehensions about Switzerland referring the matter to WTO against India for violation of TRIPS Agreement has been put to rest with the statement made by Mr. Doris Leithard, federal councilor in the department of economic affairs, Switzerland\(^{43}\). This patent case is considered to be a threat to developing nations and the treatment of AIDS patients will be seriously impaired if Novartis ultimately succeeds in obtaining favorable award on its patent matter from the Higher courts in India\(^{44}\). It is a considered view that the patent laws in India do not stifle research and the section 3(d) of The Act only prevents incremental innovation and favors genuine research in invention and discovery of NCE\(^{45}\).

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\(^{39}\) See supra text 6. The terms of reference were (a) whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and b) whether it would be TRIPS compatible to exclude micro-organisms from patenting.


B. Revival of Yoga and Impact of Baba Ramdev

Yoga is considered to be a distinct system of medicine and also a complete ancient Indian therapy associated with Life Science that cures almost all of the physical and mental medical condition without causing any side effects and providing cure for most of the incurable diseases\(^{46}\). Baba Ramdev revived Pranayama which acts as the best medicine involving rhythmic control of breath through bodily exercises and awakens divine powers essential for curing disease and enabling creation of "Disease Free Society - Medicines Free World"\(^{47}\). Yoga Pranayama & the Ayurvedic & Herbal medicines used at Baba Ramdev’s Yoga camps have scientifically proved to provide cure for most of the diseases including: (i) control & cure of HIV/AIDS by improving the CD4 (T-helper lymphocytes) cell count of the people affected by AIDS; (ii) control and cure of cancer; (iii) diabetes; (iv) hypertension; and (v) depression\(^{48}\). In the early 19th century, Swami Vivekananda and several other religious gurus and yoga practitioners introduced Yoga in the United States through translated works and Max Muller contributed significantly in popularizing it in Germany and other European countries\(^{49}\).

\(^{47}\) Ibid
\(^{48}\) Ibid
In the contemporary period Mr. B.K.S. Iyengar\textsuperscript{50} contributed significantly in the spread of Yoga in US and the other western countries through his work focused on improving the credibility of yoga in the scientific and medical communities using innovative means including: (i) developing anatomically precise terms to convey the body exercises; (ii) improving the learning tools; (iii) minimizing esoteric Hindu trappings without sacrificing the yoga quest for union of body, mind, and soul; and (iv) using yoga as a therapeutic tool\textsuperscript{51}.

Yoga has now started attracting big business and companies including Ford Motor, Pfizer and Clairol are pursuing well-heeled yogis with advertisements and it is difficult to measure its business potentiality with its growing popularity observed in many parts of US: (i) Guests at Resorts Atlantic City Casino Hotel take part in a yoga class; (ii) Rodney Yee, Yoga teacher, endorses advertisement for ‘Vitasol’ promoting consumer food products; (iii) Development of Yoga tourism and Yoga vacation: Kripalu Center for Yoga & Health develops as the biggest yoga retreat center in US with accommodation for 450 people; (iv) development of Yoga studios; and (v) Oprah Winfrey shows on Yoga\textsuperscript{52}.

Business yoga for managers has become very popular as it provides a good feeling and

\textsuperscript{50}Iyengar Yoga – National Association of the United States (IYNAUS), Biography of B.K.S. Iyengar, available at http://www.iynaus.org/IyengarYoga/BKS/biography.aspx (last visited Sep. 4, 2007). Mr. B.K.S. Iyengar is also known as “the Michelangelo of Yoga” and the “King of Yogs”. He has been practicing and teaching Yoga for more than 70 years and has millions of students in Iyengar yoga centers spread all over the world. His book Light on Yoga is very much acclaimed the world over. He shall soon be releasing a new book titled ‘Light on Life’. He suffered serious illnesses including malaria, tuberculosis and typhoid during his childhood owing to poverty and malnutrition. In 1937, he started teaching Yoga in Pune, India and reached US in 1956 after visiting Europe with his disciple Mr. Yehudi Menuhin, the world renowned violinist. In 1975, he established the Ramamani Iyengar Memorial Yoga Institute in Pune, India, which has now become an international center for Excellence in Yoga. He is widely recognized as one of the premier yogis responsible for introducing ‘Iyengar Yoga’ to the West. He is aged 86 years and continues to teach, preach and practice Yoga.


enormous satisfaction as per Mr. Kumud Schramm of the German yoga association.\textsuperscript{53} Yoga has emerged as one of the best ways to keep oneself fit, both physically and mentally.\textsuperscript{54} Baba Ramdev’s increasing popularity and the immense pressure exerted by the powerful global pharma lobby has made India seriously consider revising: The Drugs and Cosmetic Act, 1940 and Drugs and Magic Remedies Act, so that godmen like Baba Ramdev are prevented from claiming that Indian traditional medicine can cure diseases like HIV / AIDS, cancer, diabetes, high blood pressure etc. The Health Ministry issued notices to over 80 organizations including the high-profile ashram of baba Ramdev and also instructed them to stop claiming curing serious diseases like AIDS and cancer.

\textbf{C. Generic Pharmaceutical Manufacturing}

The government policies, programs and initiatives enabled the Indian pharmaceutical industry a smooth transition from process patent to product patent regime and resulted in its emergence as a global leader in generic manufacturing field. Indian generic drug manufacturers have been manufacturing generic versions of branded drugs. The generic drug manufacturers who had made significant investment and were marketing the product prior to January 2005 are allowed to continue marketing the product in the new patent regime and The Act granted them immunity from infringement suits by patent holders. ‘Bolar’ exception in Indian patent law allows the generic manufacturers to carry out the mandatory tests necessary for regulatory approvals without having to wait till the expiry period of the patent. It also ensures Indian generic manufacturers to compete among

\textsuperscript{53} Bio-Medicine, East or West Yoga is the Best, available at http://www.bio-medicine.org/medicine-news/East-Or-West-Yoga-Is-The-Best-4511-1/, (last visited Sep. 4, 2007)

themselves and provides continued availability of medicines at low costs for domestic and international, consumers. There is increased competition in the US and European generics market leading to considerable price reduction of pharmaceutical products. Generic players are also finding it difficult to obtain Para IV wins\(^{55}\) to effectively compete in the market. The Act has maintained a reasonable balance between stringent Intellectual Property measures while making use of some of the flexibilities that are inbuilt under TRIPS provisions.

The Indian generic manufacturing industry is strong despite pricing pressure exerted on it from the generic markets of US and Europe. The Indian generic industry has a competitive advantage due to relatively cheaper generics whose market demand may also increase due to increase in ageing population in US and Europe and it is expected that such population of Europe is expected to increase from 20% to 26% by 2025 and that of US from 16% to 25%\(^{56}\).

**D. Drug Prices and Access to Medicines for the Poor**

In the new patent regime, India is required to: (i) take concrete measures for ensuring IP protection and enforcement; (ii) carry out review of its price control policy; and (iii) provide faster clearances at customs for finished goods. The report issued by the task force under the chairmanship of Dr. Pronab Sen relates to: (i) expansion of price controls to every medicine on India’s Essential Drug List; and (ii) price monitoring


system of patented medicines. India has established National Pharmaceutical Pricing Authority (NPPA) to fix or revise the prices of controlled bulk drugs and formulations and also to enforce prices and availability of the medicines under the Drugs (Prices Control) Order, 1995. US and India have started co-operating and synergizing their efforts to prevent HIV/AIDS and also provide the required relief measures in mitigating the sufferings of the victims, mostly comprising of the deprived and depressed sections of society stratified on socio-economic reasons.

E. Competition from China

Indian pharmaceutical industry is expected to face competition from the Chinese pharmaceutical industry as China is known for its cheap manufacturing capabilities. Chinese government has introduced several initiatives in providing boost to its pharmaceutical industry and there are trends indicating increased investments by global MNCs. The advantages of Chinese pharmaceutical industry to that of Indian pharmaceutical industry include: (i) better data protection mechanism; (ii) favorable domestic pricing issues; (iii) Chinese government’s strong commitment to pro-industry

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57 See US-India CEO Forum: US-India Strategic Economic Partnership, published in March 2006 (pages 22-23), available at www.planningcommission.nic.in/reports/genrep/USIndia.pdf last visited Sep. 6, 2007. As per this document the Pharmaceutical and Healthcare sector could be a major area of US-India co-operation providing the Healthcare sector “infrastructure” status aimed at promoting FDI by US in India for the purposes of tax incentives and access to funding in matters relating to: clinical trials, other R&D services and outsourcing.

58 NPPA, Functions of NPPA, available at http://nppaindia.nic.in/function.html, (last visited Sep. 5, 2007) also monitors the prices of decontrolled drugs in order to keep the prices at reasonable levels. The other functions of NPPA include: (i) monitoring the availability of drugs, identifying shortages, if any, and to take remedial steps; (ii) collection and maintenance of data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations; (iii) undertaking and sponsoring studies in respect of pricing of pharmaceuticals; (v) rendering advice to the Central Government on changes or revisions in the drug policy.

59 See supra note 7
policies; and (iv) existence of a strong patent regime\textsuperscript{60}. More than 20 major MNC pharmaceutical companies have already established their manufacturing and R & D facilities in China and are also associated with carrying out drug discovery and Phase I-II clinical trials related activities. MNCs like Sanofi Aventis, Merck etc., are likely to establish R&D facility in China\textsuperscript{61}. The case ruling against Novartis is expected to change the plans of the Swiss pharma giant who may seriously consider reorienting its investment plans in India that may benefit China with its increased investments in pharmaceutical business\textsuperscript{62}.

IV. 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 activities\textsuperscript{63}. 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


\textsuperscript{63} See supra note 60
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 manufacturing\textsuperscript{64}.

\textit{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 Centers\textsuperscript{65}. 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/AIDS\textsuperscript{66}.

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

\textsuperscript{64} See supra note 57  
\textsuperscript{65} See supra note 57  
\textsuperscript{66} See supra note 7
vaccines exempted from excise duty; (iv) clinical trial of new drugs exempted from service tax to make India a preferred destination for drug testing; (v) anti-AIDS drugs and life saving vaccines exempted from excise duty to encourage companies like Cipla; (vi) all drugs and materials used in clinical trials to be provided customs and excise duty exemption; (vii) companies in knowledge-based pharmaceutical business to be provided equity support; (viii) customs duty reduced to 5% on 10 anti-AIDS and 14 anti-cancer drugs; and (xix) duty on certain life saving drugs, kits and equipment reduced and such drugs are also exempted from excise duty and countervailing duty. 

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 restructuring of its fine chemical industry the competitive Indian pharmaceutical industry is all set to explore and exploit the business potentiality. 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 Organizations (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

69 See supra note 7
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 plants\(^7^0\). There are several generic manufacturers in the US who are outsourcing their future generic API requirements from independent manufacturers based in countries like India\(^7^1\). Some of the MNC’s have already established their subsidiaries in India for contract manufacturing operations\(^7^2\). Large Indian companies like Ranbaxy-Eli Lily and Lupin-Cynamid have taken the lead in signing major contract manufacturing agreements\(^7^3\). 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\(^7^4\).

\(^7^0\) Sapna Agrawal, *Indian Companies readying for USFDA*, available at http://www.impactinfosys.com/admin/newspdf/India.pdf (last accessed March 17, 2007)
\(^7^1\) See supra note 68
\(^7^2\) Id at 2
\(^7^3\) Id at 2
\(^7^4\) Id at 4
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 year\(^{75}\). 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 (CPG) guidelines prescribed by USFDA\(^{76}\). The other reasons for emergence of India as a favorable 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\(^{77}\). 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;


\(^{76}\) Id at 4

\(^{77}\) See supra 75
(iii) Indian CROs operating independently eg. Siro Clinpharm; and (iv) Subsidiaries of Indian pharmaceutical companies operating as independent entities, eg. Well Quest. 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 million. There has been a considerable reduction in time gaps between the introduction of “innovative drugs” and therapeutically similar innovations resulting in Indian companies getting more focused on conducting clinical trials. Neeman Medical International, a 100% subsidiary of Max group of companies has 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 recently. These companies have started undertaking contracts from global MNCs which favor outsourcing of their clinical trials related requirements 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

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78 Ibid
79 See supra note 68
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 Max 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 patient 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) standards.

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

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providing positive rights and empowering TK holders to protect and promote their TK\textsuperscript{83}. The draft policy objectives and core principles for protection of TK have already been prepared by WIPO\textsuperscript{84} 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”\textsuperscript{85}. 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 legislations.\textsuperscript{86} 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 TK\textsuperscript{87}. As per World Health

\textsuperscript{83} World Intellectual Property Organization (WIPO), *Traditional Knowledge*, available at http://www.wipo.int/tk/en/tk/, (last visited Sep. 6, 2007)


\textsuperscript{86} 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.

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 TK. 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* system. It is also being felt that proper documentation of TK could help in checking bio-piracy. 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: (i) Traditional Knowledge Resource Classification (TKRC); and (ii) International Patent Classification (IPC) systems. 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 others.

**CONCLUSION**

The new patent regime in India touched the hornets’ nest and has raised several contentious issues relating to right to health of the people, which is in conflict with the economic right of patent holders. It is also likely to restrict access of allopathic medicines

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88 Ibid
89 See supra note 85
90 ibid
91 ibid
to only the affluent, affordable and more privileged class of people in India and other countries in the immediate future. The institutions associated with enforcement and protection of right to health of human beings whilst upholding the rights of patent holders are faced with the daunting task and challenge of devising ways and means for fulfilling their defined, designed and desired roles so that the conflict in rights pertaining to rights of intellectual property owners and the right to health of human beings is minimized whilst balancing the prevailing hierarchy of human rights\textsuperscript{93} for achieving the social and economic objectives.

The new patent regime in India has sown the seeds for revival and rejuvenation of ancient and traditional systems of medicine like yoga and ayurveda and godmen like Baba Ramdev shall act as a means for placing the right to health at a higher pedestal to that of right to intellectual property of the patent holders. The Indian pharmaceutical industry is all set for a major leap in expanding its activities, despite the prevailing maladies associated with Indian democracy. It is also required to be understood that in India there exists several statutes of mere ornamental value and the patent laws shall also prove to be ineffective in the longer run and shall serve the purpose of providing only the desired cosmetic effect.

In my view, the enabling legislations made by India for legitimizing its commitments made in various International treaties and agreements lack the desired conviction, as is evident from inadequate and meaningful enforcement mechanisms


essential for effective percolation of the essence perceived in the statutory provision. The Indian judiciary is also required to reorient its functioning and atleast display intermittent judicial activism whilst addressing the issues relating to inordinate delays in deciding matters in Indian courts, especially those under international treaties which also have significant bearing on domestic matters or else the MNCs and Foreign Institutional Investors (FII) will soon be losing interest in India and the new patent regime may prove detrimental to India’s economic prosperity.

It is also expected that the patient shall soon assume the role of a consumer in the pharmaceutical commodity market and the pricing of medicines is expected to be lowered significantly due to development and spread of alternate systems of medicine in the TK regime which is soon emerging as an important competitor to the prevailing pharmaceutical market wherein the right to health has become an obsolete right of human being suffering from dreaded diseases. The resurging TK regime is the bye-product of the current stringent product patent regime developed under compulsive TRIPS Agreement and is perceived to provide the required competition resulting in reduction of prices of medicines by global pharma majors who have established monopolies due to inherent contradictions and prevailing political and legal systems worldwide. Countries like US and India are all set and geared to reap the economic benefits in the globalized world economy and are entering into strategic alliances and partnerships in every sphere of explored / unexplored and exploited / unexploited areas of business requiring innovative and advanced technologies including: Intellectual Property Rights, Science, and New Space Industries (NSI).94

The vast potentiality in space business include activities relating to: “(a) space manufacturing; (b) space resources for both space and earth exploration; (c) space business parks; (d) satellite and space transfer services; (e) travel and entertainment (space tourism); (f) space utilities; and (k) space power gear.”