

THE PHARMACEUTICAL INDUSTRY
AND THE NEW PATENT REGIME IN THE INDIAN UNION

Sreenivasarao Vepachedu¹

Martha M. Rumore²

¹ Dr. Vepachedu is President of Vepachedu Professional Corporation, 1230 Georgetown Way, Vernon Hills, IL 60061, www.vepachedu.com, where his practice focuses on Biotechnology, Chemical and Pharmaceutical intellectual property. He holds a BS in Botany, Zoology and Chemistry from Osmania University, MS in Organic Chemistry from Kakatiya University, PhD in Organic Chemistry from Kakatiya University, JD from Osmania University and LLM in Intellectual Property from Howard University School of Law. He has worked as a scientist and a patent practitioner at various institutions, universities, industries and firms, such as the Indian Institute of Chemical Technology (IICT), National Institutes of Health (NIH), Rutgers University, University of Maryland, Eli Lilly & Company, MediChem (DeCODE), Incyte Genomics and Scully, Scott, Murphy & Presser, PC. Dr. Vepachedu is an attorney licensed to practice in India and before the USPTO. He is also President of Vepachedu Educational Foundation Inc., a non-profit educational organization, www.vepachedu.org.

²Dr. Rumore holds a B.S. in Pharmacy, M.S. in Drug Information and Biomedical Communication and Pharm.D. from St. John's University. She received her J.D. from City University School of Law in 2000 and an L.L.M. in Intellectual Property from Benjamin N. Cardozo School of Law in 2004. She is an associate at Brown Raysman (<http://www.brownraysman.com/>) specializing in pharmaceutical intellectual property and Food & Drug law. She is admitted to the bar in N.Y., N.J. and D.C. and admitted to practice before the USPTO.

The views expressed are solely those of the authors. The text herein is designed to foster academic discussion and should not be imputed to the employers of the authors, past, present or future.

TABLE OF CONTENTS

- I. INTRODUCTION
 - A. Historical Background
 - B. The Indian Patent Act of 1970
 - 1. Overview of the Indian Pharmaceutical Industry
 - C. International Patent Law
 - 1. TRIPS Agreement

- II. PATENT PROTECTION FOR PHARMACEUTICALS
 - A. The Patent Act of 1999
 - B. Doha Declaration
 - C. The Patents Act of 2002
 - D. Compulsory Licensing
 - E. The Proposed Third Amendment

- III. BHAARAT'S ROLE IN THE GLOBAL PHARMACEUTICAL MARKETPLACE- POST 2005
 - A. Innovation or Imitation- the Case for a TRIPS Compliant Patent Regime
 - 1. Economic Realities of TRIPS Compliance
 - 2. Alternative Medicine
 - 3. Unique Indian Health Needs
 - 4. Global Competition
 - B. Challenges to Intellectual Property Protection
 - 1. The Indian Constitution and the Judiciary
 - 2. Inadequate Patent Office Capacity Level

- IV. CONCLUSIONS

I. INTRODUCTION

*"The merchants used to move about in the rivers as they wished, as if in tanks,
in the forests as if in the gardens and on mountains as if in their own homes."*

Kalidasa³, Raghuvamsha, XVII (170 BC)

*"He saw the workshops thriving along the royal road, the river furrowed
by boats, and maidens flirting with youths in the parks on the outskirts of the town."*

Kalidasa, Raghuvamsha, XIV (170 BC)

The Indian Union, the largest democracy in the world, is a continental country⁴ comprising 1/5th of the world's population, which exhibits unparalleled diversity. Modern democracies such as the Indian Union (hereinafter "Bhaarat") and the United States of America (hereinafter "America") provide citizens with greater social and political rights, higher standards of living, more leisure and better educational opportunities. As one of the fastest growing economies in the world, Bhaarat is presently focusing its concerns on setting policies to promote domestic and foreign investment.

³ Kalidasa, an Indian poet and dramatist, lived sometime between the reign of Agnimitra, the second Shunga king (c. 170 BC) who was the hero of one of his dramas, and Chandra Gupta II (reigned c. 380-c. 415). Most scholars now associate him with the reign of Chandra Gupta II. Kalidasa's works include *Kumarasambhava*, *Malavikagnimitra*, *Meghaduta*, *Raghuvamsha*, *Ritusamhara*, *Shakuntala* and *Vikramorvashe*. The Aihole inscription of AD 634 praises Kalidasa's poetic skills. He is generally considered to be the greatest Indian writer of all times. The above quotes from *Raghuvamsha* throw the light on Ancient India's liberal institutions. For more on Kalidasa and *Raghuvamsha*, see also B.S.V. Prasad, *Kalidasa and Ancient India*, at <http://www.sulekha.com/expressions/articledesc.asp?cid=87420>.

⁴ India is a geographic term, like Europe. Interestingly, "India" is not an Indian word and the land is known as Bhaarat in almost all Indian languages, except English. The Indian Continent (also called South Asia) is a vast region of people of many languages, nationalities, and groups of people of widely disparate customs. The Indian Continent extends from the thirty-eighth parallel to the eighth parallel with varied climates ranging from eternal snows to tropical jungles that present an immense and diverse fauna and flora. The Indian Continent, protected by impassable Himalaya Mountains in the north and northeast and Hindukush Mountains in the northwest and vast lengths of coast in the east, south and west, is home to a myriad of races, tribes, cultures and languages. Despite the protective natural barriers, the continent has been an object of plunder and settlement for invaders across Hindukush Mountains in the present Afghanistan and through the Indian Ocean, due to the vast and rich alluvial plain that spread between the Rivers Indus and Ganga, that resulted in enrichment of already vastly diverse humanity of the continent. The Indo-Gangetic plain is the cradle of Indian civilization and the Brahmanism or Vedic religion that spread to every nook and corner of the continent and influenced numerous indigenous and diverse religions and faiths in one way or the other. The Indian Union, popularly known as India, is the core of this vast continent and is unique, having a modern democracy based on modern secular principles of tolerance and universal kinship which are also ancient Vedic principles of *Vasudhaiva Kutumbakam*. The present evolution in industrial and information technology fields are admirable and remarkable for a civilization as spiritual, rich, diverse, complex and continental as that of India.

In order to promote economic growth and development in the world context, a level playing field and equality are a necessity, not only among citizens of one country, but also among various countries.⁵ Towards this lofty goal, the world established the World Trade Organization (hereinafter “WTO”), and agreed to the Trade Related Intellectual Property Rights (hereinafter “TRIPS”) Agreement signed into effect during the eighth round of the Uruguay Round of talks on the General Agreement on Tariffs and Trade (hereinafter “GATT”) in 1994.⁶ The social purpose of Intellectual Property Rights (hereinafter “IPRs”) is to encourage creativity and advancement of knowledge by giving those who make intellectual contributions an “exclusive right to their writings and inventions” for limited times. Product patent protection is an integral part of IPRs. Under the TRIPS Agreement, developing countries, like Bhaarat, were given a 10-year transition period to integrate their patent laws with those of developed countries.⁷ By 2006, all countries that are members of the WTO will have to comply with the strict intellectual property standards set by TRIPS.⁸ Recent patent law amendments in Bhaarat are intended to bring Indian patent law closer to the TRIPS Agreement. The latest in the series of these amendments are contained in the Patents Amendment Act of 2002⁹ and the Patent Rules, 2003.

Bhaarat has a commitment to modify its patent system to provide for product patents by January 1, 2005. To comply with the obligation, Bhaarat has promulgated an ordinance¹⁰ to that effect in December 2004 and has six months to pass the legislation. Bhaarat is set to emerge as one of the top R&D powerhouses for pharmaceutical and biotech development in the world. The cost of developing pharmaceutical products is growing dramatically in the international market and Bhaarat has increasingly

⁵ Sreenivasarao Vepachedu, *Legal and Social Equality in India*, at <http://www.vepachedu.org/equality.html> (Mar. 1995). The notion of equality, which was confined merely to social and political thinking, evolved into a matter of legal consideration over a period of time.

⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, *reprinted in* The Results of the Uruguay Round of Multilateral Trade Negotiations-The Legal Texts 6-19, 365-403 (GATT Secretariat ed., 1994) [hereinafter TRIPS Agreement].

⁷ *Id.*

⁸ India was a signatory to and founding member of the WTO in 1995.

⁹ Effective May 20, 2003.

¹⁰ The Patents (Amendment) Ordinance, December 2004 available at: <http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf> (last visited January 27, 2005).

been seen as a destination to reduce the cost of development by about 30-40 percent.¹¹ Moreover, with one of the largest pools of human resources available, Bhaarat is poised to become one of the largest pharmaceutical producers and markets in the world.¹²

Today a large percent of the key ingredients in American-made generic and brand drugs come from foreign suppliers. Other countries like Canada with its booming cross-border pharmacy business which exceeds Canadian production capabilities, have begun importing huge amounts of pharmaceuticals from countries like Bhaarat to meet increased demand.¹³

This article discusses how Bhaarat evolved in the past fifty years from a country without any pharmaceutical industry to a country that is dominant in generic drugs and details what intellectual property protections are necessary for Bhaarat to become a world leader in the pharmaceutical industry. Specifically, Part I presents a historical overview of Indian Patent Law prior to the amendments, especially the advantages that were bestowed by the Indian Patent Act of 1970; Part II discusses patent protection for pharmaceuticals in Bhaarat with an overview of the Amendments of 1999, 2002 and the proposed third amendment; Part III explores Bhaarat's role in the global pharmaceutical marketplace post 2005; Part IV concludes with implications for the future.

A. Historical Background

Most of the Indian Continent, also known as South Asia, was under slavery and colonial rule for centuries. After World War II, most of the Indian Continent was liberated from the British Empire. However, there were several countries, from the largest Hyderabad kingdom to smaller states of only few square miles, which were independent and were not part of the British Empire.¹⁴

¹¹ Shaken & Sans Pharma Policy, *Industry Stirs A Global R&D Pill*, SANJAY SARDANA, Financial Express, available at http://www.financialexpress.com/fe_archive_full_story.php?content_id=49418 (Dec. 3, 2003).

¹² See generally Nichy Jatana, *Did Whirlpool Make Its Mark In India?* *N. R. Dongre v. Whirlpool Corporation*, 10 TRANSNAT'L LAW 331, 332 (1997) (analyzing the effect of TRIPS and predicting the future potential for the Indian market in the global economy).

¹⁴ PERCIVAL SPEAR, A HISTORY OF INDIA, Vol. II, 240 (Penguin Books India (P) Limited 1990).

The newly liberated Continent was divided into several countries such as Pakistan¹⁵, Myanmar, Sri Lanka, Bhaarat¹⁶, and so on. Soon after, about 600 independent countries and principalities joined Bhaarat, including the large land-locked countries such as Hyderabad and Kashmir, and small seaports like Junagadh that were reluctant to join Bhaarat. At the time of the formation of modern Bhaarat, the 1911 Indian Patents and Designs Act¹⁷ was the patent law subsequently adopted by the Union.¹⁸

Indian patent law has its historical roots in the English patent system. The first patent system appeared in 1856 in Calcutta (now Kolkata) and granted exclusive privileges to inventors for a period of 14 years.¹⁹ In 1872, the Patents and Designs Protection Act was passed, followed in 1883 by the Protection of Inventions Act. In 1911, the Indian Patents and Designs Act was enacted, under which Bhaarat was used as a colonial market without protection for indigenous production.

Prior to the formation of modern Bhaarat, none of the regions, either under the British rule or under independent rulers, had a considerable pharmaceutical industry. Due to monopolies of foreign multinational companies and the British policies, by the time of Indian independence in 1947 drug prices in

¹⁵ Pakistan is where the sacred River Indus or Sindhu flows today, from which the words like Sindh, Hind, India and their derivatives are derived. It may be interesting to note that the land of River Indus is called Pakistan and the people Pakistanis, while tribes and nations that have nothing to do with the River Indus are known today as Indians, including Native American Indians, e.g., the people of the state of Andhra Pradesh, who live on the banks of mighty rivers Krishna and Godavari in the south-central India, far away from the River Indus, are called Indians and the tribes living on the banks of rivers Missisipi, and in the forests of Amazon are also called Indians. It may be interesting to note that Afghanistan, where the Hindukush (Slaughter of Hindus) Mountains are present, was known as Gandhar and was part of Ancient India and mythological India of Mahabharat epic. Princess Gandhari of Afghanistan married Dhritarashtra and ruled Ancient India from the capital Hastinapur (Delhi) and her brother Shakuni was one of the most important kings that supported Kauravas against their cousins Pandavas. Afghanistan was an integral part of the Indian empires even as modernly as during Mogul Dynasty founded by Babur, a descendant of Tamerlane and the founder of India's Mogul Dynasty at the beginning of the 16th century. Kabul was the capital of Afghan State in the Mogul Empire, a state that continued more or less uninterrupted until late 19th century. See http://www.hindunet.org/hindu_history/modern/hindu_kush.html; http://www.terrorismfiles.org/countries/afghanistan_history.html# (last visited Mar. 4, 2004); see also ROMILLA THAPAR, A HISTORY OF INDIA, Vol. I, 107 (Penguin Books India (P) Limited 1990).

¹⁶ THAPAR, *supra* note 15; see also SPEAR, *supra* note 14, at 240, 241. Soon after, about 600 independent countries (principalities) joined India, including the large land locked countries such as Hyderabad and Kashmir, and small seaports like Junagadh that were reluctant to join the Union. Later the Indian states in the Union were reorganized on the basis of linguistic nationality. At present India is divided into 28 states. The exact number of countries or states depends on the distinction between state and estate, a fine distinction.

¹⁷ Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 518 (1996).

¹⁸ In 1942, the Council of Scientific and Industrial Research was created in order to strengthen pharmaceutical R&D.

¹⁹ See generally WILLIAM THEOBOLD, THE LEGISLATIVE ACTS OF THE GOVERNOR GENERAL IN COUNCIL (Thacker & Co. 1968) (providing salient features of the 1856 patent law, many of which were not adopted in the 1970 Indian Patent Act. It is interesting to note that under the 1856 patent law, the term for a patent was fourteen years).

Bhaarat were the highest in the world²⁰ with foreign multinational corporations controlling 80% of the Indian pharmaceutical industry.²¹ The Indian pharmaceutical industry processed ingredients imported from other countries with total dependency upon imports.

Under the stewardship of the first Prime Minister, Jawaharlal Nehru, two government committees were formed to evaluate and revamp the British patent system to suit specific Indian needs.²² After an extensive and long debate, based on the Ayyangar Commission Report, the Indian parliament enacted The Patent Act of 1970 to promote and develop the domestic pharmaceutical industry.²³ The 1970 patent legislation provided opportunities for the indigenous industry to produce pharmaceuticals for the Indian people.²⁴ This was accomplished *inter alia* by removing patent protection for pharmaceutical products. Bhaarat's rejection of patent protection for pharmaceutical products was, at the time, a pragmatic approach to the monumental task of alleviating the country's health problem. As a result, Bhaarat has had success in the pharmaceutical sector with its expertise in reverse technology and has the potential to become a global leader in the pharmaceutical industry.

B. The Indian Patent Act of 1970²⁵

Under the Patent Act of 1970, the term of a process or method patent is limited to five years from the date of sealing or seven years after the filing date, whichever is shorter.²⁶

²⁰ Adelman & Baldia, *supra* note 17, at 526.

²¹ See D. P. Dubey, *Globalization and its Impact on the Indian Pharmaceutical Industry*, at <http://www.revolutionarydemocracy.org/rdv5n1/pharmacy.htm> (Apr. 1999); see also David K. Tomar, Note, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 582 (1999).

²² *Id.* Nehru's policies were tempered by communist and socialist ideology.

²³ The 1970 Act closely paralleled the 1949 U.K. Patents Act.

²⁴ Indian Patent Act § 2(1)(j). The Act became effective in 1972. Under the present patenting system India follows a first to file patent system, in which whomever in the world first discloses an invention in an Indian application has an earlier priority date. This priority date provision extends to "an application that was first filed in another country that offers reciprocity." The Indian Patent Office performs the statutory duties with the grant of patents for new inventions and is located at Kolkata with branches at Mumbai, Chennai and Delhi. The branches prosecute applications from their respective territorial jurisdictions. The office of Controller General of Patents, Designs and Trademarks administers the Patents Act of 1970.

²⁵ The Patent Act, (1970) (India).

²⁶ Adelman & Baldia, *supra* note 17, at 507, 518-523.

The Indian Patent Act of 1970 effectively offers no protection for pharmaceutical products. The Act gave the pharmaceutical industry in Bhaarat decisive competitive advantages by allowing companies to copy the bulk drug from patented products by changing the method by which the patented molecule was produced and to market them in Bhaarat. In effect, the Act made it possible for many new companies to enter the market for patented pharmaceuticals, without having to cover large R&D expenses.

According to the Indian Patent Act of 1970, the following are not treated as patentable inventions:

- (i) An invention which is frivolous or which claims anything obviously contrary to well established natural laws;
- (ii) An invention the primary or intended use of which would be contrary to law or morality or injurious to public health;
- (iii) The mere discovery of a scientific principle or the formulation of an abstract theory;
- (iv) 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;²⁷
- (v) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
- (vi) The mere arrangement or re-arrangement or duplication or known devices each functioning independently of one another in a known way;
- (vii) A method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;
- (viii) A method of agriculture or horticulture;

²⁷ However, Indian Patent Law does not define prior art disclosure. The introduction of a common definition or harmonization of definitions or standards of prior art disclosure is necessary. Additionally, the Patent Act places the burden of proof on the patentee to prove infringement. For process patents, the patentee must ascertain that a particular product could only have been made through a patented process.

- (ix) Any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

Additionally, under the 1970 Act, “....(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves. Claims for the methods or processes of manufacture shall be patentable....”

Therefore, under the 1970 Act product patents for pharmaceuticals were simply not available. Further, the Act did not mention anything about patenting biotechnology. In practice, Bhaarat did not grant patents directed to plants, animals and human beings. Moreover, other areas of process in biotechnology were prohibited in Bhaarat.²⁸

The 1970 Act also permitted Indian pharmaceutical companies to market products with lower marketing expenses because the products were already well known to health professionals and needed less promotional efforts. However, an unfortunate and foreseeable result was the shifting of the focus of the pharmaceutical industry away from new product development and product innovation and toward process innovation to reduce production costs and compete based on volume and price.²⁹ One consequence was multiple producers of the same drug resulting in lower profits for each manufacturer and cheaper generic drugs for consumers.

²⁸ Recently several indigenous companies were able to manufacture recombinant hepatitis B vaccine and bring down the price almost ten fold.

²⁹ See generally, S. Chaudhuri, *Growth and Structural Changes in the Pharmaceutical Industry in India*, Working Papers Series, Indian Institute of Management, Calcutta, India, 1999. In addition to the Patent Act, the Drug Price Control Order of 1970 introduced strong pharmaceutical price controls in India. Several multinational pharmaceutical companies reacted to the Patent Act coupled with the price controls by pulling out of India altogether or not introducing their newly patented products onto the Indian market for fear of copying. Today price controls are maintained mostly for essential drugs. Brand names are often the name of the manufacturer as there will usually be several different products for each drug, competing based on price and quality.

An important aspect of Indian patent system under the 1970 Act was a licensing system, which allowed the government to require all private-manufacturing enterprises to be licensed. The Indian patent law provided for a compulsory licensing system, which allowed the country to select a firm in the country to produce pharmaceuticals and sell them at a prescribed price with a small royalty to the patentee. Compulsory licensing forces patent holders such as multinational corporations to provide their products at reasonable prices.³⁰

Bhaarat's patent system under the 1970 Act was a protectionist system designed to help the fledgling economy and industry to emerge from hundreds of years of colonial plunder and rule of myopic kings. It produced remarkable results by spurring the development of a powerful independent pharmaceutical industry and obliterating Indian dependence on multinational corporations.³¹ This is evidenced by the fact that since the late 1980s Bhaarat has become a net exporter,³² not net importer of pharmaceutical products.

1. Overview of the Indian Pharmaceutical Industry

Today Indian pharmaceutical companies account for between 60-70% of the Indian market, compared to only 10% in 1970.³³ Moreover, pharmaceuticals manufactured in Bhaarat are 10 to 40 times less expensive than in American pharmacies.³⁴ However, to the poor, pharmaceuticals are as affordable in Bhaarat as in America today.³⁵

³⁰ Le-Nhung McLeland & J. Herbert O'Toole, *Patent Systems in Less Developed Countries: The Cases of India and the Andean Pact Countries*, 2 J.L. & TECH. 229, 236 (1987).

³¹ David K. Tomar, *A Look Into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 582 (1999).

³² Chaudhuri, *supra* note 29, at 30.

³³ Rasmus A. Wendt, *The Pharmaceutical Industry in India*, Working Paper No. 24, International Development Studies, Roskilde University, 2000, pp. 1, 12.

³⁴ David Scondras, *A Visit to India: Drug Prices, Research, & Global Access*, at http://www.beingalivela.org/news0599/0599_visittoindia.html (May 1999); see e.g., *Indian Pharmaceutical Industry: An Overview, Pharmaceutical and Drug Manufacturers*, at <http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-industry> (last visited Feb. 17, 2004).

³⁵ In comparison, a cup of tea or coffee in India is 4.5 to 45 times less expensive than in America. A cup of tea or coffee in Indian restaurants would cost about one rupee in villages and about 10 rupees in Indian Airports, whereas in America it would cost about 45 rupees. One American dollar is equivalent to approximately 45 Indian rupees at <http://www.xe.com/ucc/>. According to the Andhra Pradesh Medical and Sales Representatives Union, Norfloxacin was available at Rs. 2 in India while the same drug was sold at Rs. 62

Currently, about 20,000 pharmaceutical manufacturers are licensed in Bhaarat, forming a highly organized sector. As a consequence of de-licensing in early 1990s combined with a protectionist patent system, the Indian pharmaceutical industry is valued at approximately \$4.5 billion, with 8 to 9 percent annual growth rate. The Indian pharmaceutical industry, endowed with highly educated scientific workforce and research capabilities is positioned to take on the international market.³⁶ For example, Astra Zeneca currently employs 100 Indian scientists in Bangalore researching new tuberculosis treatments. Many are returning expatriates who earned their doctorates and/or gained R&D experience in America.

Several pharmaceutical and biotech companies such as Dr. Reddy's, Ranbaxy, and Biocon have already made their global presence felt. These Indian companies have entered the generic markets in America for pharmaceuticals that have gone off patent. They have also, in some cases, become embroiled in patent litigation with multinational pharmaceutical companies where the patent fights over the \$17 billion generics market are particularly ferocious. Indian pharmaceutical companies are launching legal challenges to American patents. Dr. Reddy's obtained a 180 day exclusivity period for generic Prozac[®] as the product came off patent. Similarly, Ranbaxy obtained an exclusivity period on the GlaxoSmithKline antibiotic, Cefitin.[®] The intense overseas focus for these companies comes in part because the domestic market is stagnant, with hundreds of manufacturers vigorously competing with versions of big name drugs.

C. International Patent Law

The Paris Convention for Protection of Industrial Property in 1883 (hereinafter "the Paris Convention")³⁷ is considered as the beginning of international patent law. The Paris Convention is a global and multilateral treaty created to prevent protectionism among member countries and allow nationals of any member state to enjoy the same IPRs as all other member states. The Paris Convention established the

in the US, Rs. 12.55 in Pakistan. Diclofenac was priced at 50 paise in India while it was being sold at Rs. 23.44 in the US, Rs. 4.75 in UK, Rs. 5.58 in Pakistan. Rantidine was priced at 75 paise (India), Rs. 74.45 (US), Rs. 23.43 (UK) and Rs. 26 (Pakistan), at <http://www.thehindu.com/2004/07/19/stories/2004071906160300.htm>.

³⁶ Scondras, *supra* note 34.

³⁷ Paris Convention for Protection of Industrial Property, March 20, 1883, last revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

World Intellectual Property Organization (WIPO) to resolve intellectual property disputes and provide assistance in implementing the new provisions.³⁸

Globalization of trade has put a premium on the protection of intellectual property rights. Many industrialized countries became concerned with the lack of strong protection of intellectual property rights worldwide. As a result, disputes arose between the developed world and the developing world during Uruguay Round of GATT talks. Bhaarat led a fight against the establishment of product patent protection regime by arguing that patenting much needed medical products would make them unattainable to poor consumers in developing world.³⁹ However, both the developed and developing worlds were able to conclude the talks with an agreement called TRIPS Agreement largely due to the concessions provided by the developed world.⁴⁰

1. TRIPS Agreement⁴¹

Under the WTO obligations, each member country must provide for a minimum prescribed level of IPR protection to facilitate cross-border enforcement of such rights. The TRIPS Agreement lays down minimum standards to be adopted by member countries for IPR protection.⁴² As previously mentioned, under Indian law, patents may cover only manufacturing processes, not the products themselves.⁴³ As per the current TRIPS requirements, member countries such as Bhaarat, which on January 1, 1995 did not provide product patents in certain areas of technology, could delay the grant of product patents in those

³⁸ India is also a party to the Patent Cooperative Treaty (PCT). Under PCT, an Indian resident can make an international application for registering a patent. The applicant submits the patent application to the Receiving Patent Office of its country and designates other countries in which it desires to register the patent.

³⁹ INTRODUCTION: A TRIP BEGINS IN INTERNATIONAL INTELLECTUAL PROPERTY 7 (Doris Long & Anthony D'Amato eds., 2000). See generally Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819 (2003) (examining the TRIPS Agreement through a public health lens).

⁴⁰ Patrick L. Wojahn, *A Conflict of Rights: Intellectual Property Under TRIPS, the Right to Health, and AIDS Drugs*, 6 UCLA J. INT'L L. & FOREIGN AFF. 463 (2001-2002).

⁴¹ TRIPS Agreement, *supra* note 6; see also Pritesh Mehta, *WTO and Trade Related Intellectual Property Rights - An Indian Perspective*, www.indiaonline.com (last visited Jan. 23, 2004).

⁴² Obligations arising under international agreements or treaties are not, by their own force, binding in Indian domestic law. Appropriate legislative or executive action has to be taken to bring them into force.

⁴³ Indian pharmaceutical companies have been able to reverse engineer best-selling pharmaceuticals and sell copies cheaply.

areas until January 1, 2005. Consequently, Indian companies could manufacture pharmaceuticals under patent in other countries provided they use a process that is different from the original.

Inventions in all fields of technology, whether products or processes, shall be patentable if they meet the tests of novelty, involve an inventive step and are capable of industrial application, under the WTO obligations. However, specific exclusions are permissible from the scope of patentability. These exclusions encompass inventions whose commercial exploitation is to be prevented to protect public order or is found to be against morality or against human, animal and plant life or health or to avoid serious environmental damage. These exclusions are applicable to diagnostic, therapeutic and surgical methods for the treatment of humans, animals and plants other than microorganisms, and essential biological processes for the production of plants and animals other than non-biological and microbiological processes. With respect to plant patents, effective *sui generis* systems or a combination of both should provide protection. Each WTO member is free to define what is an effective *sui generis* system and its elements.

II. PATENT PROTECTION FOR PHARMACEUTICALS

A. The Patent (Amendment) Act of 1999

Transitional patent protection in the form of Exclusive Marketing Rights (hereinafter “EMRs”) was brought into force by the Patent (Amendment) Act of 1999. To fulfill commitments to WTO and the TRIPS Agreement until full compliance in 2005, Bhaarat was obliged to provide a means (Mailbox) for accepting applications for pharmaceutical or agricultural chemical products, apply applicable priority rights and provide EMRs for such products by 1995.⁴⁴ It is almost as if these applications go into a black box; said box to be opened and all applications examined when the legislation is changed in 2005.

In the transitional period until 2005, EMRs are to be granted for a period of five years from the date of obtaining marketing approval or until a product patent is granted or rejected, whichever period is

⁴⁴ Pritesh Mehta, *WTO and Trade Related Intellectual Property Rights - An Indian Perspective*, at <http://www.indiaonline.com/lega/feat/wtrr.html> (visited Jan. 23, 2004).

shorter. Although in 1994, Bhaarat promulgated the Patents Ordinance to implement EMRs, Bhaarat permitted lapse of said Ordinance in 1995, thereby delaying promulgation of relevant laws to provide patent protection for products and processes.⁴⁵ Due to fears that granting product patents would make medicines very expensive,⁴⁶ Bhaarat resisted protection of IPRs, and along with other developing countries and humanitarian organizations protested patent protection for pharmaceuticals.

Bhaarat's resistance to the implementation of stringent patent laws for pharmaceuticals was motivated by the belief that such patent laws would hamper the daunting task of alleviating the country's health problems.⁴⁷ This belief was partially based on Nehruvian, communist and socialist attitude that considered the indigenous *Ayurveda* medicine as a system of Hindu blind beliefs and, accordingly, not credible, and hence, dependence on Western medicine was a must. Accordingly, Nehru jettisoned the burden of Hindu heritage and successive governments shunned it.

Further, some Indians held the philosophical belief that Western innovators were "pirates" of indigenous knowledge and genes with the aim of making themselves richer while keeping poorer nations poor.⁴⁸ Some Indians believe that the new patent regime is a perversion of the excellent Patents Act 1970 and the subversion of Indian national interests through the GATT treaties and condemn it as brazen betrayal of people's concerns committing the country to global corporate commands. This humiliating syndrome has been called "GATTastrophe" and Operation Recolonization and it is a shameful story of the

⁴⁵ The Patents (Amendment) Ordinance, 1994, THE GAZETTE OF INDIA, NO. 81 (Dec. 31, 1994). The 1994 Patents Ordinance amended the 1970 Patents Act which stipulated that applications claiming patent protection for pharmaceutical and agricultural chemical product inventions would be accepted but their handling would be deferred until January 1, 2005. The 1994 Ordinance lapsed on March 26, 1995 when Parliament failed to take up the matter within the deadline.

⁴⁶ Tomar, *supra* note 31, at 579, 581; *see also* Nadia Natasha Seeratan, *The Negative Impact of Intellectual Property Patent Rights On Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 387-388 (2001).

⁴⁷ *See* Long & D'Amato, *supra* note 39; Adelman & Baldia, *supra* note 18, at 518, 523; *see also* David Hurlbutt: *Fixing the Biodiversity Convention: Toward a Special Protocol for Related Intellectual Property*, 37 NAT. RESOURCES J. 379 (1994).

⁴⁸ *See, e.g.* Anil Agarwal & Sunita Narian, *Pirates in the Garden of India*, NEW SCIENTIST, Oct. 26, 1996, at 14; *see generally* Shayana Kadidal, *Subject Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371, 373 (1997) (for an excellent overview of the neem controversy and how it relates to § 102).

unfortunate surrender and political cover-up landing the nation in a situation where people have to battle for winning back Patent Self-rule, inside Parliament and through campaigns outside.⁴⁹

Others simply distrusted any action taken by multinational companies. They pointed to examples such as the native Indian plant *rauwolfina serpentina* used to make reserpine, an antihypertensive with \$260 million in American sales annually for which none of the profits flowed back to Bhaarat. These individuals would like money to flow without any effort of their own.

Philosophical differences over the issue of patenting life and Indian patent law which has historically forbidden ownership of agricultural and medicinal products fueled resistance to stronger patent laws.⁵⁰ Moreover, inasmuch as a general feeling of exploitation prevails in individuals in developing nations, genuine or erroneous, they are unlikely to reciprocate enforcement of intellectual property laws.⁵¹

As mentioned before, in 1994, Bhaarat promulgated the Patents Amendment Ordinance to Amend the Patents Act of 1970 to provide a means for the filing and handling of pharmaceutical or agricultural chemical products and for the grant of EMRs.⁵² From January 1, 1995, regardless of what Bhaarat did about eventual transition to product patents, Bhaarat should have accepted applications for product patents and granted EMRs for five years.⁵³ Upon Bhaarat's failure to do this, the American and European

⁴⁹ B. K. Keayla, *Patents Jurisprudence, Report of the People's Commission on Patent Laws for India*, Book Review by V. R. Krishna Iyer at <http://www.hindu.com/thehindu/br/2003/06/10/stories/2003061000100300.htm> (last visited August 17, 2004).

⁵⁰ See generally, Emily Marden, *The Neem Tree Patent: International Conflict Over the Commodification of Life*, 22 BOSTON COLL. INT'L & COM. L.R. 279, 286 (1999) (illustrating this belief in a dispute on U.S. Patent No. 5,124,349 to W.R. Grace & Co. on an extract of the neem tree, a culturally significant Indian resource containing azadirachtin, a powerful insecticide). In the wake of the Neem controversy, there were renewed discussions within India how the nation might reorder national patent protection to assume that traditional knowledge is granted national protection and not drained from the country.

⁵¹ See Kerri A. Kazak et al., *Status of Indian Patent Law*, 8 No. 2 J. PROPRIETARY RTS. 33 (1996). In previous years India has been cited as a "priority foreign country" by the Office of the U.S. Trade Representative because of losses to United States intellectual property holders. In 1994 and 1995, India was designated as a priority "watch list" country; cf. Douglas F. Greer, *The Case Against Patent Systems in Less-Developed Countries*, 8 J. INT'L L. & ECON. 223 (1973) (advocating that developing nations should weaken or eliminate their intellectual property laws). See generally 19 U.S.C. §2242 at 261 (1989-1990) (defining "priority foreign country" as a country whose acts, practices, or policies are the more onerous or egregious, and have the greatest adverse impact on the United States; and that are not entering into good faith negotiations or making significant progress in bilateral or multilateral negotiations to provide adequate and effective protection of intellectual property rights).

⁵² As required under Article 70.8 of the TRIPS Agreement, see TRIPS Agreement, *supra* note 6.

⁵³ See WTO REPORT OF THE PANEL, *India- Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Complaint by the European Communities and Their Member States, WTO WT/DS79/R, Aug. 28, 1998. The Patents Ordinance of 1994 lapsed in March 1995. Between January 1, 1995 and January 31, 1998, a total of 2,212 patent applications for pharmaceutical and agricultural chemical products were received and their review postponed.

Communities filed complaints with the WTO.⁵⁴ The United States, as complainant, alleged that Bhaarat failed to set up a “mailbox” system to receive patent applications.⁵⁵ Bhaarat lost this dispute and the resultant appeal and had to promulgate relevant legislation by April 1999.⁵⁶

Accordingly, Bhaarat passed the Patent (Amendment) Act in March 1999 to provide for Mailbox and the EMRs in accordance with the WTO obligations.⁵⁷ As per the Mailbox mechanism it is possible to file a product patent application in Bhaarat for inventions related to drugs or medicines. These applications will remain in a Mailbox until December 31, 2004.⁵⁸ In the interim, EMRs could be applied for, provided the case qualifies for the prescribed EMR eligibility criteria.⁵⁹

In Bhaarat, the EMRs are granted for 5 years when the following conditions are satisfied:⁶⁰

- 1) A patent application filed after January 1, 1995 in any WTO country.
- 2) Patent and marketing approval has been granted in the WTO country where the patent application was filed.
- 3) An application has been filed in the Mailbox in Bhaarat.
- 4) Marketing approval has been obtained in Bhaarat.

⁵⁴ See, e.g., *Id.*

⁵⁵ See *First Submission of the United States of America, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Complaint by the United States, March 6, 1997.

⁵⁶ *Who is Afraid of WTO, US and Disputes?* Rediff On the Net, available at <http://www.rediff.com/business/1998/dec/31debroy.htm> (Dec. 31, 1998).

⁵⁷ Patents (Amendment) Act 1999, (India).

⁵⁸ Patent applications for a pharmaceutical product applied for before January 1, 1995 will be rejected. Those applied for between January 1, 1995 and December 31, 2004 which are in the “mailbox” will be examined. Those applied for after January 1, 2005 will be examined in 2005. For example, patents applications for AZT were applied for before January 1, 1995 will be rejected. However, a patent application for a combination of AZT and 3TC (Combivir[®]) applied for between January 1, 1995 and December 31, 2004 could result in the granting of a patent after January 1, 2005.

⁵⁹ *Id.* § 24A(2).

⁶⁰ Pritesh Mehta, *WTO and Trade Related Intellectual Property Rights - An Indian Perspective*, at <http://www.indiainfoline.com/lega/feat/wtrr.html> (last visited January 23, 2004).

B. Doha Declaration

At the Fourth Ministerial Conference in Doha, Qatar, in November 2001, WTO members agreed to work on the implementation of the present agreements, as well as to launch new negotiations. The entire package is called the Doha Development Agenda (DDA). In a separate declaration, ministers stressed that it was important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines. This separate declaration on TRIPS and public health, called the Doha Declaration, is designed to respond to concerns about possible implications of the TRIPS Agreement on access to medicines.⁶¹

The Doha Declaration emphasizes that the TRIPS Agreement does not and should not prevent member governments from acting to protect public health. It affirms governments' right to use the agreement's flexibility in order to avoid any reluctance the governments may feel. The separate declaration clarifies the flexibility available, particularly with regard to compulsory licensing and parallel importing. The declaration also extends the deadline for least-developed countries to apply provisions on pharmaceutical patents until January 1, 2016.⁶² Bhaarat does not fall into the category of least-developed countries.

C. The Patents (Amendment) Act of 2002

Recognizing the above facts, Bhaarat has undertaken amendments to its patent laws to bring intellectual property laws in conformity with the TRIPS Agreement. The latest among those amendments is the Patents (Amendment) Act of 2002.

The Patents (Amendment) Act of 2002 brings the following significant changes into force:⁶³

⁶¹ Doha WTO Ministerial 2001, Ministerial Declaration, at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, at <http://www.who.int/medicines/library/par/who-edm-par-2002-3/doha-implications.doc> (last visited Jan. 23, 2004).

⁶² *Id.*

⁶³ Sushil Kumar, *Indian Patent Law - The Highlights of the Recent Amendments*, at http://www.pctfiling.com/article_show.asp?article_ID=152 (last visited January 23, 2004).

- The definition of "invention" is broadened to more closely conform to Article 27 of the TRIPS Agreement. "Invention" is defined to mean **a new product** or process involving an "inventive step" and "capable of industrial application." "Inventive step" is defined to mean features to make the invention non-obvious to persons skilled in the art.⁶⁴
- Additional exclusions from patentability have been added to Section 3 of the Patent Act. These exclusions include *inter alia* plants and animals in whole or any part thereof other than microorganisms but including seeds; mathematical or business methods, computer programs *per se* or algorithms; literary, dramatic, artistic works or other aesthetic creations, including cinematographs and television products; methods of performing a mental act or methods of playing a game; a presentation of information; topography of integrated circuits; and inventions which, in effect, are traditional knowledge.⁶⁵
- "Chemical process" has been redefined to include biochemical, biotechnological and microbiological processes.
- "Single Inventive Concept" has been incorporated in Section 10(5) of the Patents Act.⁶⁶
- The term of patents is extended to 20 years from the date of filing for all patents⁶⁷ granted after commencement of the Act.
- Patent applications will be published after 18 months from the priority date or the date of filing, whichever is earlier.⁶⁸
- A patent application will be examined only on the filing of a formal request by the Applicant or any interested person within 48 months of the filing date.

⁶⁴ The phrase "capable of industrial application" is defined to mean capable or being made or used by industry.

⁶⁵ This covers anything that has its origins in history. By that token, all Ayurvedic drugs will be protected.

⁶⁶ A claim or claims may either relate to a single invention or to a group of inventions linked so as to form a single inventive concept, which enables the applicant to avoid the filing of divisional applications.

⁶⁷ See Article 33, TRIPS Agreement. Prior to the 2002 Amendments, the patent term under Indian patent law was 14 years except for inventions claiming foods or drugs, where only limited term process patents of 7 years from filing were allowed. Patent applications will be published after 18 months from the priority date or the date of filing, whichever is earlier.

⁶⁸ Once the patent publishes in the Official Gazette, the patent term begins. Publication in the Official Gazette also marks the beginning of the opposition period, during which the public has four months to oppose a patent on statutory grounds. During this period the applicant enjoys the benefits of an issued patent. Oppositions are decided by the Controller of Patents.

- The time period to file the reply to the First Examination Report (FER) and put the application in order for acceptance is reduced to 12 months from the date of forwarding of the FER by the Indian Patent Office. The same is non-extendible.
- In a suit for infringement of a process patent, the court may direct the defendant to prove that the process employed by him or her is different from the patented process, provided the subject matter of the patent is a process for obtaining a new product, there is substantial likelihood that the identical product is made by the process and the patentee is unable through reasonable efforts to determine the process actually employed. However, the patentee must first prove that the product is identical to the product directly obtained by the patented process.
- With respect to biological material patents, a deposit of the biological material with a depository designated by the government of Bhaarat is required.
- Non-disclosure or wrong disclosure of source or geographical origin of a biological material used in the invention and anticipation of the invention through prior knowledge, oral or otherwise, within any local or indigenous community are additional grounds for opposition/revocation.

Therefore, under the 2002 Amendments, product patents will be allowed. Previously, only process patents were obtainable. However, for chemical compositions, provisions of § 3(e) and 5(b) were used to obtain product patents. Additionally, §107A is aimed at bringing the “Bolar Exception Provisions” to Indian patent law. Under this provision, an act of making, constructing, using or selling a patented invention solely for obtaining regulatory approval under the laws of Bhaarat or another country do not constitute an act of infringement.

At this juncture, it should be noted that a majority of pharmaceuticals sold in Bhaarat are outside the purview of the new product patent regime, since product patents will be granted only to those drugs that are patented after 1995. Indian manufacturers will continue to sell those grandfathered pharmaceuticals. The impact of product patents will be felt once new products patented after 1995 enter the domestic market, as the Indian companies will not be able to manufacture generic versions of the same. However, mechanisms exist, e.g., compulsory licensing and parallel importing, to enable the government to take

action to ensure availability of medicines to the population for any epidemics. That is there are legal tools in the Indian patent law to overcome patent monopolies if necessary. Further, under Article 27, a country may exclude an invention from patentability if exclusion is necessary to prevent commercial exploitation of that invention “to protect public order or morality, including to protect human, animal or plant life or health.”⁶⁹

D. Compulsory Licensing⁷⁰

The existing pharmaceutical industry in Bhaarat is in many ways a product of state regulations and interventions. The Indian government has regulated the pharmaceutical industry through *inter alia* price controls and license systems. Strict implementation of TRIPS compliant laws will result in expensive new drugs that will be available only to the rich, e.g., drugs for the treatment of diseases such as cancer and AIDS.⁷¹ Under such circumstances, countries like South Africa have invoked compulsory licensing and parallel importing available under the TRIPS Agreement and the Doha Declaration.⁷² Of course, even America needs and uses special provisions for extraordinary situations. For example, the Anthrax scare in America resulted in an agreement between the government and Bayer to provide the antibiotic drug Cipro[®] (ciprofloxacin) at lower prices.⁷³ In fact, even in America, such latest drugs are very expensive and, of course, new pharmaceuticals are more expensive compared to generic alternatives.⁷⁴

⁶⁹ TRIPS Agreement, *supra* note 6, Article 27(2). Additional circumstances under which product patents can be voided may include war, epidemics or antitrust violations by patent holders. One easily exploitable provision is “failure to work the patent.” Under this provision, a patent can be voided if the patent holder fails to make or import the product, or fails to sell it at prices affordable to the average citizen. In view of salaries, affordability is a low threshold.

⁷⁰ TRIPS Agreement, *supra* note 6, Article 31; *see also* B.K. Keayla, *TRIPS Patent System and Doha Declaration - Implementation Process by India*, at <http://www.patentmatics.com/pub2004/pub1b.doc> (last visited January 23, 2004). Compulsory licensing is when a legal authority grants a license without permission from the patent holder.

⁷¹ Lloyd Matowe, *Access to Essential Drugs in Developing Countries: A Lost Battle?*, 61 AMER. SOC. HEALTH-SYST. PHARM. 718, 721 (2004); *see, e.g.*, Ralph T. King, *Graces Patent on a Pesticide Enrages Indians*, WALL STREET JOURNAL, Sept. 13, 1995; VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 56 (South End Press 1997) (discussing how the price of neem has risen dramatically).

⁷² TRIPS Agreement, *supra* note 6; *see also* Okediji *supra* note 39; *Generic AIDS Drugs Offer New Lease of Life to South Africans, Importation of Generics Cuts Price in Half*, Joint Press Release MSF, TAC, Oxfam, available at <http://www.accessmed-msf.org/prod/publications.asp?scentid=2912002105937&contenttype= PARA&> (Jan. 29, 2002).

⁷³ HHS, *Bayer Agree to Cipro[®] Purchase*, at <http://www.cptech.org/ip/health/cl/cipro/dhhs10242001.html> (last visited March 18, 2004).

⁷⁴ *Anxiety Over Cost Of New AIDS Drug*, CBS NEWS, available at www.cbsnews.com (Mar. 13, 2003). . For example, the price tag for Fuzeon[®] is about \$20,000 a year in America. That is almost triple the cost of the most expensive treatment now available, and has

Broadly speaking, given certain stated eventualities, compulsory licensing is a TRIPS-compliant means to bypass patents, to enable the government to take suitable action to ensure accessibility and affordability of medicines to the population. Article 31 allows for private manufacturers to produce generics through “compulsory licensing” in cases of national emergency. Previously, under the TRIPS Agreement, production under compulsory licensing must be predominantly for the domestic market.⁷⁵ In August 2003, WTO member governments made changes that will facilitate importation of generic drugs by poorer countries under compulsory licensing when unable to manufacture the drugs themselves.⁷⁶

There are nine possibilities for structuring the grant of compulsory licenses arising from TRIPS Agreement and Paris Convention:⁷⁷

- (i) Voluntary licenses registered by the patent holder (this provision exists in a number of patent laws)
- (ii) Authorization for meeting the government requirements by the Government enterprises or the third parties authorized by the government⁷⁸
- (iii) Compulsory license abuse of patent rights by the patent holder⁷⁹
- (iv) Compulsory license for reason of unsuccessful attempt by an enterprise to obtain voluntary license directly from the patent holder⁸⁰
- (v) Authorization of license due to national emergency⁸¹

put Fuzeon[®]'s manufacturer, the Swiss drug giant Roche, on the defensive while heating up the debate over pharmaceutical companies' pricing and profit strategies for AIDS drugs. The main reason for such a high price tag is the complicated manufacturing process for Fuzeon,[®] requiring 44 ingredients and 106 process steps, more than four times the average.

⁷⁵ See generally Suresh Koshy, Note, *The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B. U. J. SCI & TECH. L. 4, 15 (1995) (suggesting that an artificially imposed low royalty ceiling on compulsory licenses contributes to the lack of protection for pharmaceutical patents).

⁷⁶ TRIPS Agreement, *supra* note 6, at Article 31; see World Trade Organization, *Decision Removes Final Patent Obstacle to Cheap Drug Imports*, WHO Report, November 10, 2003; technical report series.

⁷⁷ B.K. Keayla, *TRIPS Patent System and Doha Declaration - Implementation Process by India*, at <http://www.patentmatics.com/pub2004/pub1b.doc> (last visited January 23, 2004).

⁷⁸ TRIPS Agreement, *supra* note 6, Article 31, at paragraph 1.

⁷⁹ Paris Convention, Article 5; TRIPS Agreement, *supra* note 6, Article 8.

⁸⁰ TRIPS Agreement, *supra* note 6, Article 31(b).

- (vi) Authorization of license due to circumstances of extreme urgency⁸²
- (vii) Compulsory license in cases of public non-commercial use⁸³
- (viii) Compulsory license to remedy anti-competitive practices⁸⁴
- (ix) Second patent for an invention involving important technical advance of considerable economic significance over the existing patents⁸⁵

Under the Indian law, a party may request a compulsory license beginning three years from the date of issuance.⁸⁶ In addition, “parallel importing” or importing of competing generic goods from other countries, to provide cheaper access to necessary drugs (e.g., AIDS drugs) is also permitted.⁸⁷

The second amendment in 2002 incorporated national emergency, circumstances of extreme urgency, and public non-commercial use of a patented product as grounds for invoking compulsory license. However, there have been demands from domestic lobbies for a review of the grounds for compulsory licensing to broaden the grounds for invoking compulsory license and under easier practical terms than declaring a national emergency, a process that requires legislative and presidential assents. The proposed appellate tribunal under the second amendment can settle disputes when the patent controller’s decisions are questioned. However, there is a demand for an administrative committee to arbitrate disputes of economic significance.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.* at Article 31(k).

⁸⁵ *Id.* at Article 31(l).

⁸⁶ See generally Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349 (1993) (discussing compulsory licensing and the cap on patent royalties at 4% of the total wholesale cost of a shipment to the buyer).

⁸⁷ In simple terms, parallel importing is cross border trade in a product. Parallel importing involves the purchase of proprietary drugs from a third party in another country rather than from the patent holder, and allows countries to take advantage of the fact that the prices of drugs vary considerably from one country to another. The weakness of differential pricing include a reliance on company specific decisions at a given time.

In the Patent (Second Amendment) Act 2002, some of the above possibilities have neither been incorporated nor adequately provided. The framing of appropriate amendments compulsory licensing provisions in a proposed third amendment bill is under consideration.

E. The Proposed Third Amendment Act⁸⁸

The first and the second amendments in 1999 and 2002 did not make the Indian patent regime fully TRIPS-compliant. Additionally, although it is not required under TRIPS, Bhaarat has yet to implement so-called “pipeline” protection, which would extend patent status to products already under patent elsewhere when their subject matter first becomes available in Bhaarat. Hence, a third amendment is necessary before January 2005. Last year, the government initiated the process for the third amendment to the Patents Act of 1970 introducing the Patents Amendment Bill of 2003. The proposed third amendment would finalize and introduce a TRIPS-compliant product patents regime for food and pharmaceuticals and chemicals.⁸⁹ The “mailbox” applications, which number around 5000 will also be taken up for examination from January 1, 2005. The amendment would also introduce provisions that address domestic concerns and balance the concerns of national and public interest, especially those relating to Indian public health. To that end the government has planned to hold 15-20 interactive sessions in different cities.⁹⁰

There has been a demand that product patents be given for food and fine chemicals as well. The pharmaceutical research and development committee, headed by Dr. Mashalkar, the Director General of CSIR and Secretary to the Government of Bhaarat, in its report suggested to provide for New Chemical Entities (NCEs) and New Medicinal Entities (MMEs) to be patentable.⁹¹ The government must take notice

⁸⁸ Comparative Statement of Amended Patents Act 1970 (after 199 and 2002 amendments) and suggested provisions for Patents (Third Amendment) Bill, at <http://www.patentmatics.com/pub2004/pub1a.doc>; Govt. Trade Bodies Discuss Patent Act Amendments Add to Clippings, TIMES NEWS NETWORK, available at <http://economictimes.indiatimes.com/articleshow/115545.cms> (Aug. 6, 2003).

⁸⁹ It also incorporated the safeguards provided in the Doha Declaration and incorporates provisions for protection of biodiversity and traditional knowledge.

⁹⁰ *Supra* note 88.

⁹¹ Gina S. Krishnan, *Getting India's Drug Act Together: An Exclusive Look at the Mashelkar Committee's Formula for Revamping India's Pharma Regulatory System*, at <http://www.businessworldindia.com/Dec0803/indepth03.asp> (last visited Jan. 23, 2004).

of this and other proposals from the domestic lobbies as well as multinational corporations and has attempted to satisfy all in the proposed third amendment.

Some have advocated postponement of the third amendment another 10 years until 2016 for Bhaarat to become fully TRIPS compliant, a concession allowed only to least developed countries and not to developing nations like Bhaarat. However, any delay in meeting the 2005 deadline will invite retaliatory action under the WTO disputes mechanism. If Bhaarat defaults on its obligations under TRIPS there will be no mechanism to examine and dispose of the Mailbox applications. Not only will this aggravate the consequences of any default but it will also result in an erosion of Bhaarat's credibility in the international community.

III. BHAARAT'S ROLE IN THE GLOBAL PHARMACEUTICAL MARKETPLACE POST 2005

A. Innovation or imitation- the case for a TRIPS Compliant Patent Regime

1) Economic Realities of TRIPS Compliance:

Post 2005, as Bhaarat embraces stronger intellectual property rights, Bhaarat stands to gain from greater direct investment by multinational pharmaceutical companies, new focuses for Indian pharmaceutical companies in brand development, and an expansion of Bhaarat's role in the global marketplace, especially in research trials, and production.

As a result of previous Indian patent policies and the liberalization of Indian economy that began about a decade and a half ago, Bhaarat has emerged as a powerful and independent economy, no longer requiring extensive protectionist patent laws. In fact, today such a patent system is detrimental to the indigenous pharmaceutical industry.

One negative aspect of the protectionist 1970 patent system was demotivation of the pharmaceutical industry to conduct R&D. The so-called "free-riding" allowed the Indian Pharmaceutical

industry to devote little investment in developing new drugs, with scientific research mainly limited to government institutes and agencies.

On the other hand, strict patent protection will significantly increase the price of new patented drugs such as AIDS drugs for the Indian people. A new AIDS drug patented in January 2, 2005 will not be able to be copied by Indian manufacturers using a different process.⁹² However, under TRIPS, Bhaarat does not have to provide actual patent protection for such new drugs until 2006 and local prices usually depend on the purchasing power of the population and the competition.⁹³ If Bhaarat grants a patent for a mailbox application for which generics versions are marketed via a new process, the question also exists as to whether or not existing generic versions of such products will be allowed to remain on the Indian market.

Recently, Indian generic makers have offered 4% of their turnover as royalty to the drugs' originator. The move is designed to offset the onslaught of litigation likely to result in 2005 under the new patent regime.⁹⁴ There are reports global drug makers are planning an onslaught of lawsuits against Indian generic makers to shut down the entire industry as soon as they obtain patents for their drugs in Bhaarat.

Fortunately, most of the essential drugs are not under patent protection. Less than 10% of Bhaarat's list of essential drugs are covered by patents worldwide. Moreover, only one drug in 250 in the WTO's list of essential drugs is currently under patent. Further, a large number of off-patent substitutes are available to patients for patented drugs.⁹⁵ In addition, between 2005-2010, patents of many widely used drugs will expire, e.g., in 2005, the drugs going off patent include glimepiride, ondansetron, clarithromycin,

⁹² See Stephen Barnes, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 2003; see also UNAIDS, Report on the Global HIV/AIDS Epidemic 2002, 190, 194, 198, available at <http://www.unaids.org/barcelona/presskit/barcelonareport/table.html> (last visited Jan. 23, 2004). As of 2002 about 2.9 percent of all men in Manhattan were HIV infected and 4.2 percent of men ages 40 to 49 in all five boroughs of New York City were infected. About 2.5 percent of all black men in the city were infected; see, e.g., *Nationwide HIV Reporting to Bring Trends Into Focus*, NEW YORK TIMES, Feb. 17, 2004. The AIDS epidemic has affected India, but thankfully not as devastatingly as in South Africa. The 0.8% adult rate of AIDS in India approximates the 0.6% rate in the U.S., whereas the rate in South Africa is a devastating 20%.

⁹³ Adelman & Baldia, *supra* note 17, at 507, 531.

⁹⁴ Anon, *Indian Generic Makers Offer 4% of Turnover in Royalty Under New Patent Regime*, IP LAW BULLET, July 27, 2004.

fluconazole, pamiotronate disodium, zidovudine, pravastatin sodium, pranlukasf, azithomycin, paroxetine, simvastalin and sertraline. This basically implies a huge potential in national and international generic markets. Accordingly, fears that a new product patent regime would escalate drug prices, displace the local pharmaceutical industry, result in re-colonization of Bhaarat by multinational corporations, increase drug imports, and wipe out small farmers are gross exaggerations.⁹⁶

The pharmaceutical industry IPR situation parallels other Indian industries. For example, the Indian "Hi-tech" companies in Bangalore, the so-called Silicon Valley of Bhaarat, including the famous Infosys, do not develop any technologies or products. They provide development services and have engineers who specialize in programming languages rather than in technologies. Their chief resource is the huge mass of low-cost labor. Such companies do not seek patents and IPRs. These companies start with zero risk and do not bet on their ideas or inventions.⁹⁷ Nor do they pose a real threat to Silicon Valley companies that have inventions and products that are protected by patents. The situation can be changed only, if the new product patent regime is implemented with vigor, so that Indians also develop new technologies and products to compete.

America has been urging developing nations to join the global economy. Consequently, millions of skilled workers have joined the world labor force in the past decade. As previously mentioned, offshore outsourcing is growing in America involving the migration of jobs, ranging from call center operators to computer programmers, to lower-cost countries like Bhaarat. The resilient American economy has adapted to such unsettling new waves of competition in the past. The chairman of President Bush's Council of Economic Advisers, N. Gregory Mankiw recently said it was "just a new way of doing international trade"

⁹⁵ Muhammed Ashar Khan, *Opinion Swells in Support of Government Patents*, Rediff On The Net Business, at <http://www.rediff.com/199/feb/01patent.htm> (last visited Jan. 23, 2004).

⁹⁶ See Suresh Koshy, *The Effects of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1B.U.J.SCI. & TECH. L. 4, 47-49 (1995); see also Adelman & Baldia, *supra* note 17; Modifications to the Drug Policy of 1986, 2 (1994) (India) amending the Drug Policy Control Order of 1987 which established Category I pharmaceuticals, deemed necessary for national health programs and Category II pharmaceuticals, deemed Essential Drugs, and creating separate price markup ceilings for each category, termed Maximum Allowable Post Manufacturing Expenses. The 1994 Modifications decreased the number of drugs subject to these price controls. *But cf.* Lakshmi Sarma, *Biopiracy: Twentieth Century Imperialism in the Forms of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107, 140 (1999) (discussing a detrimental effect of the TRIPS Agreement on lesser developed countries); see generally Keayla, *supra* note 49.

⁹⁷ *Bangalore: Silicon Valley or Coolie Valley?* at <http://us.rediff.com/money/2004/mar/03guest1.htm> (last visited Mar. 4, 2004).

and "a good thing" that would make the American economy more efficient and would free American workers to eventually get better jobs.⁹⁸

In addition, Bhaarat, who had made limited commitments at the end of Uruguay Round in some sectors like engineering, computer-related, hospital and tourism, has revised them now. The Cabinet Committee of WTO headed by the Prime Minister of Bhaarat had approved the broad strategy for service negotiations at the WTO in June 2003. Bhaarat has submitted its offers at the World Trade Organization to open up various services including health, telecom, engineering, construction, bookkeeping and accounting, travel and tourism, maritime and computer-related services.⁹⁹

However, these offers may be in jeopardy due to the recent change of guard from a secular right wing alliance to communist propped left wing alliance, which has been traditionally anti-business and free market. In fact, recent antibusiness statements by Sitaram Yechuri, a communist leader, single-handedly crashed the Indian stock market to a record 129-year low on May 17, 2004, thereby wiping out billions of investment dollars.¹⁰⁰ It would be unwise and detrimental to both countries to hide behind protectionist and populist measures.

In the election year 2004 outsourcing has become an issue in America. On February 16, 2004, the then Indian Commerce Minister, Mr. Jaitley, held an hour-long meeting with Mr. Zoellick, American Trade Representative. Mr. Jaitley said that it was strange that, on the one hand, people were talking about opening up of markets and, on the other hand, banning outsourcing, referring to a ban proposed by

⁹⁸ *Jobs Lost Abroad: Host of New Causes for an Old Problem*, NEW YORK TIMES, available at <http://www.nytimes.com/2004/02/15/business/15JOBS.html?hp=&pagewanted=print&position=> (Feb. 15, 2004).

⁹⁹ *India Tables Offers at WTO*, a report by nrlinks, at <http://www.nrlinks.com/frame.asp?url=http%3a%2f%2fin.rediff.com%2fmoney%2f2003%2fdec%2f30wto.htm> (visited Feb. 18, 2004).

¹⁰⁰ Saritha Rai and Amy Waldman, *Stocks Plunge in India Over Fears of New Government*, NEW YORK TIMES, available at <http://www.nytimes.com/2004/05/17/business/worldbusiness/17CND-INDI.html> (May 17, 2004); see generally Dan Morrison, *Surprise Change at the Top*, NEWSDAY, May 24, 2004, at A32-33.

America. Referring to the American demands on opening up markets in agriculture, he said the sector here was fragile, as it was not subsidized as in America. Mr. Zoellick later tied opening up of the services and agriculture sectors of Bhaarat with lifting the ban on American outsourcing.¹⁰¹ Despite the popular fears, globalization has been creating jobs in America also.¹⁰²

After January 2005, America will have new opportunities, fears and challenges in Bhaarat. America will face new competition for jobs from Bhaarat in yet another area, the biotechnology and pharmaceutical and chemical industry. An Indian computer programmer making \$20,000 a year or less can replace an American programmer making \$80,000 a year or more.¹⁰³ Similar replacement is possible in the biotechnology, chemical, and pharmaceutical industry as well. Forrester Research predicted in late 2002 that by 2015 America would move offshore 3.3 million service jobs, a miniscule in the American labor force that has more than 130 million workers.¹⁰⁴ Yet, this will be a great opportunity for both Indian and American industries, if only a strong TRIPS compliant product patent regime is established. America will no longer have a lock on the biotechnology, chemical and pharmaceutical industry. In fact, even the legal work is already being outsourced to Bhaarat and many American law firms are setting up their back offices in Bhaarat to take advantage of cheap labor.¹⁰⁵ Reverse outsourcing from Indian pharmaceutical companies will get a big boost after January 2005, due to the new patent regime.

¹⁰¹ Sushma Ramachandran, *India, U.S. Clash on Outsourcing Issue*, THE HINDU, at <http://www.hindu.com/2004/02/17/stories/2004021705660100.htm> (Feb 16, 2004). The G-20 has been a thorn in the flesh of the E.U. and the U.S. ever since it was formed last year in the run-up to the Cancun ministerial conference of the WTO. The group was constituted by developing countries as a reaction to the proposals submitted by the E.U. and the U.S. on reduction of their enormous agricultural subsidies. See Sushma Ramachandran: *Bid to Break G-20*, THE HINDU, at <http://www.hindu.com/2004/04/18/stories/2004041805640100.htm> (April 18, 2004).

¹⁰² *More Work is Outsourced to U.S. Than Away From It, Data Show*; THE WALL STREET JOURNAL, available at <http://www.sulekha.com/hoppercomments.asp?cid=329514> (March 15, 2004).

¹⁰³ *Supra* note 100.

¹⁰⁴ *Id.*

¹⁰⁴ See WALL STREET JOURNAL at <http://online.wsj.com/article/0,,SB107919804320754591-search,00.html?collection=autowire%2F30day&vq1_string=Outsourcing%3Cin%3E%28a+rticle%2Dbody%29>>, (visited Mar. 15, 2004).

¹⁰⁵ *Id.*

In America the costs of discovering and bringing a new drug to market was estimated to be close to \$1 billion in 2003.¹⁰⁶ Further, it takes at least 15 years to bring a new drug to market, involving rigorous FDA procedures. Despite the steadily increasing investments made in R&D of new drugs, the total number of drugs introduced worldwide is falling.¹⁰⁷

The need to reduce the total cost of drug development has resulted in the increasing trend toward outsourcing research to specialized Contract Research Organizations as well as conducting clinical trials in countries like Bhaarat, where costs are one seventh of that in America or Europe. Indian hospital care is on a par with London or New York with high quality healthcare. In addition, infectious diseases are common in Bhaarat, providing researchers with a supply of ready patients. Accordingly, the Indian companies will also have opportunities in contract manufacturing and contract research and co-marketing.¹⁰⁸

Accompanying stronger patent protection there will also be greater incentives for collaborative research and global alliances. Bhaarat is currently focusing on attracting multinational pharmaceutical companies to choose Bhaarat as the preferred hub for their global R&D and manufacturing operations.

Further, R&D initiatives undertaken by Indian pharmaceutical companies could see the launch of innovative “blockbuster” drugs by these companies. Product patent protection is important for both multinational corporations as well as Indian pharmaceutical companies such as Hyderabad-based Dr. Reddy's Laboratories and Delhi-based Ranbaxy Laboratories that are increasingly becoming multinational corporations. Indian pharmaceutical corporations need protection for pharmaceutical products to recover the costs incurred in lengthy and expensive R&D that is essential for new product development. Moreover,

¹⁰⁶ DiMasi JA, Harsen RW, Gatowski HG, *The Price of Innovation, New Estimates of Drug Development Costs*. J HEALTH ECON 1-35 (2003); *Time Doubles the Costs of Drug Discovery and Development*, *NeuroRX*, 3, available at <http://www.asent.org/newsletter/2003/july/> (July 1, 2003).

¹⁰⁷ Andrejus Koralkovas, *Cost and Place of Development of Drugs*, in ESSENTIALS OF MEDICINAL CHEMISTRY 55-58 (John Wiley and Sons Inc. ed.,1988).

¹⁰⁸ The FDA regularly inspects and approves Indian pharmaceutical manufacturing facilities.

the potential of the global generics market, given the fact that majority of the blockbuster drugs are expected to go off patent soon, is also a good opportunity for domestic pharmaceutical companies.¹⁰⁹

On May 4, 2004, America placed Bhaarat on the Priority Watch List for lax IP laws along with 14 other countries.¹¹⁰ The lack of product patent protection was specifically cited. The 301 report also states that Bhaarat should fulfill obligations to protect confidential test data submitted by innovative pharmaceutical companies for market approval.¹¹¹ Bhaarat has yet to implement the TRIPS obligation to protect confidential test data submitted by pharmaceutical firms. The report added that there was large scale counterfeiting of pharmaceuticals which were exported from Bhaarat to other countries. America intends to approach the WTO, if countries such as Bhaarat do not put in place TRIPS compliant IPR mechanisms.

As long as Bhaarat avoids product patent protection and infrastructure to enforce the relevant patent laws, there will not be any incentive for either Indian or foreign multinational companies to conduct R&D in Bhaarat to provide new life saving drugs for Indians. Without R&D in developing new drugs for the unique and specific health needs of Bhaarat, Indians will remain at the mercy of foreign multinationals and dependant on the Robin Hood piracy methods of the Indian pharmaceutical industry. According to industry experts like Dr. Anjireddy Kallam, the chairman of Dr. Reddy's Laboratories, Indian firms need product patent protection to encourage research for development of inexpensive drugs tailored to the Indian disease profile.¹¹²

A country with product patent protection will reap the benefits of increased foreign investment in R&D and production of new pharmaceuticals.¹¹³ A single example will drive home the point. Pfizer has not

¹⁰⁹ India acceded to the Patent Cooperation Treaty effective December 7, 1998.

¹¹⁰ UNITED STATES TRADE REPRESENTATIVE'S 2004 SPECIAL 301 REPORT, May 4, 2004.

¹¹¹ Also known as data exclusivity regulations.

¹¹² Khan, *supra* note 94. The Council of Scientific and Industrial Research is a government body established in 1942 in order to strengthen R&D in India. It has about 40 facilities spread throughout the country many of which are involved in pharmaceutical R&D.

¹¹³ Adelman & Baldia, *supra* note 17.

introduced any new drug in Bhaarat in the past two decades for fear of copying (process patent). However, many members of the Indian Pharmaceutical Alliance, a powerful industry body which works closely with the government on policy issues, support stronger IPRs but advocate either extending the deadline for TRIPS compliance to 2016, that for least developed countries and maintaining an effective compulsory licensing regime.

In 1995, 235,440 patent applications were filed in America whereas the number in Bhaarat with a population four times larger was only 6,566, approximately 36 times lower.¹¹⁴ A comparison with Kenya, a third world country, is not heartening either. Kenya, 32 times smaller than Bhaarat with a population of only 32 million,¹¹⁵ saw four times more patent applications in 1995.¹¹⁶ America's preeminence in science and technology is, without a doubt, due to a large extent to its patent regime. Indian realization of the potential of its individual citizens to unleash their creativity via providing protection to their products and inventions is overdue.¹¹⁷

Furthermore, lack of product patent protection limits Bhaarat's ability to exploit its own successes. Bhaarat has developed about 25,000 varieties of crops ranging from cereals to vegetables. Indian successes include 300 varieties of wheat, 200 varieties of rice, and hybrid varieties of cotton, millet, castor, pea and *arhar*. Currently, these are not protected due to a lack of product patents in Bhaarat. As a result, other countries can exploit these varieties including obtaining patents in other countries, e.g., turmeric, *neem* and Basmati.¹¹⁸

¹¹⁴ Kaushik Basu, *Whither India? The Prospect of Prosperity in Romilla Thapar, in INDIA ANOTHER MILLENNIUM?* (Penguin Books India (P) Ltd. 2000).

¹¹⁵ See, e.g., <http://www.cia.gov/cia/publications/factbook/geos/ke.html#People> (last visited Jan. 23, 2004).

¹¹⁶ Basu, *supra* note 113.

¹¹⁷ Of course, India must take special measures to increase the literacy of its population, without which the fruits of the new patent regime and privatization will not reach everybody and there will be an increase in poverty among the uneducated masses. India lags behind China and many third world countries in this aspect.

¹¹⁸ Khan, *supra* note 94; cf. Shubha Ghosh, *Traditional Knowledge, Patents, and the New Mercantilism (Part II)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 885 (2003) (describing the moral rights position for traditional knowledge holders and their autonomy in deciding how knowledge gets used).

Despite the Indian commitment to make IPRs TRIPS compliant by 2005, there is a debate among those with different interests in Bhaarat about the effect of changes to patent protection and IPRs in the ways required under the TRIPS Agreement. The present authors counter that anti-patent arguments made by eminent environmentalists such as Dr. Vandana Shiva are, to a large extent, outdated. Dr. Shiva refers to patenting genetic sources as "biopiracy" and "a silent takeover of biological resources".¹¹⁹ To add to the Indian leftist fears, an editorial in *The New York Times*, on January 18, 2005 in an attempt to scare Indians, proclaims, "[h]eavily influenced by multinational and Indian drug makers eager to sell patented medicines to Bhaarat's huge middle class, the decree is so tilted toward the pharmaceutical industry that it does not even take advantage of rights countries enjoy under the W.T.O. to protect public health."¹²⁰ Such anti-patent arguments¹²¹ have lost appeal as an increasing number of people realize that despite the inequality of bargaining power inherent in TRIPS, there is an imperative need for Bhaarat to accept its obligations under TRIPS in order to profit from the tremendous trade benefits available.¹²²

2) Alternative Medicine

In addition, the Indian argument against patenting new uses to ancient knowledge is flawed at least in one other aspect. Indians have had this knowledge for thousands of years through ancient texts of *Ayurveda*. So far they have not used that knowledge to help the world at large by supplying inexpensive drugs for the third world in a large scale. However, some Indians view any new use of the ancient knowledge, or identification of active principles from these ancient medicines under the patent protection, as plunder of ancient Indian knowledge by the West.¹²³ This resistance to the so-called "20-year monopoly," while continuing to have thousands of years of monopoly without even attempting to provide the benefits of the knowledge to the entire world cannot be rationalized.

¹¹⁹ VANDANA SHIVA, *THE PLUNDER OF NATURE AND KNOWLEDGE* (South End Press 1997).

¹²⁰ See India's Choice, <http://www.nytimes.com/2005/01/18/opinion/18tues2.html?ex=1106974800&en=45afebf8bae5c16a&ei=5070&8br> (last visited January 18, 2005).

¹²¹ Joint Action Committee Against Amendment of the Indian Patents Act Declaration, available at: <http://www.cptech.org/ip/health/c/india/ngodeclaration12292004.html> (last visited January 18, 2005).

¹²² Meetali Jain, *Global Trade and the New Millennium: Defining the Scope of Intellectual Property Protection of Plant Genetic Resources and Traditional Knowledge in India*, 22 *HASTINGS INT'L & COMP L. REV.* 777, 791-792 (1999).

¹²³ See also, <http://www.vshiva.net/archives/biopiracy/pil.htm> (last visited Feb. 15, 2004).

The fears are not only exaggerations, but also baseless, especially in medicine and healthcare, because Bhaarat has a traditional knowledge of health and medicine, known as *Yoga*¹²⁴ and *Ayurveda*¹²⁵ respectively, having a history of more than 5,000 years. In addition, Bhaarat is also endowed with Islamic and Arabic traditional *Unani* medicine and European homeopathic medicine. The claims that these Indian traditional systems work wonders,¹²⁶ are being tested in America and India. Accordingly, even if the new medicines developed by the Western modern medicine turn out to be very expensive and not affordable to the Indian poor, thousands of years of time-tested and invaluable Indian healthcare products should come to their rescue. For example, an Indian, who cannot afford to buy a statin cholesterol lowering agent, can obtain relief with an *Ayurvedic* medicine such as *guggulu*¹²⁷ under the strict supervision of an *Ayurvedic* practitioner and following the *Yoga* and *Ayurvedic* principles that must be followed with the use of

¹²⁴ Yoga is an ancient Indian discipline and method of living. Sage Patanjali laid down the principles of Yoga around 2nd century BC. The Bhagavad Gita (the Divine Song) of Lord Krishna contains yoga concepts to help seekers perform one's duty. The discipline of Yoga enables its followers to meet the challenges of life and move into a state of peace and harmony. According to the National Institutes of Health, when people actively seek to reduce the stress in their lives by quieting the mind, the body often works to heal itself. In this sense, yoga can be seen not only as a way to get into shape on several levels, but also as a tool for self-healing. There are numerous ways to work on the physical fitness. Few, however, bring as many benefits to the body, mind and spirit as yoga. *See also*, Christen Bowles, *Into the West: Yoga Outlasts the Exercise Fads*, TODAY'S CHEMIST AT WORK, at 31-33, Sept. 2002; There are several types of yoga, including *hatha yoga*, *karma yoga*, *bhakti yoga* and *raja yoga*. These types vary in the proportions of the eight branches. In America and Europe, *hatha yoga* is commonly practiced, including *pranayama* and *asana* <http://www.intelihealth.com/IH/ih/H/WSIH000/8513/34968/358876.html?d=dmContent>. *Yoga: Moving and Breathing Your Way to Relaxation*, at <http://www.mayoclinic.com/invoke.cfm?id=CM00004> (last visited Mar. 4, 2004).

¹²⁵ *Ayurveda* is the extraordinary mind-body medicine of India with its great *yogic* spiritual tradition, a tradition, and a tremendous resource for bringing wholeness to all levels of our existence. It is one of the worlds oldest and most complete systems of natural healing, containing great wisdom for all humanity. *See also* <http://www.floridavediccollege.edu/ayurveda/history.htm> (last visited Mar. 4, 2004). *Ayurveda* is a completely natural way of obtaining health, harmony, and happiness. *Ayurvedic* principles are known to have influenced the development of Chinese, Arabic, Greek, and Roman medicine. More recently, Western medicine has also adopted *Ayurvedic* concepts and therapies. India, a society that has thousands of years of monopoly over *Ayurveda* - one of the oldest and effective systems of medicines in the world - need not worry about a petty 20-year monopoly over a new product, especially when America is increasingly looking for alternative medicines.

¹²⁶ An increasing number of clinical studies are demonstrating efficacy of *Ayurvedic* medicine in America, despite Indian apathy and disinterest. Such efficacious *Ayurvedic* medicine include *Terminalia arjuna*, *Zingiber officinale* (ginger), *Prunus amygdalus*, *ashwagandha*, *Boswellia serrata*, *Thymus vulgaris*, *Coccinia indica*, *Curumina longa* (turmeric) etc. *See also*, Burton Goldberg, *Ayurvedic Medicine*, in ALTERNATIVE THERAPIES 86-93 (2002). *Ayurvedic* Institutes and hospitals are growing in America. www.ayurvedicscience.com; www.ayurveda.com; www.theraj.com; www.sharp.com; and <http://www.lancasterhealth.com/>. It should also be noted that the American Congress established the Office of Alternative Medicine in 1992 and the National Center for Complementary and Alternative Medicine (NCCAM) in 1999. The funding appropriated by Congress for NCCAM for fiscal year 2004 is \$117.7 million and the estimated funding for the year 2005 is \$121.1 million. The National Center for Complementary and Alternative Medicine (NCCAM) is one of the 27 institutes and centers that make up the National Institutes of Health (NIH). The NIH is one of eight agencies under the Public Health Service (PHS) in the Department of Health and Human Services (DHHS). NCCAM is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training complementary and alternative medicine (CAM) researchers, and disseminating authoritative information to the public and professionals. *See also* <http://nccam.nci.nih.gov/about/appropriations/> (last visited Mar. 4, 2004); Rekha Ramani, Note, *Market Realities v. Indigenous Equities*, 26 BKLYN. J. INT'L L. 1147 (2001).

¹²⁷ Karuparthy and Vepachedu, *Guggulipid and Cholesterol Levels*, *JAMA*, 290: 2800-2801 (2003), available at <http://jama.ama-assn.org/cgi/content/full/290/21/2800-a>.

Ayurvedic medications. Such *Ayurvedic* alternatives can be found for, almost all, expensive Western medications.

3) Unique Indian Health Needs

Moreover, the Western pharmaceutical industry has minimal interest in diseases such as malaria, leprosy and tuberculosis that plague India. As a result, there is no "free ride" available for Indians in this area.¹²⁸ To the extent that Bhaarat has special needs that are not as acutely felt in the West, technological development that affects such needs will not occur. Lack of product patent protection does not help the local industry in such an endeavor. Thus, Bhaarat has been paying a stiff price for the absence of an effective patent system.¹²⁹ Accordingly, the Indian drug industry and the Indian government no longer have an excuse for any "free ride", and must invest in research related to unique Indian problems and develop drugs.

4) Global Competition

The pharmaceutical industry worldwide devotes a great amount of its resources for R&D. In America, the pharmaceutical industry spent 18.5% of total 2001 sales toward R&D, versus the approximately 4% for all American industries.¹³⁰ Bhaarat must catch up with the investment in R&D to be competitive in the global economy. Currently, the Indian pharmaceutical industry's R&D spending is a paltry 1.8% of the total turnover.¹³¹ This low investment in R&D is reflective of the "free ride" and lack of product patent protection, which hinders Indian R&D. Indian pharmaceutical companies need product patent protection to encourage drug development research for both domestic and lucrative Western markets.

¹²⁸ *India Claims Herbal Malaria Cure*, BBC NEWS, available at http://news.bbc.co.uk/1/hi/world/south_asia/988316.stm (Oct. 24, 2000). In India, more people die of malaria than of AIDS. The World Health Organization estimates one million people die from malaria annually in India.

¹²⁹ Adelman & Baldia, *supra* note 17, at 507, 511.

¹³⁰ Stephen Barnes, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, (2003).

¹³¹ Muhammed Ashar Khan, *Opinion swells in support of government patents*, Rediff On The Net Business, at <http://www.rediff.com/199/feb/01patent.htm> (last visited Jan. 23, 2004).

The above possibilities would foster a competitive environment for the availability of drugs and pharmaceuticals in the country, a potential market of over one billion consumers. Patent law changes in 2005 could consign smaller, weaker Indian pharmaceutical manufacturers to bankruptcy but for the successful firms, the American healthcare system's need for less expensive generic drugs presents a great opportunity. Unlike the past, when American consumers would not accept a product made in India, consumers are willing to obtain medication cross-border and via mail order to avoid higher prices.

There has been a rise in foreign direct investment into Bhaarat in 2002 despite falls in foreign direct investment across the world.¹³² IPRs reduce uncertainty for multinational foreign pharmaceutical companies which plan to enter the Indian market.

Another anticipated consequence of strengthening patent protection to be TRIPS compliant is job displacement from developed countries to India, due to the availability of competitive scientific talent. Offshore outsourcing to lower cost countries like India, a new phenomenon that involves the migration of jobs, ranging from call center operators to computer programmers, is growing.¹³³ In the future, similar job movement from America to Bhaarat will occur in the pharmaceutical sector as well.

B. Challenges to New IP Laws in the Indian Union

India, being the largest and modern democracy in the world, faces several challenges in implementing the international laws- including the need to create intellectual property legislation that is both a sword and a shield. The challenges are at least threefold. The first challenge is to pass new pieces of legislation through the Parliament. As a thriving democracy with a multiparty system, where political coalitions are the order of the day, it is a daunting task to legislate any laws that are perceived as anti-people or anti-poor. Secondly, even if the laws are promulgated through the parliamentary process, they could be challenged on various Constitutional or other grounds in the Supreme Court. Thirdly, after

¹³² UNCTAD's WORLD INVESTMENT REPORT 2003.

¹³³ *Jobs Lost Abroad: Host of New Causes for an Old Problem*, NEW YORK TIMES, available at <http://www.nytimes.com/2004/02/15/business/15JOBS.html?hp=&pagewanted=print&position=> (Feb. 15, 2004).

surviving the above challenges, the laws would be toothless and useless, if not supported by an efficient system to implement the laws without corruption¹³⁴, to the fullest extent of the law.

A decade ago, there were apprehensions that medicines would have to be purchased in dollars under the TRIPS Agreement Compliant Patent Regime. Referring to that debate, last year the Indian commerce and industry minister Mr. Arun Jaitley stated: “Let alone having to pay in dollars, Bhaarat is getting ready to supply quality drugs to the rest of the world, at prices equivalent in rupees. This is a significant change that has taken place in the last decade. With our large knowledge base and propensity for research, why should we be on the back-foot as far as IPR protection is concerned?”¹³⁵

The Indian government has recently started awarding EMRs on some pharmaceuticals as a precursor to patents. The first and recent grant of an EMR to Novartis for its anti-cancer drug 'Glivec' has reinstated faith in government's commitment towards the patent regime.¹³⁶ However, domestic drug manufacturers opposed the EMR grant on technical and legal grounds. Thus, granting of the EMR has silenced those who might argue that the government is not serious about implementation of product patents post 2005. Nevertheless, the opposition that the EMR approval has received from domestic pharmaceutical industry indicates that bringing a third amendment to The Patent Act, 1970 and its implementation will be easier said than done. For now, Bhaarat has promulgated an ordinance¹³⁷ to comply with TRIPs and delayed passage of the required legislation in the Parliament.

¹³⁴ A household survey released by Transparency International on 17 December 2002, reported high levels of corruption in public institutions in South Asia. Of the seven major public institutions, the police emerged as the most corrupt in all five countries surveyed (Bangladesh, India, Nepal, Pakistan and Sri Lanka). The judiciary was identified as the second most corrupt area in all countries except Pakistan, where land administration and the tax authorities were identified as the second and third most corrupt areas respectively. Land administration figures prominently in the list of the most corrupt sectors in four out of the five countries. The TI report identifies high levels of corruption encountered by citizens attempting to access seven basic public services, at <http://www.transparency.org/surveys/index.html>.

¹³⁵ *Govt. Trade Bodies Discuss Patent Act Amendments Add to Clippings*, TIMES NEWS NETWORK, available at <http://economictimes.indiatimes.com/articleshow/115545.cms> (Aug. 6, 2003).

¹³⁶ *Should Phase I Trials be Permitted in India? - Debate Continues*, PHARMA NEWS, at <http://www.nishithdesai.com/Pharma-update/Pharma-update-Nov15-2003.htm> (visited Nov. 15, 2003).

¹³⁷ The Patents (Amendment) Ordinance, December 2004 available at: <http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf> (last visited January 27, 2005).

1. The Indian Constitution and the Judiciary

Bhaarat is a democratic Republic and the Constitution of Bhaarat is the supreme law of the land. Similar to America, the Indian constitution guarantees certain basic rights even to foreigners. For the enforcement of these rights, the High Courts and the Supreme Court are empowered to issue writs. Courts can invalidate any law enacted by the State Legislature or the Parliament that infringes fundamental rights. Arbitrary acts by the Government or its agencies or other authorities are liable to be quashed if challenged in Courts by the aggrieved party. Unlike other constitutions, the Indian constitution functions as a political as well as a financial document. It lays down the legal rules relating to various aspects of finance, trade commerce and business. All other laws, rules and regulations, are subject to the provisions of the Constitution. However, the Indian Parliament is supreme and the Indian Constitution can be amended, as in America.¹³⁸

The constitutional validity of the patents (Amendment) Act of 1999 was challenged in the Supreme Court by a public interest litigation (PIL) petition alleging it was against the public interest, public health and national interest.¹³⁹ The PIL was filed by five organizations - the Research Foundation for Science, Technology and Ecology (RFSTE), the Lok Shakti Abhiyan, the Bharatiya Kisan Union, the People's Union for Civil Liberties (PUCL) and the Azadi Bachao Andolan. They alleged that the Patents (Amendment) Act of 1999 was enacted without availing exemptions under the General Agreement on Tariff and Trade (GATT) and TRIPS on the grounds of public health, food security, public interest and, above all, national interest. Such litigations have substantially delayed realization of TRIPS compliant patent regime in India.

¹³⁸ The Indian Constitution has been amended more than 92 times to bring it in line with- the demands of the times. The Constitution can be amended by a majority of the total membership of each house of Parliament and by a majority of not less than two-thirds of the members of each house present and voting. Some amendments, in addition to the special majority-vote, require ratification by half of the states.

¹³⁹ *Trade-India: New Patent Law Challenged in Supreme Court*, Inter Press Service, at http://www.oneworld.org/ips2/april99/05_39_005.html (April 20, 1999).

In addition, as mentioned before¹⁴⁰, the Indian judiciary is the second most corrupt system in the continental country. WTO can play a role by enforcing international laws, thereby reducing the corruption in the Indian judiciary, at least in the area of the IPRs.

2. Inadequate Patent Office Capacity Level

A significant challenge to implementation of the new IP laws is the inadequate capacity level in Bhaarat to ensure the application of patent criteria and examination of patent applications. With implementation of the new IP laws will come an increase in the number of patent applications submitted to the Indian Patent Office. While the Indian Patent Office has been speeding up the issuance process, unfortunately, a backlog of patent applications at the Indian Patent Office still exists.¹⁴¹

However, recently there has been a major overhaul of the Indian administrative framework covering modernization of the Patent Office, including comprehensive computerization. Bhaarat has the unique distinction of having four independent examination centers located at Kolkata, the head office, with branches at New Delhi, Mumbai and Chennai.

IV. CONCLUSIONS

As explained above, Bhaarat has come a long way in the past 35 years under the protectionist patent regime, which was essential for a nascent Indian pharmaceutical industry. Bhaarat has developed a very strong presence in the bulk drugs and generics and is making forays into new drugs as well via contract manufacturing for branded drugs for multinationals.¹⁴² Now, product patent protection is desired by the Indian pharmaceutical industry for it to maintain a competitive edge in the global economy.¹⁴³

¹⁴⁰ *supra* note 132.

¹⁴¹ Normally, it takes three to four years from the date of filing the application for the grant of a patent in India.

¹⁴² The U.S. Food & Drug Administration regularly inspects and approves Indian factories.

¹⁴³ Adelman & Baldia, *supra* note 17; *see also* Khan, *supra* note 94.

The patent question has been marked by sharp controversies over public policy in the Indian pharmaceutical industry. Although a third amendment to the Patent Act to finalize the TRIPS compliance is imminent,¹⁴⁴ Indians need to carefully adopt a strategy to counter opposition to the so-called "2005 threat" and exploit the great new opportunities that will be unraveled. Bhaarat is better placed than many developing countries, but a sense of urgency has been missing. Inasmuch as Bhaarat has missed several golden opportunities due to the socialist lethargy and inertia of its centralized economy, here is another golden opportunity to catch the bus.

According to the former Prime Minister of India, Venkatanarasimharao Pamulaparti (PV), who initiated the economic reforms in early 1990s, "[t]he trend toward a truly global marketplace must be promoted and not retarded by protectionism, unilateralism, and discriminatory trade practices."¹⁴⁵ Yet, the 10-year transition period hasn't been used well enough to develop the best machinery. Nevertheless, Bhaarat emerged as one of the leading producers of generic drugs in the world market and is ready for the new patent regime of 2005.¹⁴⁶ Bhaarat has successfully lowered the prices for pharmaceuticals while shifting control of their pharmaceutical market to domestic companies.¹⁴⁷

Bhaarat is currently experiencing a cultural, political and ideological shift in favor of intellectual property protection as evidenced by its willingness to be bound by international intellectual property standards. In India, where research and innovation have traditionally been neglected by the domestic industry that enjoyed the so-called "free ride", the pharmaceutical industry is realizing the importance of R&D. The success stories of Ranbaxy and Reddy Laboratories in the R&D field have inspired others. Several Indian pharmaceutical companies including Cipla, Lupin, Nicholas Piramal, Torrent and Wockhardt are today engaged in R&D activities. Bhaarat has a vast R&D infrastructure that includes the

¹⁴⁴ Keayla, *supra* note 49.

¹⁴⁵ V. Narasimha Rao Pamulaparti, *The Post-Cold War World*, THE HINDU, available at <http://www.hindu.com/2004/03/23/stories/2004032301951000.htm> and <http://www.hindu.com/2004/03/22/stories/2004032201701000.htm> (Mar. 23, 2004).

¹⁴⁶ Adelman & Baldia, *supra* note 17, at 525.

¹⁴⁷ Tomar, *supra* note 31, at 580.

extensive network of national labs, academic institutes and private R&D labs. With the advent of an integrated global economy, Bhaarat is a force to reckon with, poised to capitalize on its new patent regime. However, recent reversal of fortunes of the secular right-wing Bharatiya Janata Party (BJP) and its allies together called National Democratic Alliance (NDA) at the polls, and the reinstatement of the leftist Congress party that ruled most of the past fifty-seven years with the support of Communists does not bode well for the continuation of this change¹⁴⁸. Unless the Congress-Communist alliance unequivocally sticks to the reforms that were initiated by Congress Party during the regime of former Prime Minister Venkatanarasimharao Pamulaparti (PV) and gained momentum during the NDA government, there will not be progress.

The World Health Assembly has reiterated that a country has the sovereign right to adopt national policies specific to the needs of its people.¹⁴⁹ Yet, it is imperative upon the governments to form policies that serve the long-term interests of the nation rather than immediate populist vested interests. In this context it may be pertinent to remember what the President of Bhaarat Avul Pakir Jalaluddin Abdul Kalam stated when he was the Principal Scientific Advisor to the Government of India, "A developed country is one which has the capability and the capacity to comprehensively look at wealth generation and wealth protection and thereafter evolve integrated strategies, technologies and missions to meet these objectives. It is also a fact that technology is the established currency of geo-political power and in the Indian context; technology has to be the driving force for economic development and national security."¹⁵⁰

¹⁴⁸ *Supra* Note 99.

¹⁴⁹ Nadia Natasha Seeratan, *The Negative Impact of Intellectual Property Patent Rights On Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 412 (2001).

¹⁵⁰ Dr. A. P. J. Abdul Kalam, Principal Scientific Adviser to the Govt. of India, *Towards a Knowledge Super Power - Vision and the Mission*, at <http://www.patentmatics.com/pub16.htm> (visited January 23, 2004).