LEGISLATIVE COMMENTS

THE EFFECT OF THE INDIAN PATENTS (2005) AMENDMENT ON THE PHARMACEUTICAL INDUSTRY AND ACCESS TO MEDICINES IN INDIA

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> *That he the inventor, ought to be both compensated and rewarded …will not be denied …it would be a gross immorality of the law to set everybody free to see (or use) a person's work without his consent and without giving him an equivalent*
>
> John Stuart Mill (1848)

> *The United States will henceforward implement its health care and trade policies in a manner that ensures that people in the poorest countries won't have to go without medicine they so desperately need*
>
> Bill Clinton[1]

I. INTRODUCTION

These abovementioned quotes sum up the debate between developed and developing countries over the issue of patent rights and access to medicines as a human right.[2] The Indian Patents (Amendment) Act, 2005[3] (*hereinafter* Amendment) marked a new phase in Intellectual Property Rights (*hereinafter* IPR) with the fifth amendment to the Act introducing significant statutory provisions.[4] Previously, the Ayyangar Committee[5] recommended, *inter alia*, the exclusion of product patents from the Indian Patents Act, 1970 as Multi-National Companies (MNCs) had numerous applications pending for grant of

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1 William J. Clinton, Remarks as a World Trade Organization Luncheon in Seattle, 35 WEEKLYCOMP PRESS DOC 2494 (December 1, 1999).

2 *See* Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa, Case No. 4183/98.

3 *See* The Gazette of India, Ministry of Law and Justice, *The Patents (Amendment) Act, 2005 (15 of 2005*), received assent of President on April 4, 2005 and published on April 5, 2005, entered into force on January 1, 2005 available at http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf (Last accessed on April 4, 2012).

4 The Act has been amended five times - The Repealing and Amending Act, 1974 (Act 56 of 1974); The Delegated Legislation Provisions (Amendment) Act, 1985 (Act 4 of1985); The Patents (Amendment) Act, 1999 (17 of 1999); The Patents (Amendment) Act, 2002 (38 of 2002); The Patents (Amendment) Act, 2005 (15 of 2005).

5 *See* N.R. AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW (1959).

patents, apart from the scores of patents that already existed in India.[6] The MNCs acquired patents for protecting their imports in India. Therefore, the recommendations of the Ayyangar Committee were accepted and product patents were not granted from 1970 till 2005 as a measure to protect the Indian industry. The latter three amendments were the result of India's obligations as a signatory to the Trade Related Aspects of Intellectual Property Rights[7] (*hereinafter* TRIPS), the Indian government fulfilled its TRIPS obligations in three instalments the last being the 2005 Amendment.[8]

The seeds were sown in 1999 when interim protection for pharmaceutical products was granted by way of *mail box*[9] applications which were opened in 2005, till when these applications enjoyed Exclusive Market Rights (*EMRs*).[10]

The paper shall be segregat such a regime. The second section shall be devoted to the interpretation of the Amendment which it is argued effectively makes the current threshold of patentability more stringent. The author shall analyse the new additions to the Patents Act and argue whether these changes are justified. In the third section the author shall delve into the question of Compulsory Licensing being the tool that will provide the balance between the rights of the patent holder *vis-à-vis* the fundamental right of health enshrined in the Constitution of India. And finally the author shall analyse the effect of the Amendment on the pharmaceutical industry and whether the Amendment has been able to strike a balance with the Human Right to Access to Medicines and the need for innovation in the industry.

II. The Changes Brought in by the Amendment and their Significance

The Amendment has brought in an array of changes to the Act.[11] These

6 The Indian Government introduced the Patents Act, 1970 which categorically excluded pharmaceuticals and agrochemical products from eligibility for patents. This exclusion was initiated to address India's dependence on imports for bulk drugs and provide for development of a self-reliant, indigenous pharmaceutical industry. *See* Sheja Ehtesham and Niranjan Mansingh, *Conflicting Interests in Drug Pricing: Innovation v. Social Needs*, 94(2) Current Science 168 (January 25, 2008).

7 The text of TRIPS is available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (Last accessed on June 15, 2012). India signed the TRIPS w.e.f. 1994 and entered the World Trade Organization w.e.f. 1995.

8 Product patents were introduced in compliance with Article 27 of TRIPS.

9 The Mailbox Application is a facility that enables the filing of a patent application for chemicals, foods, drugs till the time the product patent regime has been devised and enacted.

10 This is in accordance with Article 70.8 of TRIPS. For further understanding of the mail box applications and the applicability with TRIPS see www.wto.org/english/tratop_e/trips_e/intel2c_e.htm#transitional. (Last accessed on June 15, 2012)

11 Section 3(k) excluded *a computer programme per se* from the scope of patentability, the pre-grant opposition has been widened and provisions for post-grant opposition have been introduced. For a more detailed understanding *see* Shamnad Basheer, *India's Tryst With TRIPS:The Patents (Amendment) Act, 2005*, 1 The Indian journal of law and technology 19 (2005).

changes were apparently[12] in compliance with TRIPS and were in furtherance of raising the patentability threshold.[13]

A. New Invention Defined

The definition of *new invention*[14] which has been added by the Amendment is a debatable feature in the Act on two counts. Firstly, the Act already had a definition of *invention*[15] which clearly lays down the criteria for a valid patent[16] which contains the word *new.* The presence of this term is sufficient for statutory and interpretative purposes. The Amendment, in defining *new invention,* brings out ambiguity in the legislative intent and hence in interpretation. It appears that the intent was to address and include terms like *state of the art* and *technology* in furtherance of which the granting of patents would be more stringent.[17]

Further, if the legislature had intended to clear the ambiguity that existed in the Act before the Amendment, a prudent step would have been to define the terms that were to be added such as *state of the art, technology* and the terms that were ambiguous such as *new.* The introduction of the *new invention* definition proves to be cyclical and redundant, as it leaves much for interpretation and thus creates a vacuum in the law, with no indication as to the Legislature's real intention. Secondly, the standard of novelty is not consistent throughout the Act. S.25 of the Act provides grounds under which patents can be opposed.[18]

12 The validity of Section 3(d) was challenged in Novartis AG v Natco Pharma and Others(2007) 4 MLJ 1153 on the grounds of not being in compliance with TRIPS. The constitutionality of Section 3 (d) was upheld. For a detailed discussion see Section II (C).

13 Manoj Pillai , *The Patents (Amendment)Act, 2005 and TRIPS Compliance- A critique*, INDIANJOURNAL OF INTELLECTUAL PROPERTY RIGHTS 236 (May 2005).

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

15 Section 2(1) (j) reads as "*invention" means any new and useful-(i) art, process, method or manner of manufacture;(ii) machine, apparatus or other article;(iii) substance produced by manufacture, and includes any new and useful improvement of any of them and an alleged invention*"-----.

16 Under the Patent Act the three necessities that need be fulfilled for an invention to be granted a patent are novelty, inventive step and industrial application.

17 The framers should have realised that not defining these terms would be a potential gateway for unnecessary litigation as has been the case in England, *See* General Tire and Rubber Co. v. Firestone Tyre and Rubber Co., [1972] RPC 457: The plaintiffs claimed infringement of the patent for the oil extended rubber by the defendants who counterclaimed for the revocation for the patent, *inter alia,* on the grounds of novelty. It was alleged that the patent should have been anticipated by cert ain documents published. The prior publication should not be in a manner that is capable of being understood by anyone who is skilled in the art. *Also See* Novartis AG v Natco Pharma and Others (2007) 4 MLJ 1153.

18 This section is based on novelty restricted for the patent to be invalid if it is *known or used in India* while Section 2 (1)1 stipulates for patent invalidity if it is known or used in the *entire*

This inconsistency means that a competitor of the patent applicant would not be able to successfully oppose a patent if the invention is known or used in any part of the world except for India. It can be thus concluded from the sloppy, inconsistent and hasty manner in which the Ordinance was promulgated and the Amendment drafted, that it was simply in lieu of the deadline of 1st January, 2005.[19]

B. Inventive Step

Prior to the amendment the inventive step required *non-obviousness to the person skilled in the art.*[20]

The amendment conveniently has added further prerequisites of *technical advance* and *economic significance* that is *non-obvious*[21] to an expert. The sole purpose of the inventive step is to achieve a higher degree of technical progress for a patent to be granted and with it the monopolistic rights. However, the *non-obviousness* test has been criticised on account of its complicated nature.[22]

Further, the added terms of *technical advancement* and *economic significance* reiterates the same prerequisites of non-obviousness and industrial application respectively but a careful reading of the amended section reveals that the patent could satisfy the inventive step test if it has *economic significance* alone i.e there could be a patent which does not have sufficient degree of advancement.[23] Also the phrase *technical advances as compared to existing knowledge* may dilute the novelty requirements.[24] The amended terms adds to the ambiguity and also gives discretionary powers to the patent officer to interpret the undefined terms not to mention the increased probability of superfluous litigation. Thus the desired higher degree of patentability now seems unfulfilled.

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world or in India; For a more detailed discussion *see* Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005* 1 Indian Journal of Law and Technology (2005).

19 In order to meet the deadline stipulated in the TRIPS agreement, the Patents (Amendment Bill), 2003 was passed by a Presidential Ordinance [Patents (Amendment) Ordinance, 2004]. The Amendment was published in the Gazette of India on April 1, 2005 with retrospective effect from January 1, 2005.

20 Section 2(ja) defines 'inventive step' as *a feature that makes the invention not obvious to a person skilled in the art.*

21 *See* Article 27.1 of TRIPS.

22 *See* Biogen Inc. v. Medeva plc, [1997] RPC 1; Benmax v Austin Motor Co Ltd 1970 RPC 284; Biswanath Prasad Shyam v Hinudstan MetalIndustries (1979) 2 SCC 511.

23 K M Gopakumar & Tahir Amin, *Patents (Amendment) Bill 2005: A Critique,* 40 Econ & Pol. Weekly 1503-1505. (April 9, 2005).

24 *See* Pillai, *supra* note 13, p. 236

C. The Maligned Section 3(d)

The much maligned Section 3(d) of the Amendment suffers from two counts of obfuscation. Firstly, in the vague and unclear wording of the Section itself which lends itself to unnecessary litigation, and secondly, in the confused interpretation of the courts in clearing up the inadequacies inherent in the law.

The intention of Section 3(d) ostensibly, is to prevent the phenomenon of 'ever-greening'[25] , i.e. the practise of stockpiling patent protection by obtaining separate 20 year patents on multiple attributes to a single product. This unique section sought to achieve this by prohibiting the patenting of new forms of existing pharmaceutical products that do not demonstrate significantly enhanced efficacy.[26]

The underlying assumption is that there is significant difference between ever-greening and incremental innovation, and that the distinction between the two is always clear to the adjudicating authority, which may not always be true as courts have interpreted it in several ways, none of which clearly bring to light the intention of the Legislature. Furthermore, an analysis of the terms in the section brings to light the injudicious drafting of the section. Section 3 is the main section on qualifying patents under the Indian Patent Act. Part (d) of this section lists particular non eligible patent matter. The Amendment inserts Section 3(d):

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

The Amendment poses more questions than it solves. There are several terms in the inserted clause that prove vague and unclear. The term *enhancement of the known efficacy* goes unexplained. Given that the statute provides no explanation towards the same, the precise meaning of the term efficacy is unclear. It is important to note that the definition of efficacy needs to be looked at in the light of the intention of legislation. It may be argued that proving efficacy, especially with respect to making the new form of the substance patentable in its own right, can be done not just with respect to the definition as it is widely understood, i.e. therapeutic efficacy, but also with

25 Shamnad Basheer and Prashant T. Reddy, *The Efficacy of Indian Patent Law: Ironing Out the creases in Section 3(d)*, 5(2) SCRIPTed 238 (2008).

26 *Id*.

respect to efficacy in various other terms such as efficiency in the manufacturing process, heat stability of the reactants and derivatives of the known substance being used in the manufacture of the drug, drug delivery mechanisms etc.

In the *Novartis* judgement at the Madras High Court, the Court applied the restrictive interpretation of efficacy, i.e. the definition of efficacy as therapeutic efficacy only.[27] This interpretation left out of its scope the bio availability of differentiated forms of derived substances. The Court held that even 30% of increased bio-availability[28] was not enough to be considered as proof of significantly enhanced efficacy. In any case, the definition of therapeutic efficacy being restricted to only "*how effective the new discovery made would be in healing a disease / having a good effect on the body*" leaves out of its scope the various other forms of increased efficiency in producing and making available the drug to the general public, such as heat stability, humidity resistance, side effects, toxicity and dosage (in the form of quantity, frequency, form and manufacturing efficiency).[29]

Furthermore, the interpretation of efficacy as therapeutic efficacy is short-sighted on the part of the judiciary as various substances other than pharmaceuticals such food, agri-products and other chemicals are also covered under the application of this section.

Thus, it seems that Section 3(d), in exhibiting compliance to the TRIPS, does not take into account the issue of access to medicines as an integral part of the fundamental right to health read under Article 21 of the Indian Constitution.[30] The increased efficacy of derivatives of the known substance are realised not just through the significant increase in therapeutic efficacy of the said derivative but also with respect to how that accessible that particular end product or medicine is to the general public.

The Madras High Court may have reached what many experts widely regard as the right decision, but for all the wrong reasons.[31] The availability of

27 Novartis AG v Natco Pharma and Others (2007) 4 MLJ 1153. Novartis filed a patent application covering *the beta crystalline* form of *imatinib mesylate*. However, Novartis claims that that the beta form "*stores better, is less hygroscopic, is easier to process and guarantees a constant quality of the final drug product*."

28 Bioavailability has been defined as: " *the proportion of a drug which reaches its site of pharmacological activity when introduced into the body; more loosely, that proportion of any substance so introduced which enters the circulation.*" *See* Oxford English Dictionary Online, Oxford University Press (2nd edn, 1989).

29 See Aditya Kant, *Section 3(d): 'New' Indian Perspective*, 14 Journal of Intellectual PropertyRights 385-396. (September 2009).

30 *See* Consumer Education and Resource Centre v Union of India AIR 1955 SC 636, State of Punjab and Others v Mohinder Singh AIR 1997 SC 1225.

new forms of patentable pharmaceuticals which exhibit increased efficacy, for example with variations in the manufacturing process that reduce the costs of production, or more bio available derivatives of the original patent protected drug are important to the public health policy initiatives of the Indian government. The methods for maintaining the balance between TRIPS related patent protection and the interests of public policy will be discussed in the following section.

D. Bolar Provisions

As a widely accepted international principle, the Bolar Exception allows research and development work to be carried on during the lifetime of the patent for the purpose of obtaining information to be submitted to a regulatory authority without any infringement of the patent. The 2005 Act recognizes this exception in Section 107A and also brings the act of importing within the ambit of the exception. This, therefore, will no doubt aid the generic industry to oppose those patents which have been frivolously granted.[32]

E. Parallel Imports

The doctrine of parallel imports allows the importation of patented drugs which have been previously exported abroad with the consent of the patent-holder, into the domestic market at cheaper costs. Section 107A(b) of the 1970 Act as amended by the 2005 Act introduces a modified version of this concept by providing that importation of patented products from a person who is duly authorized under the law to produce and distribute the product will not amount to an infringement of patent rights. This provision, however, is subject to the principle that the patent-holders' rights have been exhausted through the first sale in order to protect the interests of the patent-holders.[33]

Thus, from the above discussion, it may be concluded that although the 2005 amendment sought to strike a balance between the conflicting interests of "intellectual property protection with public health concerns and national security"[34], it ended up tilting the balance more towards the public health lobby by considerably restricting the scope of patentability of pharmaceutical products as well as by providing a series of exclusionary provisions, thereby undermining the strengthening effect of the product patent regime to a great extent.

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31 *See* Basheer, *supra* note 11.

32 *Id*.

33 Prabhu Ram, *India's New "TRIPS-Complaint" Patent Regime: Between Drug Patents and the Right to Health*, 5 CHI-KENT J. INTELL. PROP. 195, 204 (2005-2006).

34 Press Release, MINISTRY OF COMMERCE & INDUSTRY, *Kamal Nath's Statement on the Ordinance Relating to Patents (Third) Amendment* (December 27, 2004), ¶ 14, available at http://pib.nic.in/release/rel_print_page.asp?relid=6074 (Last accessed on June 15, 2012).

III. Compulsory Licensing and Public Health Policy

A. International Recognition of Right to Health

The product patent regime, introduced in pursuance to India's obligation under the TRIPS, is beset with its very own merits and demerits. While it provides the pharmaceutical industries with the necessary incentive to invent and innovate, its potential effect upon the availability of generic drugs has been the topic of discussion for long. Article 30 of the TRIPS Agreement further allows member countries to provide for limited exceptions to the rights of the patent holder. The pharmaceutical industry should be considered as an exception to the general product patent regime and compulsory licensing provisions should be generously made applicable in situations where generic drugs are required to address public health matters.

A sovereign nation had the right to protect public health even at the cost of not honouring intellectual property rights.[35] Article 25 of the Universal Declaration of Human Rights states that '*everyone has the right to a standard of living adequate for the health and the well-being of himself….*". A similar provision finds reference in Article 12 of the ICESCR that states that "*….. right of everyone to the enjoyment of the highest attainable standard of physical and mental health*". A reading of the abovementioned provisions would suggest that the '*human right to health*' includes '*accessibility to medicines*'.[36]

The Declaration on the TRIPS Agreement and Public Health (*hereinafter* Doha Declaration) adopted at the Ministerial Conference of the World Trade Organization in Doha affirms that the WTO Agreement on the Trade Related Aspects of Intellectual Property Rights "*can and should be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health and, in particular, to promote access to medicines for all…*".[37] This Declaration

35 See WTO Ministerial Conference, Declaration on Public Health, WT/MIN(01)/DEC/2, ¶2 (14 November2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (Last accessed on June 15, 2012).

36 In Minister of Health v. Treatment Action Campaign, The Constitutional Court of South Africa explicitly recognized that accessibility to medicine is a part of the human right to health, Minister of Health and others v. Treatment Action Campaign and others, 2002 (5)SA 721 (CC).

37 Declaration on the TRIPS Agreement and Public Health (Nov. 14, 2001), Doc. WT/MIN (01)/DEC/2(Nov.20, 2001). The Doha Declaration and many other WTO documents referred to in this article are available at the WTO Web site, http://www.wto.org, ¶4 (referring to Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr.15 1994, in World Trade Organisation, Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 321 (1999). The TRIPS Agreement is applicable to all the members of the WTO.

was followed by the Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health in August, 2003.[38]

One of the primary objectives of the Decision was to facilitate and support countries lacking sufficient production capacity in pharmaceuticals to use provisions of compulsory licensing in an effective way to solve and mitigate public health problems.[39] The following section will discuss the effect of the new product patent regime post the Amendment on accessibility to medicines in India in the backdrop of severe public health concerns.

The absence of any stringent product patent regime in Indian patent law acted as a catalyst to the unprecedented growth of the pharmaceutical industry. This facilitated the availability of cheap drugs in a country that lacked sufficient manufacturing capacity. The generic production of *Fulcanazole*, a drug that treats HIV, was priced at $55 for 150 milligrams compared to $697 in Malaysia and $ 817 in Philippines.[40] With the advent of the product patents pursuant to the Indian government fulfilling its obligations under the TRIPS, the availability of generic medicines in the country will be adversely affected. A Product patent on a certain drug will grant pharmaceutical companies the right to prevent generic production for the next 20 years.[41] Such non-availability of cheap drugs will impair the human right to health.

Pharmaceutical companies argue that the advent of product patents has acted as a boon as it will encourage further R&D, leading to the manufacture of newer essential drugs to alleviate public health troubles.[42] This argument is based on the assumption that developing countries like India have the required capacity to indulge in path-breaking research. The question therefore is whether India's obligation to comply with the TRIPS can be assisted by a regime that facilitates easy access to drugs.[43] To answer this, one can seek support from Article 8 of the TRIPS[44] to deny obligations imposed under Article 27 of the TRIPS arguing that such an obligation would be detrimental to public health.

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38 Implementation of 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug.30, 2003), Doc WT/L/540 (September 1, 2003), available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (Last accessed on June 15, 2012).

39 *Id.*, ¶ 6(i).

40 *See* Human Development Report, 2000, p. 84.

41 The TRIPS Agreement obliges all the countries to provide patent protection to the patent holder for a period of 20 years.

42 P. Cullet, Intellectual Property Protection And Sustainable Development 394-398 (2005).

43 Prabhash Ranjan , *Understanding the Conflicts between the TRIPS Agreement and the Human Right to Health*, 9(6) Journal of World Investment and Trade 24 (2008).

44 Article 8 of the TRIPS explicitly allows members to adopt measures *"necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development"*

Article 30 of the TRIPS Agreement allows for '*limited exceptions*' to the rights of the patent holder in municipal law. The term limited exception is subject to much criticism in situations where there is an imperative need to issue compulsory licensing in cases of public emergency.[45]

In the *Canada-Generic* Pharmaceutical case the Panel opined that 'limited exception' would mean 'narrow exception' to patent rights.[46]

B. The Constitution of India Mandates for Health

Article 51(c) of the Constitution which is one of the Directive Principles of State Policy enshrined in the Part IV of the same provides that the State *shall* endeavour to foster respect for international law and treaty obligations.

This needs to be read in the light of Article 37 of the Constitution which states that the principles laid down in Part IV are fundamental to the governance of the country. In other words, it shall be the *duty* of the State to keep in mind the international principles while legislating new laws. It is thus prudent to believe that the *raison d'etre* of Article 51(c), when read with Article 37, is to introduce and implement various international instruments which are consistent with the fundamental rights and in harmony with its spirit[47]. Since India is a signatory, she is bound to fulfil its obligations enumerated in ICESCR & UDHR and facilitate the enjoyment of *right to health* by its citizens.

Also, Article 21 of the Constitution has been held to include *right to health*.[48] Article 21 of the Constitution provides expressly the protection for life and personal liberty by stating that *no person* shall be deprived of his life or personal liberty except according to the procedure established by law. The Supreme Court has conveniently and quite rightly has extended the ambit of Article 21 so as to make life meaningful and not a mere vegetative existence. In addition, it has to be emphasised that the improvement of public health is one of the paramount duties that the State necessarily needs to execute.[49]

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45 *See* Cullet, *supra* note 42.

46 Canada –Patent Protection of Pharmaceutical Product, WTO Doc. WT/DS114/R (adopted Apr. 7, 2000) discussed in Frederick M. Abbott, Compulsory Licensing for public health needs: The TRIPS agenda at the WTO after the Doha declaration on public health (UNO Occasional paper no.9, Feb .2002), Available at http://www.geneva .quno.info/index.php?pageid+indo1 (Last accessed on April 4, 2012).

47 *See* Vishaka v. State of Rajasthan AIR 1997 SC 3011; *Also see* People's Union for Democratic Rights v. Union of India AIR 1982 SC 1473.

48 M.K. Sharma v. Bharat Electronics Ltd, AIR 1987 SC 1792.

49 Article 47 of the Constitution of India.

C. Compulsory Licensing is the Rescue

In India, the Amendment permits manufacturers to continue producing generic versions of new drugs which are in the mail box and which can now be patented, as well as pre-mailbox drugs on the condition that the eventual patent holder of a mailbox application, who has made a significant investment in Research and Development, be entitled to receive a '*reasonable royalty*' from those generic manufacturers under the provisions of compulsory licensing[50]. The Amendment also introduced S. 92A, wherein compulsory licensing is made available for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector, for the concerned product, to address public health problems.[51]

However, the issue is whether the compulsory licensing provisions, despite being comprehensive[52], will be able to sufficiently address the inefficient supply of generic drugs in India following the introduction of the product patent regime. Even the Doha Declaration provides an *ad hoc* solution with no suggestions to the prudent use of compulsory licensing provisions under adverse situations.[53]

IV. The Effect of the New Patent Regime on Pharmaceutical Companies

The major question that needs to be tackled to analyze the impact of the new product patent regime of India imposed in 2005 is whether Indian pharmaceutical companies are actually creating innovative drugs or simply marginally improving the existing drugs, obtaining patents on them and selling them off in the pharmaceutical market. After 2005, the Indian pharmaceutical industry has found a new lifeline in research and development. Indian Pharmaceutical Industry has emerged as the world's fourth largest producer in terms of volume, producing about 8% of the world's total production, while in terms of value it accounts for 1.5% of the world's production with a rank 13th in the world.[54] India's pharmaceutical market grew at 15.7 per cent during

50 Through *automatic licensing*, a generic manufacturer, who has made a significant investment and is already manufacturing and producing a drug in India that was patented before January 1,1995 can continue to do so by payment of a reasonable royalty to the patent holder.

51 The provisions of Section 11A need scrutiny as it stipulated granting compulsory licenses to those manufacturers which made a 'significant investment' and were 'producing and marketing' a drug pending in the mailbox applications in lieu of a *reasonable royalty* and *other remuneration*.

52 The terms *reasonable royalty* and *other remuneration* give the patent holder leeway to make unreasonable demands. The use of ambiguous terms makes loopholes which could be exploited by the patent holders. The absence of ceiling prices could be used by the patent holder in gathering an injunction to the compulsory license and slowing down the process through litigation.

53 E.R. Gord and D. K. Bam, *Balancing Trade in PATENTS: Public Non-Commercial Use and Compulsory Licensing'*, 6 Journal of World Intellectual Property 13(2003).

54 Fox and Mandal Associates, Indian Pharmaceutical Industry and Intellectual Property Laws: An Attempt to Strike a Balance , available at http://foxmandallittle.com/Publications/upload

December 2011, with appreciable enlargement in anti-diabetics, derma and vitamins.[55]

To tackle the restrictions on manufacturing patented drugs posed by the Amendment, Indian as well as foreign pharmaceutical companies have altered their strategies and resorted to other innovative methods in several sectors. The most important of these strategies shall be dealt by the author in this part.

A. Investment in Research and Development

While in the 1970, foreign firms had more than two-thirds of the Indian market share, this had diminished to less than 23% in 2003, before the new patent regime came in.[56]

With the new regime becoming effective, the Indian pharmaceutical industry is entering into an era in which it is becoming a global hub for research and development.[57]

Prior to the Amendment, the domestic companies also invested far lesser in research and development than the MNC's. For instance, in 2005 Ranbaxy and Dr. Reddy's Laboratories invested 7 and 10 percent of its total sales into R&D, which by comparison is far below the average R&D investment of 15 percent for 15 of the top global pharmaceutical companies.[58] Yet, in spite of increase in the research expenditure of the few major Indian Pharmaceutical companies, the average R&D spending of Indian companies are very small compared to their international counterparts. In India, average R&D spending comes to about 4 percent of the total turnover which is in stark contrast to that of Germany which stands at 9 percent.[59]

Indian_pharmaceutical_industry_and_intellectual_property_laws.pdf, February 2010, (Last accessed on June 15, 2012). *Also see* www.ibef.org/industry/pharmaceuticals.aspx which states India as 3rd in terms of volume and 14th in terms of value. The Indian pharmaceutical market is expected to touch US$ 74 billion sales by 2020 from US$ 11 billion now, according to a PricewaterhouseCoopers (PwC) report.

55 According to data compiled by market research firm All India Organisation of Chemists and Druggists (AIOCD). *See id.*

56 Sudip Chaudhari, The WTO And India's Pharmaceutical Industry : Patent Protection, Trips And Developing Countries 18(New Delhi: 2005).

57 Ravi Kiran & Sunita Mishra, *Performance of The Indian Pharmaceutical Industry In Post-Trips Period: A Firm Level Analysis*, International Review of Business Research Papers, Vol.5 No.6, 6th November 2009, p. 149.

58 Katherine Connor Linton and Nicholas Corrado, *A "Calibrated Approach": Pharmaceutical FDI and the Evolution of Indian Patent Law* Journal of International Commerce and Economic, August 2007, available at <http://www.usitc.gov/publications/332/journals/pharm_fdi_indian_patent_law.pdf> (Last accessed on June 15, 2012).

59 Uwe Perlitz, *India's Pharmaceutical Industry on course for Globalisation*, Deustche Bank Research, April 9, 2008, p. 7.

Thus, if we see the situation at face-value, we see that not much development has been done to the sphere of research and development even after the Amendment. It is only the big players in the Pharmaceutical market who have improved their expenditure, whereas the small and medium pharmaceutical enterprises which mainly lived on reverse-engineering till 2005 have fallen apart. The effect of the new Amendment was instantaneous. While the expenditure of the major spenders in the Indian Pharmaceutical Industry was 7.83% in 2004-05, it improved significantly to 8.79% in the year 2005-06[60], that of the other smaller companies have decreased considerably from 1.4% to 1.2%.[61] As a result of this Amendment, the Indian companies, if they have to survive in the market have to resort to new and innovative research. The previous extensive usage of the reverse-engineering process has thus been completely neutralised by this Amendment.

B. Mergers, Alliances and Acquisitions

Large Indian companies have started expanding their business to foreign countries through mergers and acquisitions. As of 2008, before Ranbaxy itself was acquired by Daichii Sankyo, it exported products to more than 125 countries, had subsidiaries in nearly 50 countries and had production plants in 20 countries across the globe.[62] In effect, nearly 80% of its total sales were generated abroad.[63]

One of the biggest issues which are triggering buyouts of Indian Pharmaceutical firms by foreign companies is that the Amendment grants patent protection to the product itself and not the process by which the product is made. The earlier kind of patenting would mean that the local manufacturers could use the reverse-engineering process to create a similar product and sell it off at lower prices in the domestic market.[64] Under the Amendment, such reverse-engineering process is prevented. Thus, mergers and acquisitions have picked up after the passing of the Amendment.

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60 Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS*, Working Paper Series WPS No. 614/ September 2007 retrieved from http://www.iimcal.ac.in/res/upd/Sudippercent20Wppercent20614.pdf (Last accessed on June 15, 2012).

61 *Id*.

62 *See* Kiran & Mishra, *supra* note 57, p.9.

63 *Id*.

64 Rajesh Garg, Gautam Kumra, Asutosh Padhi and Anupam Puri, *Four Opportunities in India's Pharmaceutical Market*, The McKinsey Quarterly, No. 4 (1996), available at < http://www.questia.com/googleScholar.qst?docId=5000463125 > (Last accessed on June 15, 2012).

C. In-licensing and out-licensing

The Amendment reduces opportunities of companies to benefit from reverse-engineering. Thus they no longer can rely on generics or export of bulk drugs to boost sales. To balance the negative effects of such an Amendment, Indian companies have resorted to a symbiotic relationship with foreign companies. Through such licensing agreements, the foreign and Indian companies collaborate on research and development. As it is hard for Indian companies to come out with absolutely new molecules, they often enter into licensing agreements with multinational companies for the development of such molecules.[65]

The recent deals of Nicholas Piramal with BioSymtech Inc. and Morvus Technology involve researching for a drug to relieve chronic heel pain and to undertake research in the area of cancer, diabetes and arthritis respectively.[66] These mutual alliances to research and develop new drugs often meet with enormous success, considering the research potential of the Indian companies backed up by the infrastructural support from the foreign companies.

While in-licensing involves the carrying out of research and development of a drug for a foreign company by a local company, out-licensing is exactly the reverse. Out-licensing involves licensing out molecules under development to foreign MNC's who can support their research and development. By out-licensing, Indian Pharmaceuticals can partner with global players by coming out with innovative molecules and relying on foreign players for their research and development.[67] Multi-million dollar out-licensing deals have come through post the Amendment, with Ranbaxy's deal with PPD Inc. for the RBx 10558 molecule for $44 million and Glenmark's deal with Eli Lilly for $ 135 million being some of the largest deals by Indian players.[68]

Thus we see that the Amendment, which imposed the new product regime in 2005, has to some extent achieved what it aimed at. By completely curbing the reverse- engineering process, it has tightened the noose on the necks of smaller

65 M. D. Janodia, S. Pandey, J. Venkara Rao, D. Sreedhar, V. S. Ligade & N. Udupa, *Patents Regime in India: Issues, challenges and opportunities in Pharmaceutical Sector*, The Internet Journal of Third World Medicine, Volume 7 Number 1, 2008, available at <http://www.ispub.com/journal/the_internet_journal_of_third_world_medicine/volume_7_number_1_17/article/patents_regime_in_india_issues_challenges_and_opportunities_in_pharmaceutical_sector.html> (Last accessed on June 15, 2012).

66 Ernst and Young's Report to India Brand Equity Foundation (IBEF), Pharmaceuticals: Markets and Opportunities, available at <http://www.ibef.org/download/Pharmaceuticals_210708.pdf> (Last accessed on June 15, 2012).

67 Sasikanta Mishra, Interview with Nagesh M. Joshi, *SME's may explore out-licensing for expansion*, Express Pharma, 1-15 September, 2007 Issue, available online at http://www.expresspharmaonline.com/20070915/interphexindiaipaconventionspecial02.shtml (Last accessed on June 15, 2012).

68 *See* Garg et al., *supra* note 64.

companies, forcing them to invest in research and development or merge with other larger multinational companies. To tackle such a rigid regime, we can see a lot of mergers between foreign and Indian players alongside sharing of mutual resources and the development of a symbiotic relationship between them.

V. PUBLIC HEALTH & THE NEED TO ACCESS ESSENTIAL MEDICINES

Since India is a country which has to deal with underdevelopment, poverty as well as many other issues plaguing society, the most important argument which has been made is that the rising drug prices as a result of this new patent regime will lower the access to medicines, especially life-saving medicines, for most Indian people. Whenever we question the issue of public health, two diverging questions arise – that of providing wider access to medicines to all those who need it at affordable prices, and that of granting incentives to invest in the research and development of new therapeutic products.[69] These are issues that are intertwined and can sometimes run contrary to one another both in the short run as well as the long run. This is because a product patent regime usually leads to an increase in drug prices as it gives monopoly rights to some companies who can invest extensively in research and development and thereby destroying competition from generic drug industry.

The arguments made against this regime thus say, following the mandate of the World Health Organization's essential drug policy which imposes an obligation on the governments of all countries alike to bring down drug prices, no such policy can be supported which negatively affects the right to access essential medicines at affordable prices in the developing and least-developed countries.[70] Apart from this, it has been argued that a product patent regime in India should be opposed because it might induce 'evergreening' strategies, i.e. techniques to maintain and extend patent benefits by filing new patents over the process, dosage form, or method of administration rather than the active ingredient itself as observed in the US, which in turn stall the introduction of the patented drugs in the public domain even after the expiry of the original patent protection term, thereby restricting cheaper availability of these drugs by delaying their generic production.[71]

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69 Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, Innovation Policy and the Economy, Vol. 3, 2002, 4.

70 *See* Sajeev Chandran, Archna Roy & Lokesh Jain, *Implications of New Patent Regime on Indian Pharmaceutical industry: Challenges and Opportunities*, Journal of Intellectual Property Rights, Volume 10, No. 4, July 2005, pp. 273, 274.

71 Discussion Meeting on: EU Competition Commission's Report on The Pharmaceutical Sector: What Lessons for India, August 7, 2009, New Delhi, available at http://www.centad.org events_56.asp (Last accessed on June 15, 2012).

As a result of all these negative arguments, most Indian pharmaceutical companies opposed the passing of this amendment and this new patent regime, while the Indian Drug Manufacturer's Association (IDMA) specifically warned that this kind of a strengthened patents regime could have adverse repercussions for the drug industry and consumers in India.[72]

But the Indian pharmaceutical industry has been thriving on 'reverse-engineering' since 1970. A gestation period of 35 years is sufficient to gather enough foothold in the industry to invest in R & D. also India boasts of the most comprehensive compulsory licensing regime in the world.[73] In spite of the loopholes in the compulsory licensing provisions, it is imperative that innovation is encouraged and not reverse engineering. Thus, in the Indian context, a stronger patent regime was required for spurring innovative drug manufacturing activities within the country rather than merely producing copied versions of branded drugs through reverse engineering.[74]

However, in reality, the Amendment has had huge positive progress as well. With increased investment in research and development, and along with that collaboration, mutual licensing, mergers and acquisitions coming up galore, it indeed seems that the Amendment has increased access to medicine, by allowing foreign medicinal research to be shared in India and Indian indigenous research to be shared outside.[75]

All the questions and issues with respect to massive price increase in drugs have been silenced because of the very minor increase in costs. According to government authorities, price rise in prices of medicines that are under price control is only 1%, whereas drugs that are not under price control have an average price rise of around 7% in the past decade.[76] Thus, we can see that the drug prices have not risen dramatically post- 2005. The reasons for this can be attributed to the change in the face of Indian Companies post the Amendment as well as the preventive measures like compulsory licensing and

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72 Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformationof India's Patent System and the Rise of Indian Pharmaceutical Innovation*, University of Pittsburgh Law Review, Vol. 68, 2007), p. 540.

73 *Id.*, p. 580.

74 *Id.*, p. 496.

75 Corporate Catalyst of India, Report on the Indian Pharmaceutical Industry, available at < http://www.cci.in/pdf/surveys_reports/indias_pharmaceutical_industry.pdf> (Last accessed on June 15, 2012).

76 Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry,* United Nations University-Institute for New Technologies (UNU-INTECH) available at http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf (Last accessed on June 15, 2012).

stern price control measures imposed by the Government. This, in effect, implies that not only has the access to medicines increased post-2005, but also access to a diversity of medicines. Thus, the right to health as envisaged by the Constitution and as illustrated by this Amendment is justified.

VI. Conclusion

India is a developing country with a vast population, most of it below the invisible line of safety from disease and qualitative healthcare standards. Despite its remarkable progress in various fields with respect to technology and innovation and its excellence in intellectual capital, there are very grave public policy questions that face administrators today. The need to guarantee qualitative healthcare to its masses is more than just an election promise. It forms a part of the core fundamental rights guaranteed to the individual under the Indian Constitution. Even on the international level, there are various instruments that India is signatory to that make imperative the basic human right to health such as the UDHR, ICESCR and others. This is in stark contrast with India's obligations under the TRIPS and the patent protection norms that come along with it.

India has a flourishing domestic industry in generic drug manufacturing, present mainly due to the protection from patentability provided to it thus far by the Indian government. But this has all changed with the introduction of the 2005 Amendment Act that brought India in line with the TRIPS regime and made it accountable to intellectual property considerations. Thus, India has a decision to make with respect to the future of the patent regime in its country, and the questions of access to medicines for its masses.

The quest to balance out competing interests should not be held hostage to the relative importance of these competing interests. While fulfilling its obligations under the TRIPS is definitely a responsibility of no small significance, India needs to consider the much more staggering responsibility to it in allowing access to medicines, in pursuance of its welfare objectives for the common man, to whom it has guaranteed the basic human and constitutional right to health.

The revolutionary 2005 amendment to the Patents Act, 1970 was brought in to give effect to the mandate of the TRIPS Agreement by effecting a shift from a mere process patent regime to a product patent one with respect to pharmaceuticals in India. Now, since pharmaceuticals is a special kind of products having a significant bearing on people's lives in modern days, especially so because of the growing AIDS concern and the higher demand of life-saving medications in developing countries, imposition of a stronger patent protection

regime for pharmaceutical products in any developing country like India has to face the challenge of striking a delicate balance between protection of long-term investment in the pharmaceutical industry and keeping essential medicines available to the general public at affordable rates. The 2005 Act has very tactfully achieved this fair balance by imposing a product patent regime thereby strengthening the scope of pharmaceutical patent protection in India, while making maximum use of the flexibilities offered by the TRIPS Agreement. Thus, the amended Patents Act has an effective opposition system for challenging frivolous patents, limited patentability exceptions, elaborate provisions pertaining to effective compulsory licensing, and parallel importation facilities. As a result, the post 2005 pharmaceutical industry has witnessed a tendency to invest more in research and development by both domestic and international pharmaceutical companies and a paradigm shift of focus from a generic drug industry to an originator one. This, therefore, leads to the conclusion that the new patent law in India is full of the required potential for taking the balance between stronger patent protection and public health to newer unachieved levels subject to the effective utilization of the provisions of the new law. The effective cultivation of this potential however, remains to be seen.