Optimal policy for biopharmaceutical drugs innovation and access in India

Paper to be presented at Globelics Academy 2008 on Innovation and Economic Development at Tampere, Finland, June 2nd to 13th

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Introduction

Useful inventions in the field of biotechnology have contributed significantly in recent years for the benefit of humanity as many different technologies in chemistry and biology are being combined to develop new therapeutics.1 For example, advances in the recombinant DNA technology, study of the cell growth, gene therapy proteomics, and bioinformatics contribute to the development of proteins can provide cures for many chronicle and hereditary disease as Alzheimer disease.2 These inventions are important for a country like India where there is widespread of these diseases. At the same time investment for these drugs innovations is negligible, therefore availability through technology transfer from the multinational innovator companies are desired. The empirical finding shows that there was negligible investment through foreign technology transfer too for the neglected diseases drugs innovation in India even after the TRIPs regime. Although after the introduction of product patents in India has enhanced the innovator's incentive to innovate but still multinational biopharmaceutical companies have been vociferous with regards to higher patent standards and data exclusivity provisions in the Indian patent laws in order to transfer their technology in India.3 In the absence of such provisions they are reluctant in introducing new drugs in India. In biotechnology sector, discovery of entirely new drug takes years and costs million of dollars, where as the copy of the same can be manufactured in very little time and in fraction of the money spend in the discovery of new drugs. In biotech innovation only 22 percent of drugs that enter clinical trials eventually receive FDA approval.4 Also, it costs about $400 million, on an average, in out-of-pocket expenses to develop a new drug.5 Thus, in order to recoup the high and rising costs of biotech R&D, inventors need to capture enough of the economic returns to make their investment worthwhile through stronger patent protection. As patents grant an exclusive right to exploit a specific product or process for a set period of time, which protects new products from competitors, and enable exclusive right to market.

Thus, stronger patent protection is crucial for the commercial success for the biopharmaceutical companies as they sustain the large and risky R&D expenditure needed for the product innovation.[6] It also enables them to recoup the significant investments they have made in developing and discovering the new products

[1] http://www. Bvgh.org accessed on 29th Oct 007
[2] ibid;1

[3] Rashmi R, Indian biopharmaceutical industry in the era of globalization: Path for novel drug industry in the Book titled "Genetically Modified Organisms: Emerging Law and Policy in India" published by TERI Press, New Delhi Sept 2007.

[4] J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics 22, no. 2 (2003): 151–185.
[5] ibid; 4
[6] Lall, Sanjaya, 2003. "**Indicators of the relative importance of IPRs in developing countries**," Research Policy, Elsevier, vol. 32(9), pages 1657-1680, October.

and processes and bringing them to the market. Further, patent protection enables companies to generate sufficient income to support future research and develop new products. Patents, therefore, are the lynchpins of the biopharmaceutical industry.[7] Thus, from the private interest point of view, patents are important as a reward to the innovator to stimulate private investment for research and development, which leads to economic growth.

As discussed before, the importance of biotechnology is unquestionable as biotechnology research has much to promise human society. Beyond the obvious benefits of biotechnology tools, such as genomics promise to increase the pace of target molecule validation, which will in turn shorten the time required to develop a number of drugs for the same disease.[8] Also, there are many practical applications that are beneficial to human society directly. Rare blood types might be created from specialized use of biotechnology. Paralysis from spinal cord trauma may be reversible by using stem cells to replenish damaged and severed nerve cells in the spinal column. Also there are chances that badly needed organs will seemingly be by the application of biotechnology Damaged skin from fires and accidents can be replaced with skin tissue that is grown in the lab from the patient's own stem cells; perhaps even severely scarred tissue from fires can be healed by injecting the damaged skin with potent stem cells**.**

Such necessary technology needs to be developed by putting more and more investment into R&D and transferred to developing countries to reduce the spread and impact of disease which improves socio economic standing of the improvised populations.[9] Now question comes up that if the potential is so great of biotechnology research, then what is all the opposition and controversy for? Actually patenting of DNA sequence is related with the blueprint of life. So, several moral and ethical issues are attached with the patenting of the same.

Also, there are issues like accessibility which have been raised by the health advocates with regard to strong patent protection to biopharma products. They have showed their concern about the impact of the higher patent standards and data exclusivity on access to drugs. As price increase shall be a regular feature and not an accident of strengthening of patent protection in developing countries.[10]

Thus, there are challenges related to research and development, creation of investment capital, technology transfer, patentability and intellectual property, affordability in pricing, regulatory issues and public health, morality and ethics. Central to this are two key factors: innovation and accessibility to the products of biotechnology. Policies that foster a balance between innovation and facilitating technology diffusion need to be put in place. The demanding TRIPS provisions for stronger patent protection are not to be read in isolation. They have to be interpreted in the light of other provisions found in the preamblular Article 7 of

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[7] Tabitha Parker, *Biotech companies call for patent reform*, Managing Intellectual Property, 2001.

[8] The Biotechnology Promise Capacity-building for Participation of Developing Countries in the Bioeconomy, UNCTAD/ITE/IPC/2004/2

[9] Evenson, R.E. and L.E. Westphal. (1995) Technological change and technology strategy. In J. Behrman and T.N. Srinivasan, eds., Handbook of Development Economics; Amsterdam: Elsevier Science.

[10] Correa.C; Implementing the TRIPs Agreement; General context and implications for developing countries, Third World Network, Penang, 1998

the text. The text attempts to balance the rights and privileges of the patent holder with his obligations and responsibilities to the society. This is succinctly stated in the preamble which takes into account the need to promote effective and adequate protection of IPRs but at the same time stresses the need to ensure that measures and procedures to enforce IPRs which do not themselves become barriers to the legitimate trade. In theory, patents work by providing the inventor an incentive to invent in the first place and then to disclose. Disclosure to the public is rewarded by giving the inventor a monopoly. Striking the right balance between incentive and public access creates a tension that must be carefully balanced.

Therefore this study suggests optimal policy (Patent and other regulations) to have a balance between biopharma drugs innovation and their access in India while complying with the provisions of the TRIPs agreement. The paper discuss optimal scope of biotech patent in maintaining a balance between free flow of technology and access to drugs, it advances the notion that a patent is not the only legal right that influences innovation and access but rather a collection of other independent variables too that have impact on the incentive to invest in innovation. Altogether these variables can be broadly categorized as (1) patent policy such as the scope of biotech patents and the extent of the right in terms of breadth and length; and (2) regulatory environment such as the taxation incentive, Investment policy, Government initiative for the development of this sector etc.

This chapter focuses on optimal policy for biopharma drug innovation and access to drugs by taking into account essential part of the controversy with regard to biotechnology patent on the compliance with the provisions of TRIPs. Also, it throws light on the Indian drug regulations, fiscal and trade legislations to achieve the same.

The chapter is divided into two segments. In the first segment optimal patent policy has been designed in order to have a balance between access and innovation. In the second segment, the paper makes a suggestive analysis of other regulations which are relevant for the technology transfer and foreign investment in Indian biopharma sector. The first part of the chapter scrutinizes the amended provisions of Indian Patent Act and suggests optimal patent length and patent breadth. As for a balanced patent policy, patent subject matter, patenting requirements and patent breadth are three basic tools for policy makers to consider. In order to design a balanced policy which could be used to enhance both innovation and access[11] taking into account inherent flexibilities of the TRIPs provisions have been taken into account as the agreement leaves considerable room for legislating national law.[12] So, the study takes into account the India needs and circumstance, also the flexibilities such as compulsory licensing provision, Parallel importation, bolar provisions etc which are inherent in the TRIPs, for the promotion of the societal interest and provides adequate safeguards and deterrent to prevent and control abuses of patents in an effective, efficient and predictable manner to have balance between both the interest groups. At the same time, the optimal scope

[11] Encaoua, Guellec and Martinez, Patent systems for encouraging innovation: Lessons from economic analysis; Research Policy; Volume 35, Issue 9, November 2006, Pages 1423-1440.

[12] Carlos Correa, Implementing the TRIPs Agreement; General context and implications for developing countries, Third World Network, Penang, 1998

of patent policy needs to be balanced along with the coherent interaction with other regulatory or economic policies in order to attract investment flow in the country.[13] Thus, the second part of the chapter takes into accounts the drug regulations and fiscal policies of Government of India.

I Optimal patent policy for India to balance drug Innovation and access

Scope, is an important measure of the degree of patent protection.[14] The scope of patent is defined by its breadth, its length and by the degree of novelty.[15] The length of the patent protection characterizes the duration of monopoly power; the breadth of patent defines range of products that are encompassed by the claims of the patent. Therefore protects the patent holder against potential imitators.[16] On the basis of the above discussion, this segment is divided into two sub segments: optimal length and breadth of the patent for India. Degree of novelty is included in patent breadth segment. Each will be discussed in the light of the issues in controversies and then take into account interest of both the groups for the suggestion of best suitable option.

A. Optimal breadth for biopharmaceutical patenting in India:

A patent holder has the right to prevent others from making, selling or using the invention protected by the patent, so the *breadth of a patent* is the extent of protection granted to patent holders against imitators and follow-on inventors.[17] In principle, patent breadth is determined by the claims accorded by the patent examiners to the patentee, defining the boundaries between what is protected and what is not, and by the courts interpretation of these claims during litigation procedures.[18]

As mentioned previously, a biotechnology patent could in practice contain product claims encompassing either in the form of substance of cloned genes, recombinant proteins, monoclonal antibodies, plasmids, vectors etc or composition of matter such as multivalent vaccines, pharmaceutical mixtures etc.[19] The scope of biotechnology patenting consists of several factors and the acceptability and non acceptability of the same determines the broadness or narrowness of biotech patents.[20] These factors are: animal and plant patenting, microorganism patenting, patentability of genes and DNA sequence etc.[21]

So, patent claims can have literal as well as broader interpretations. On the scope of biotech patentability currently, two schools of thought exist with different interpretations. The first school states that there is no scientific basis to support the patenting of genes and genomes, which are discoveries at best, while the

[13] Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines;James Love; Consumer Project on Technology; September 22, 2003

[14] Patent and public Health under countries lessons from Japan – Reiko Aoki, Kensuke Kubo, & Hiroko Yamane; bulletin of World health organization; May 2006, 84 (5).

[15] van Dijk, Theon (1996), Patent Height and Competition in Product Improvements, in: The Journal of Industrial Economics 44, 151-167.

[16] Merges, R. & Nelson, R. R. (1990), "On the complex economics of patent scope", Columbia Law Review 90,

[17] Encaoua, Gullec and Martinez, Patent systems of encouraging innovation: Lessons from economic analysis; Research Policy; Volume 35, issue 9, November 2006

[18] Patents and Innovation: Trend and policy challenges; Organization For Economic Cooperation And Development (2004);2004

[19] Applying the patent to living material in India; Robyn Ott, 2004; 2 Okla J.L. & Tech .17

[20] S.J.R. Bostyn; Narrow trousers and narrow patents, a health risk? Product protection or purpose bound protection for biotechnological inventions; Bio-Science Law Review; [2004/2005] 2 BSLR 95

[21] ibid;20

second school states that characterization of genes is not straightforward, so it does constitute an inventive step and therefore should be patentable.[22] Different countries have different practices and following to different schools. In order to find the optimal breadth of patent for India the study takes into account each components discussed before which constitute the scope of biotech patents in the light of the needs and circumstances of India by making comparison of the practices in US, EU. Thus, this segment of the chapter first analyse the Indian patent policy (Indian Patent Act 1970 with all amendments) in the light of requirements of TRIPs agreement and also in order to understand the current scope of the biotechnology patent. Then taking the needs and circumstances of India and compare the same with the provisions of TRIPs agreement, US and EU laws to know the maximum limit to maneuver the same in order to maintain the international patenting standard which should ensure fair and reasonable remuneration to the patent holder, and facilitate prompt transfer and dissemination of technology while maintaining public interest.

Most liberal approach for biotech patents is adopted by Australia as the landmark judgment of Australian patent office (APO) held in Rank hovis Mc Dougall case[23] that living organisms are patentable implying that they are inventible. Other than human beings there is no prohibition in Australian patent Act against patenting of life forms. This liberal approach has been followed by USA if we refer to the landmark judgment of Diamond Vs Chakrabarty[24] which declared inventions related to genetic engineering and living organisms as inventive. The court granted patent to a genetically modified bacterium and held that inventor's claim is not hitherto unknown natural phenomenon but to a non naturally occurring manufacture or composition of matter or product of human ingenuity having a distinctive name, character and use." Looking at the trend of the judicial decisions in US, it can be easily inferred that patent can be granted for developing manufacturing processes of the biological substance which is discovered in the nature and isolated from its source. [25] Thus after the Supreme court decision in Chakrabarty case it became apparent that non naturally occurring organisms that have been man made or man altered satisfy the novelty requirement. The same decision paved the way for patentability of transgenic animal when it qualifies under the standard of novelty. Genes are also qualified to be patented if they are isolated and purified form but not if they are simply in the form in which the scientist discovered the sequence.[26]. So, in US the isolated and purified gene sequences are awarded patent protection in accordance with the novelty standard as per USC 102.[27] On the issue of utility requirement, it is generally assumed that scientist create transgenic animals with a specific use in mind. So, transgenic animals and human gene sequences are clearly useful and utility requirement does not pose a significant barriers to the patent protection. If the patent applicant of gene sequence is capable of showing that his sequence can be utilized for different types of markers, probes and primers for various genetic research then that is enough to qualify the utility requirement under 35 USC

[22] ibid;20
[23] Rank hovis Mc Dougall case; 1978; FSR, 588
[24] United States Supreme Court, June 16, 1980, 447 U.S. 303, 206 USPQ 193

[25] *See* Diamond v. Diehr, 450 U.S. 175, 185 (1980) ("Excluded from such patent protection are laws of nature, natural phenomena")
[26] Matthew Erramouspe, Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races, 43 UCLA L. Rev. 961, 988-90 (1996)
[27] 35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent

101.[28] About the non obviousness requirement, the basic tenets remained the same as for ascertaining the obviousness of an invention, the invention must be viewed in the light of other inventions in the prior art the invention will not be granted a patent. Moreover, in re Duel case[29], the Federal circuit seemed to relax the obviousness standard by stating that general motivation to search for some gene that exists does not make obvious a specifically defined gene that is subsequently obtained as a result of that search. More is needed and it is not found here. This decision allowed patents to be granted for DNA molecules even if the method for finding the DNA was obvious to satisfy the non obviousness requirement. Looking at all the landmark decisions of US on the cardinal principle of patenting, it can be said that the scope of biotech patents in US is quite broad which include the patenting of animals and plants as in Diamond vs. Chakrabarty, the Supreme court held that everything under the sun is patentable if they satisfy the cardinal principle of patenting.

Now, if we take the example of Europe then we will find that although as per Article 4[30] of the Biotech Directive (98/44/EC) animals and plant variety is not permitted for patenting but Article 4.2[31] of the same directive states that inventions which concerns plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. In 1998 the European patent office released a directive and clarified matters related to patentability of biotechnological inventions. As per Article 5 of EC directive (98/44/EC)[32], DNA sequences are patentable subject matter as these are considered as synthetic molecules isolated from the organisms and characterized and produced as recombinant molecules containing the information in the natural genes once if qualifies the cardinal principle of novelty, inventiveness and industrial applicability. In case of Biogen vs. Medeva,[33] the court of appeal ruled that even one miniscule part of the genetic code is responsible for the production of relevant protein and then that circumstance the process of choosing a particular sequence among many is an

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[28] 35 U.S.C. 101 Inventions patentable; Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

[29] re Thomas F. DEUEL; No. 94-1202; March 28, 1995; United States Court of Appeals, Federal Circuit.

[30] 1. The following shall not be patentable:
(a) plant and animal varieties;
(b) essentially biological processes for the production of plants or animals.

[31] Article 4.2 *The following shall not be patentable: (a) plant and animal varieties; (b) essentially biological processes for the production of plants or animals. 2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. 3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.*

[32]
1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

[33] 1997; RPC; 1

inventive step of invention. The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996)[34] establishes that "biological material" and substances isolated from nature (such as new antibiotics) will be considered patentable.[35] European Directive (98/44/EC) provides broader definition of "Biological material" to include "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system" and bring that under the scope of patentable subject matter.

The above discussion was on the practices of cardinal principal of patentability in the policies of USA and Europe, however, the debate has never really been the ability of biotechnology to satisfy the requirements but more contentious debate hovered around the social and ethical aspect of biotech patents regardless of their novelty, utility and non obviousness.

Thus, from the above discussion, it is evident that by making a comparison with US patent laws and European patent law is quite conservative in terms of biotechnology patenting. This basically stems from the fact that UK along with Europe prefer to stick to the notion of not wanting to grant patents which would invoke mixed reactions from different sections of the society. The European Union's patent system has some starkly different rules and regulations regarding patents. Central to these differences is the European Patent Convention's (hereinafter "EPC") statutory moral utility doctrine. On account of the differing structures and level of use of the moral utility doctrine, the US and EU responded differently to biotechnological innovations in general.[36] In fact, the US system adapted more readily and actually promoted biotechnological innovation, whereas the EU system seemed for a time to stifle it. European law tries to strike a balance via the Council Directive 98/44 on the Legal Protection of biotechnological Inventions (hereinafter "Directive 98/44/EC"), which is an attempt to reign in the EPC's strong codified moral utility doctrine. As article 6 of the EPC states that inventions must not violate ordre public or morality.[37] If they do, then citizens are given standing to show that it violates ordre public or morality and can block the issuance of the patent. In many EU member states, unlike the US there are laws prohibiting certain biotech inventions from being patented.[38] Under EPC 52 (4) gene therapy patents are prohibited "because they are not susceptible to industrial application."[39] Unlike the US system, the Article 53(a) of the EPC prohibits patents for inventions that are contrary to the morals of society. This concept is called ordre public gives "automatic standing to concerned citizens, empowering them to challenge individual patents on the ground that issuance would be morally offensive and allowing the use of the judicial process to shape the law regulating bio tech patents.[40] This type of standing, public ordre is not available in the US. The issue of patentability of the animals being against the morality or public order was dealt in Harvard oncomouse case in which patent was granted to a genetically modified mouse carrying a specific called an

[34] Patentable Subject Matter; accessed from http://www.southcentre.org/publications/publichealth/publichealth-04.htm#P327_38330#P327_38330 on 12th Jan 2008
[35] ibid; 34
[36] Jasmine Chambers; Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How Much Patent Policy is Public Policy?, 34 GEO. WASH INT'L L. REV. 223 (2002)
[37] ibid; 36
[38] ibid;36
[39] ibid;36
[40] ibid;36

activated oncogene. Although In EU in Florey/relaxin case[41], it was held that RNA for deriving the corresponding cDNA encoding a human protein was not immoral and neither is the patenting of a DNA fragment unethical. However, the grant of the patent application was questioned on the basis of public order and morality under Article 53 (a)[42] in which it was held that transgenic animal is patentable but denied the patent to rodent species. In principle under EC directive 98/44/EC transgenic plants and animals are patentable in Europe but not plant and animal varieties.

Now after this discussion if we see the provisions of the TRIPs agreement of WTO, required to be complied by India seems to go with EU practices. As the TRIPS provides that patents shall be available for any inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step (non-obvious) and are capable of industrial application (useful). It is important to note at the onset that TRIPS in this regard is similar to the requirements of the EPC. Therefore, it seems that the International community is currently following the EPC in this regard. In addition, article 27 of TRIPS has a statutory moral utility doctrine, again similar to the EPC over against the US patent code. Though US case law shows a general trend towards minimizing the US common law moral utility doctrine, cases minimizing the moral utility doctrine (such as Chakrabarty) were decided before the passage of the TRIPS.

Therefore, it seems that what patent protection TRIPS does provide, resembles the EPC over against the US patent law system. Finally, TRIPS like the EPC provides patents for "technological innovations." In other words, US business methods under the EPC and under TRIPS do not seem patentable, unless they are patents for technological innovations.

Now in the wake of the above discussion, it is important to find out the scope of biotech patenting in India. In order to bring the Indian law in compliance with the TRIPs provisions of Art 27(3)[43] under which the members are under obligation to provide patents for microorganism a new clause to section 3 was added by Patent Amendment Act 2002. This provision excluded from patentability, plants, animals in whole or any part thereof other than microorganisms but includes seeds varieties of seeds varieties species and essentially biological processes for production or propagation of plants and animals. So, invention related

[41] 1995; O.J.E.P.O, 388

[42] European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

[43] Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement

to animals is not patentable in India as a whole. Also, disallows patenting of living subject matter but draws an exception to microorganism patenting. Thus, India recognized the patenting of microorganism by Patent Amendment Act. Although the landmark judgment of Dimminiaco AG vs. Controller of patents[44] had paved the way for microorganism patenting way back in 2001 in which it was held by Kolkata high court that the biotech matter as patentable even if the end product of a process is a living virus/ microorganism / living entity. Further the court affirmed that the patent claimed was useful as it protected poultry against contagious disease and the end product resulted in a new article. The court came out with 'vendibility test' as the most effective test to determine whether the process of manufacture ought to be patentable or not. As per the court, a vendible product is one that can be commercially transacted. Thus, a more flexible attitude had been shown. A year after the decision of this case microorganism got the validity to be patented by the Patent Amendment Act 2002. Thus we can make out that although Patent amendment Act 2005 has accepted living entities of artificial origin such as microorganism and vaccines which fulfills the cardinal principle of patentability and not harmful to human, animal or plant health or unethical. Presently there is controversy with regard to the definition of microorganisms as there is absence of a working definition of microorganism in the TRIPs text. In the absence of the same, there are difficulties to clearly differentiate the microbes claimed from the naturally occurring microbes and show that the biological material is an outcome of invention and not a mere discovery. In the wake of the same, a key question comes up – whether India should adopt a very narrow and limited definition of microorganism to exclude everything other than microscopic organisms including algae, bacteria, fungi, protozoa and viruses or whether it should expand the scope as in the Europe where all biological material containing genetic information and capable of reproducing itself or being reproduced in a biological system? It is in the interest of India to opt for the higher life form patenting by choosing expanded definition of microorganism by biological material and include DNA fragments, genes and proteins to keep pace with the advances of biotechnology and broader definition will give companies reasons to expand their research in these areas and ensure that research will continue. The same cardinal principle of novelty, inventive step and utility should be satisfied in order to patent a microorganism. For novelty criterion to be satisfied, the microorganism should be isolated from the nature for the first time.

At the same time to have proper check in order to maintain the morality and ethics, the need to be a properly and efficiently framed legislation based on moral utility doctrine similar to Article 53 of EC Directive 98/ 44. In this regard it is apt to mention that Government of India has formulated ethics policies to harmonize with Ethical Guidelines for Biomedical Research on Human Subjects developed by the Indian Council of Medical Research in 2000. The Ethics committee set up by the Government of India covers the areas of basic research, genetics, genomics, and education and legal aspects. Also it is important to mention about the Government of India's recent policy on stem cells which is directly linked with morality and ethics. In India, the new stem cell policy which came into force last year has put in place a mechanism for

[44] Dimminaco A.G vs Controller of patents and others, AID No. 1 of 2001, Jan. 15, 2002

greater private participation and compliance. Review and monitoring of stem cell research has been decentralised at the institutional level. Stem cell research and its funding have been classified into three levels — permissive, restricted and prohibited.

"Permissive researches are disease-specific and are being addressed locally at institutional levels. Restricted and prohibited level proposals are to be referred to the central committee and this addresses broader issues like cloning, cell-based engineering and works on reproduction," According to the Policy, stem cell research should be promoted in the country in the view of its potential for clinical use. Research based on stem cells derived from adults, bone marrow or foetal cord blood may be undertaken after obtaining appropriate informed consent and with adequate safety measures. For embryonic stem cell research, embryos should not be generated for the sole purpose of obtaining stem cells. Only surplus, spare or supernumerary embryos can be used after obtaining informed consent of both spouses. Such collection of embryos should be done only from registered Assisted Reproductive Technique (ART) clinics. To safeguard national interests, it is also perceived that all human genetic research, stem cell research and stem cell research involving international collaboration must be undertaken after formal clearance of the national government. Consent form for use in collection of tissue to be used in human stem cell research has also been prepared by the National Bioethics Committee. This policy of India shows that Government of India is liberal towards the biotech innovation at the same time by keeping proper check on the practice so that they should be done maintaining morality and ethics.

Overall, from the above discussion we can make out that in recent years Indian patent legislation has broadened the scope of patentability for biotech products but still not as broad in scope as Australia and US. The scope of biotech patent should be designed in the similar line as EU by keeping the scope broader by extending the same to more biotechnological applications, once they satisfy the cardinal principal of patentability with in the framework of TRIPs. Along with broader breadth of patent, there is need to formulate strict morality provisions in the same legislation. In this regard a very active role of judiciary is desirable also efficient and judicious members in the courts are highly recommended.

Now, we will discuss another controversial aspect of India's Patent Act which is related with the breadth of the patent such as exclusion from patentability for derivatives of known substances, unless it can be shown that they are significantly more efficacious than the original substance (India Patents Act, §3(d)).[45]
On August 6, 2007, on a writ petition filed by Novartis AG and its subsidiary, Novartis India, challenging the legal validity of Section 3 (d) [46] of the Indian Patents Act (IPA). Challenge was done by Novartis AG and its subsidiary on the ground that Section 3 (d) denies its rights under Article 27 of the TRIPS

[45] Section 3 (d) reads: '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 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.
[46] ' *Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.*'

Agreement, which obligates WTO member states to provide patent protection to all fields of technology without discrimination, and therefore violates the obligations under the TRIPS Agreement. Second, it argued that in the absence of a definition or guideline, phrases like 'enhancement of the known efficacy' or 'differ significantly in properties with regard to efficacy' give uncontrolled as well as unguided powers to the Controller of Patents. The same would result in an arbitrary exercise of power, and violates the right to equality under Article 14 of the Constitution of India. On the issue of non compliance with TRIPs the court refused to examine whether Section 3 (d) violates the obligations under the TRIPS Agreement[47] and rejected Glivec patent application on the ground that a patent cannot be granted for "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." While making the decision the court equated the meaning of efficacy with a therapeutic effect on the body, the court also accepted the argument of the respondents that "… petitioner is not a novice to the pharmacology field but it being pharmaceutical giant in the whole of the world, cannot plead that they don't know what is meant by enhancement of a known efficacy and they cannot show the derivatives differ significantly in properties with regard to efficacy". the court further held that "… in sum and substance what the amended section with the explanation prescribes is the test to decide whether the discovery is an invention or not is that the patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy". Hence it was held that a patent applicant has to show enhanced therapeutic effect in order to obtain a patent for a new form of a known substance or for its derivatives. So, what the patent applicant is expected to show how effective the new discovery made would be in healing a disease/having a good effect on the body". Patenting of drugs, the protection to various forms of same substance (salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixture, etc.) is often seen as 'ever-greening' (extending incremental protection to a subsisting patent) and hence such protection is objected. As on denial of patent grant to derivatives of known substances unless there's proof they differ in terms of 'efficacy' can be denial to a demonstrably new and better version of an existing drug. Due to this many genuinely better drugs are actually improvements on existing formulations.

Ever-greening refers to an extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product, 'incremental innovations' are sequential developments that build on the original patented product and may be of tremendous value in a country like India. Incremental innovation has value not just in improving therapeutic efficacy, but also in providing significant benefits in terms of drug delivery, patient safety and compliance. Therefore, such incremental development needs to

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[47] and held that "*…this court has no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of TRIPS, we are not going into the question (of) whether any individual is conferred with an enforceable right under TRIPS or not. For the same reason, we also hold that we are deciding the issue namely, whether the amended section is compatible (with) Article 27 of TRIPS or not*".

be encouraged by the Indian patent regime. Incremental innovation should be patented but not frivolous patents so that patent officials can differentiate between frivolous patents and incremental patents. As far as the implication of the judgment is concerned, it suggests that the meaning of the term 'efficacy' should be judged in light of the therapeutic effect of the new form on the body. The judgment accepts patent for incremental innovation only where the cardinal principal of patent is satisfied as a combination of two drugs may offer substantial improvement in therapeutic effect and may be held patentable. Thus it can be interpreted that instead of placing Swiss claims outside the purview of patent protection, the judgment allowed such claims in limited circumstances. As, the application of therapeutic effect as a standard for efficacy does not rule out the possibility of incremental innovation but in a limited way which needs to be broadened. For instance, a combination of two drugs may offer substantial improvement in therapeutic effect and may be held patentable. This should be further broadened and it is recommended that patents on salts, esters etc. should indeed be granted if such products meet the internationally accepted conditions of novelty, involving an inventive step, and capable of industrial application (TRIPS Article27(1)) in order to have better flow of investment in India. Allowing broader patents on biotechnology will encourage investment in studies for valuable search to combat diseases. This is good for the progress of science and ensures balance between the interests of the consumer and the innovator.

Broader patentability will act as incentive because biotechnology is a high risk and a high cost form of research which ultimately improves public health and Indian patent standard will in the line of international patent standard. So, it will gain confidence of the investors.

B. Optimal length for biotechnology patent in India

The length of the patent protection characterizes the duration of monopoly power. By the patent (Amendment) Act 2002, India implemented the TRIPs required 20 years patent term as an obligation to WTO as its member to comply with Article 33. Prior to 1999, Indian law provided for relatively short patent terms for pharmaceutical processes term was only five to 7 years. So, the length of the pharma patents has been increased after the 2002 amendment to Indian Patent Act 1970 which is fixed.

Maximum duration of protection is decided on a case to case basis which varies in different sectors. So, it is not possible to know with any certainty what, exactly, is the optimal duration of protection for any particular invention. For the pharmaceutical products, the requirement for Government regulatory approval to market pharmaceuticals limits the effective life of the patent monopoly. Thus longer patent protection is desirable also because biopharmaceutical industry is highly technical and investment intensive. So, the duration of patent should be maximum in order to promote investment for the innovation. In this context we will discuss issue in controversy which is with regard to data exclusivity and Article 39.3 of the TRIPs text. Although data exclusivity or protection is part of drug regulation but it is discussed in this section as it can be termed as the substitute of patent life. There is demand of data exclusivity by the MNCs for having law to protect the clinical trial and other data used to obtain marketing approval of new pharmaceutical products in order to comply with TRIPs provision. Data Exclusivity is a period during which Government

health authorities respect confidentially of data submitted to them for a fixed period of time. During that period, regulatory authorities may not disclose or rely on test and clinical trial data of one company to grant marketing approval for generic drugs.[48]

The multinational pharmaceutical firms claims that TRIPs provision requires "data exclusivity," therefore India should implement data exclusivity legislation. However, generic pharmaceutical companies have been advocating 'new chemical entity' to be defined on the lines of novelty under the patent regime, while the pharma MNC have been advocating a definition to mean a new pharma product which has been introduced for the first time in a country irrespective of the fact whether it is patented or not.[49] Another controversial matter is that what constitutes 'unfair commercial use' under Article 39.3.[50] In US and EU any use of data submitted by the originator, for granting approval to a subsequent applicant without the authorization of the originator of the data must be considered as unfair commercial use. So there is an obligation for granting the originator of data a period of exclusivity during which national authorities would not be permitted during the exclusivity period to rely on data they have received in order to assess subsequent applications for the registration of similar products.

As per the scholars of developing countries Article 39.3 does not require the recognition of exclusive rights, but protection in the frame work of unfair competition rules.[51]

Bringing solution to the different and opposing views and interests of public health and strong IP protection is important. The predicament before the developing countries like India is how to strike a fine balance between public health and the demand of increased IP protection. Before attempting to analyze these issues it is important to understand the meaning of 'data exclusivity, its genesis, impact on drugs and the reasons for conferment of this privilege. As per Article 39.3, if in respect of pharmaceutical or agricultural chemical products which utilize a 'new chemical entity', the regulatory authority of a country requires submission of 'undisclosed clinical and test data' for granting marketing approval it is under obligation to protect the data against 'unfair commercial use' and also to protect the data against 'disclosure' where it is necessary to protect the public or unless steps are taken to ensure that the data are protected against 'unfair commercial use'.

The disclosure is permitted only in case to protect the public and secondly, where the data is protected from unfair commercial use. Thus, we can make out from the content that individual members can take steps as they deem fit for protecting data against 'unfair commercial use'. The purpose of Article 39.3 can be

[48] Data Protection: Emerging Trends, Deepu M. Accessed on 3rd March 2008 http://www.vidhiglobe.com/Data_Protection_1_.pdf

[49] ibid; 48

[50] Members when requiring as a condition of approving marketing of pharmaceutical or of agricultural chemical product which utilize new chemical entities, the submission of undisclosed test or other data, the originator of which involves considerable efforts shall protect such data against disclosure, expect where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use"

[51] ibid;48

inferred from paragraph 1 of the same article that is to '*ensure effective protection against unfair competition'*. Article 39.1 provides-

In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 below with data submitted to governments or governmental agencies in accordance with paragraph below.

'Unfair commercial use' is not defined in the agreement thus there are different interpretations. The term 'unfair competition' has been defined in article 10bis of Paris Convention but that does not identify the actual practice of 'unfair commercial use.

Article 6 of the WIPO model on protection against unfair competition provisions lays down the acts that would amount to unfair competition in respect of secret information, as it says:

Article6 (1) -*Any act or practice, in the course of industrial or commercial activities, that results in the disclosure, acquisition or use by others of secret information without the consent of the person lawfully in control of that information (hereinafter referred to as "the rightful holder") and in a manner contrary to honest commercial practices shall constitute an act of unfair competition.*

Two points emerge from this general principle, firstly the disclosure, acquisition or use of the secret information must be without the consent of person lawfully in control of that information and secondly it must be in a manner contrary to the 'honest commercial practices'. Thus, the protection is to be granted against "unfair commercial use" of confidential data. Thus, Article 39.3 does permit a national regulatory authority to rely on data in its possession to assess subsequent applications, relating to the same drug, since this would not imply any "unfair commercial use."[52].

Although the TRIPs text only speaks about the data protection against unfair commercial practices but at the same time such protection is desirable for country like India in order to attract continuous foreign investment to step forward towards the path of novel drug industry. A the Satwant Reddy Committee[53] constituted by Government of India has also recognized that not providing data exclusivity for pharmaceuticals could adversely impact FDI and discourage the launch of new products in India.[54]

So, it can be said that it is a good move on the part of the Government by recognizing the importance of protection of the confidentiality of data against its unauthorized use in order to protect the proprietary interests of scientists and to maintain the economic incentives for further pharmaceutical research and development by more inflow of foreign investment. The government must seek a middle path and provide

[52] TRIPS and Public Health, Paper submitted to TRIPS Council, 29th June 2001, IP/C/W/296

[53] Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement; Reddy Satwant 2007,

[54] Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement; Reddy Satwant 2007,

five years of data exclusivity either starting from the date on which the company markets its product or ending with the expiry of patents whichever is earlier provided that company must have filed a patent in India. Five year of exclusivity seems to be ideal to attract investment. Such legislation is important in order to give strong competition to the competitors like China which gives 6 years of data exclusivity by creating an environment which will attract foreign investors. According to National Institute of Health, lack of data exclusivity in India is the primary reason of India remaining at 9th position whereas china ranked 2nd in funding given by the NIH outside the US.[55] Also as per Pfizer India, the lack of data protection is part of the reason that "people are talking about India but investing in China.[56]

As investors in the field of bio medical sciences or biotechnology look for the country where their intellectual property (IP) enjoys the best protection, and where the environment is most conducive to the creation of new IP. The implementation of DE will support and accelerate the development and growth of biotech industry as it will be key to pharmaceutical companies' decision on the location of clinical trials. India presently has the brain power and economic advantages to carry out clinical trials in local hospitals other public research institutes. Having experience in conducting clinical trials is already a competitive advantage for India to increasing foreign direct investment in pharmaceutical sector. In many instances, a patent will cover the discovery at hand. However, more and more compounds which are not patent protected are being developed and thus in these instances data exclusivity is the only available intellectual property protection. DE would actually allow for more products to be available in the pipeline for generic companies. After DE period expires, the data becomes public domain and can be referenced by generics companies.

So, in order to attract foreign investment for biopharma drug innovation five years of data exclusivity is needed as this will gain the confidence of the foreign investors to invest in India and will give edge over its competitor China.On the other hand it is apprehended that implementation of data exclusivity will bring devastating effect for the India biopharmaceutical industry which basically has a generic base. On this issue it should be kept in mind that India is different from the other developing countries in various aspects. India has a well-developed Pharmaceutical industry, which has already put stable feet in US generic market. Also, India has good outsourcing opportunities for clinical trials, R&D and technical services. India has highly trained scientists. Thus, we can make out data exclusivity for attracting innovations and for the development of industry Indian manufacturers generally work on off patented molecules and will keep on working on off patented molecule as around $ 72 billion worth drugs will go off patented between 2006 and 2010.[57] Indian generic manufactures will continue manufacturing and marketing of generics into the vast and profitable US market. So, there will not be any adverse effect on Indian Generic industry (see

[55] Data Exclusivity; The Indian Perspective, Manisha Singh Nair, Lex Orbis; 21/09/2004, Mondaq publication
[56] KPMG Report 2006, 18
[57] Does the new Intellectual Property regime impede innovation in developing countries: A case study of the Indian pharmaceutical industry; Moutshi hati (2006); http//www.globelicsindia2006.org /Moutushi%20 hati.pdf, accessed on Feb17th 2008-05-29

table: 1). In this way it can be concluded that exclusivity of data for suggested period of time can work as pull factor in enhancing the biopharmaceutical innovations.

Also, for having a balance towards public health, Government of India has included section 107 A (a)[58] of the India Patent Act 2005, so called bolar provision to allow generic manufacturers to start producing a patented drug in limited quantities during the period of the patent for collecting data submitted to a drug approval authority. This exception enables generics to enter the market soon after the patent expires.[59] Bolar provision will enable smooth flow of technical skills and knowledge which in turn will give boost to the domestic companies to invest in research. At the same time, the empirical data is not clear whether data exclusivity definitely has adverse impact on the prices of drugs. The multinational Pharmaceutical companies practice the policy of differential pricing that is to say that the prices of the drugs vary from country to country depending on the purchasing capacities of the consumers.

Other than this the flexibilities, which are inherent in TRIPs like compulsory licensing under Article under Article 31[60] or the parallel importing from other countries, can always be used as a tool for making the drugs more affordable in cases of emergencies and on the grounds permitted by the TRIPS agreement. Compulsory Licensing is "*an authorization given by a National authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights*":[61] (detail in the next section).

Thus, 20 years of patent protection is fine for giving incentive for the innovation as at least the innovator will get 10 years of effective patent life to realize his money. This will be more efficient if it is combined with 5 years of Data exclusivity against misappropriation as data exclusivity will bring more confidence in the minds of the investors to invest in India. At the same time we should remember that not only the longer patent length will make patent length optimal as biopharma sector is related with enormous social value.

For the optimal patent design there is a need to have flexibility for the curtailment, of the monopoly during the duration of patent protection of 20 years in case of extreme social need or national and the biopharmaceutical sector is connected with the health of the people. For the same, efficient use of compulsory mechanism is permitted by the TRIPs agreement under Art 31. Under licensing mechanism, Government permit persons other than the patentee to use a patented invention prior to the expiration of the

[58] any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.

[59] Shamnad Bashir; India's tryst with TRIPs: The Patents (Amendment) Act, 2005; The Indian journal of Law and technology, volume 1, 2005

[60] Other Use Without Authorization of the Right Holder where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government.

[61] Correa, Carlos. 1999. *Intellectual property rights and the use of compulsory licenses: options for developing countries*. Trade-Related Agenda, Development and Equity, Working Papers, South Centre, Geneva.

patent without the consent of the patentee, where the national interest so requires in case of national emergency or extreme emergency. Hence, by the compulsory licensing mechanism the maximum duration of patent protection can be reduced.[62]

Effectiveness of Compulsory Licenses (CL)

In order to know the effect of compulsory licensing on India we will take into account the example of Thailand and Brazil who have used this compulsory licensing mechanism. Then we can make out the effectiveness of compulsory licenses in curbing the negativity of the broader patent protection such as high prices of the drugs.

Lets discuss Thailand's example first. The first set of Thai compulsory licenses was issued after the negotiations with patent holders for affordable prices failed. In late 2006 and early 2007, Thailand took active steps to promote access to medicines for its people, when it issued a compulsory license on two HIV drugs and one Heart disease drug. In January 2007, compulsory license for Kaletra Patented by Abott, and Plavix pretended by Sanofi Aventio These actions are seen as the most serious attempt to date to override patents[63] Abott initially responded by withholding a number of new medications from the Thai market including the heat stable form of Kaletra. The company has since offered the medicine to Thailand and 39 other countries for US$ 1000/patient/year, although it continues to withhold other medications.

As a result of compulsory license, Merck immediately cut the price of first line antiretroviral clavirez from 1400 baht /bottle to 767 baht/bottle in Thailand and slashed the prices for of other developing countries too.[64] Abott laboratories cut the price of second line drug lopinavir / ritanavir and a heat stable form of the same drug that does not require refrigeration, to $ 1,000 / month from $ 2, 200 / month for 45 lower and middle income countries.

Thai Government has also issued 4 compulsory licenses for 4 cancer drugs Doceteral, Letrozole, Enlotinib, Imatinib. After this, Thailand has finally issued three CL on Docetaxel, Letrozole and Erlotinib to allow universal access to essential medicine for all beneficiaries of the publicly financed national Health Security System. Novartis made a last minute offer to the Thai Government to provide Glivec free to all patients index the universal healthcare scheme as a trade off for not seeing its patent overridden.

In this way seeing the Thailand practice we can conclude that compulsory license is an effective mechanism to curb the high prices of the drugs as a result of stranger patent protection and a balance between innovation and access.

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[62] Shanker A. Singham, *Competition Policy and the Stimulation of Innovation:TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 363, 388-89 (2000).

[63] TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines? Vanessa BradfordKerry, Kelley Lee Globalization and Health, 3:3, 24 May 2007

[64] Thailand Presents Report On Compulsory Licensing Experience by Tove Iren S. Gerhardsen; Intellectual Property Watch; 12 March 2007

After Thailand, we take the example of Brazil. In case of Brazil threat of compulsory license pressured pharmaceuticals trail companies like Abott Merck and Roche (manufacturer of Lopinavir, indinavir, melfinavir and saquinavir respectively) to substantially reduce the price, thus enabling 100,000 people to receive free treatment.[65] On the precedents around the world particularly in Brazil and Thailand, where drugs that are used for HIV therapy have been grated compulsory license and successfully used to bring down the prices of the drugs (See Table: 2). It will be interesting to find whether the same thing can happen in India? Although India has yet to use compulsory license but it is apt to mention about Indian firm Natco pharmaceuticals plea for the country's countries first 'compulsory license" to patent office as it bids to make generic' copies of pfizer's sutent and Roche's Tarceva cancer drug. One drug called erlotinib was patented in India last year by Swiss manufacturer Roche under the brand name Tarceva. The other is also a cancer drug called Sunitinob and is sold by US manufacturer Pfizer under the brand name Sutent. The case is still in the court but if Natco gets the verdict in its favour then that will be the first such case.

In case of Hoffman La Roche Ltd Vs. Cipla ltd[66] the court denied the injunction and held that the cases of medicines specially the life saving drugs such as Erlotinib is granted then the court in effect be stifling with Article 21 so far as those would have or could have access to Erlotinib and court can not be unmindful of the right of the general public to access life saving drugs by issuing injunction. As a result of which the foreign drug makers plan to offer medicines at different tiers of prices for Government supply, patient access programmes, and hospitals in rural areas. The companies such as Pfizer are developing a three tier price model for their anti cancer drug sutent.[67] Thus, medicines are likely to be affordable. MNCs may adopt the same prices in their Indian markets as in their foreign markets. In this case, Roche filed a case against Indian generic company Cipla in early 2008 for seeking permanent injunction for restricting Cipla from manufacturing, offer for sale, selling and exporting the drug evolution. The prices of generic version of Cipla drug was 1600 tablet while the Roche price in the Indian market is Rs 4800/tablet.[68] So, looking at these examples it can be said that in India too compulsory license can be used as an important tool to bring down the price and maintain the balance between innovation and access. Also if we also take the example of Novartis case (the famous glivec case) then we will find that when the case was pending in the court Indian Health Minister asked Novartis to withdraw the case otherwise Government will take resort of compulsory licensing. At that time Novartis did not take back the complaint but after the adverse judgment of the Chennai High court, the decision of not going for appeal to the Supreme Court can be understood that the threat of compulsory license worked. Seeing the abovementioned example of perceived threat of compulsory license worked in bringing down the drugs prices it can be said that even the threat of CL works in bringing down the price of the drugs even without actual imposition. Although the imposition of Compulsory license has certainly worked for making the drug affordable (See Table: 2 highlighted once are

[65] ibid;63

[66] In The High Court Of Delhi I.A 642/2008 IN CS (OS) 89/2008 19.03.2008
[67] Roche vs NATCO: India's First "Doha Style" Compulsory License? January 16, 2008
http://spicyipindia.blogspot.com/2008/01/roche-vs-natco-indias-first-doha-style.html accessed on February 18 2008
[68] ibid;66

the threats of CL). We saw in the abovementioned examples successful usage of Compulsory license by developing country like Thailand and Brazil. The decision of Cipla case reflect that judiciary can play a vital role in balancing access and innovation by protecting unfettered monopolies on the vital medicines and also balancing between Indian obligation to global trade laws and constitutional and human rights obligations.

On the other hand at the same time, there is another dimension of this issue as the drug companies worry that countries will abuse compulsory business, employing there in the absence of any public health crisis, simply because the Government wants to pay less for the drugs. But it is interesting to note that non of the interviewed generic accompanies were really interested in using section 92 A[69] as they did not think that the margins would have been great and most of them wished to focus on the regulated markets of developed countries of course now it presents a huge business opportunity for them as they must have recalculated potential business gains from these markets. Also, in order to curb misuse or mischievous use of compulsory licensing, broader scope of patentability as broad as possible within the limit of morality and ethics by deleting most of the restrictive provisions on patentability. This will give a real business impetus in investing in innovations.

Empirical evidences suggest that stronger intellectual property protection will facilitate the flow of FDI in the developing countries. A study conducted by Mansfield indicated that effective intellectual property rights protection could be an important factor in securing foreign direct investment and technology transfer especially in high technology industry like biopharmaceutical. As mentioned previously technology transfer is vital for developing countries like India for the economic as well as for improving her standard of health and environment. The arguments that IP rights increases costs is actually Government posed taxes and tariffs that raise the price of life saving drugs. For example, in India the combined taxes and tariffs on imported medicines are 55 percent.[70] To control the drugs prices, there is proper drug price control mechanism of Drug Price Control Order (DPCO). Moreover, there are always the weapon of compulsory licensing to undermine IP in case of national emergency or other circumstances of extreme urgency or in case of public non commercial use. As there is need to balance between innovation and access.

So, it can be concluded that optimal scope of patent policy for India needs to be broader with higher life form patentability, incremental innovation and 5 years of data exclusivity in order to attract investment which is the need of the hour with a balanced flexibility provisions, such as proper implementation of compulsory license mechanism, other regulatory and fiscal policies to have a proper balance.

[69] Here the condition of obtaining compulsory licence is expanded, (in case of LDCs having no Patent Law or provision for compulsory licence) to include an 'authorisation' or notification from such a country. This is done by modifying sub-section (1) of section 92A as follows:

Adding the following words after the words "provided compulsory licence has been granted by such country" "or such country has by notification or otherwise allowed importation of the patented pharmaceutical products from India."

[70] Wilson Tim, In defense of patents, Times of India, New Delhi, April 26, 2008

Part II: Optimal Regulatory Policy

As mentioned previously an efficient rule based system of IPR strike a balance between creation and dissemination along with the coherent interaction with other regulatory or economic or fiscal policy.[71] According to the report of the Investment Commission 2006,[72] the major impediments to investment have been identified as investment restrictions and/ or entry route barriers, absence of long-term policies, inflexible labour laws, bureaucratic delays, discretionary interpretation, vested interest, bias and subjective practices, high cost of entry, transactions and exit; ineffective dispute resolution, poor infrastructure. These impediments can be categorized in two groups, tariff barriers and non tariff barriers. Tariff Barriers in India arise due to higher rate of taxation, royalty, interest, gains from sale of capital assets located in India higher fees for techincal services etc.

Non-tariff barriers in India include attitudes and bias toward foreign products, a rigid distribution system, and Government bureaucracy. Of these elements, Government bureaucracy poses the most important non-tariff barrier to entry in India and one that is likely to frustrate foreign investors. We will discuss this in the light of drug regulations of India. So, in this part of the part first we will identify non tariff barriers and tariff barriers for the foreign investment in biopharmaceutical sector by looking at the Government of India drug and fiscal policy to eliminate the same. Now firstly we will discuss about the tariff barriers and Governments initiative to eliminate the same.

At the moment, major impediments for the global companies are the complex and cumbersome processes involved in getting regulatory approvals in India which is quite time consuming too. The regulatory uncertainties about time of approval, involvement of multiple agencies for the approval of biotech products, and for processing import/ export licenses are other important stumbling blocks in planning a clinical trial. In addition, ethics committees generally don't function well because of red tapism. Whole lots of documents are required for exporting human samples which are much in comparison to US and Europe. Also, approval processes are frustratingly lengthy, such as those for breeding or importing genetically modified animals. Also, most institutions lack organized patient databases and as a result the patient recruitment rates are either under estimated or over estimated. Additionally, there is problem of inefficient investigators. The cost of imported equipment and biological reagents is also high in the country. The main problem which has been found in the study regarding India's federal regulatory system is bureaucratic setup and corruption. The bureaucratic scuttle has been particularly hard on biologics manufacturers in India, who must seek approval from multiple state, district, and federal agencies for routine activities such as the

[71] Evidence regarding Research and Development investment in innovative and non innovative medicines; James Love; Consumer Project technology;2003
[72] Investment strategy for India; Report of Investment Commission;2006; Ministry of Finance Government of India

importation of recombinant molecules and cell cultures for research purposes.[73] India has recently begun to tackle its red tape to accelerate drug development. In 2005, India's legislature enacted an amendment to the prevailing Drugs Control Act, modifying its rules on clinical trials.[74] Previously, for example, Phase 3 trials in India of a drug intended for market in the country were allowed to proceed only if all prior had been completed in Western countries.[75] Now, in contrast, only Indian companies are permitted to conduct first-in-human studies and involve substantial effort to gain approval. There is lack of state-level regulation in certain areas. The state regulatory authorities suffer from staffing problems as they have very limited technical experience on regulatory issues, which is a serious handicap.[76] India has recognized the importance of these issues for some time, but it has taken the country several years to go from the talking stage to the implementation of solutions. Although, the Government of India is making efforts to promote biotech sector by various incentives and by eliminating loopholes by making sound regulations but still there are persistent chronic problem which is difficult to eliminate.

Now we will discuss specifically Governmental initiative to stimulate foreign investment as there are certain steps which the Government of India is taking to promote health innovation in long run by adopting pull and push mechanism and then we will talk about the issues which are left with suggestions.

The National biotechnology strategy[77] 2007 provides many fiscal and non fiscal benefits to the industry. These are, 100 percent FDI approved in biotech units, which implies that there will be no restriction on the quantum foreign direct investment (FDI) in biotech companies and there may not be the need for FIPB (Foreign investment promotion board) approval for equity investment in biotech companies. Under this scheme the international patent costs will get R&D weightage. More importantly, two major regulatory initiatives have been taken. The first is the creation of the National Biotechnology Regulatory Authority (NBRA), under the Department of Biotechnology (DBT), as part of India's long-term biotech sector development strategy will be an "independent, autonomous, and professionally led body to provide a single window mechanism for the biosafety clearance of genetically modified products and processes." In other words, the NBRA will replace many of the other bureaucracies with which biologics makers in India now must interact for biosafety issues. The NBRA reportedly will also include a training center for its biotech regulators, to enhance their professional competence. [78]

One very important step is legislation to establish Central Drug regulatory authority (CDA) with a single, central, FDA-style agency, the Central Drug Authority (CDA). Over a five-year transition period, this new

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73 Indian government to set up biotech regulator; The Hindu, Business Daily Wednesday, Nov 14, 2007 http://www.thehindubusinessline.com/2007/11/14/stories/2007111452301000.htm Accessed 2008;January 16

[74] Basu I. India's clinical trials and tribulations. Asia Times Online. 2004; Jul 23. Accessed 2008;January 16 at www.atimes.com/atimes/South_Asia/FG23Df03.html

[75] ibid; 74

[76] ibid;74

[77] National Biotechnology Development Strategy draft 2005; Department of Biotechnology, Ministry of Science and Technology; Govt of India

[78] ibid;74

agency will take on nearly all facility-inspection, manufacturing-license, and data-evaluation functions concerning drugs in India. The CDA is expected to have separate, semi-autonomous departments for regulation, enforcement, legal, and consumer affairs; biotechnology products; pharmacovigilance and drugs safety; medical devices and diagnostics; imports; quality control; and traditional Indian medicines. It will set up offices throughout India and will be paid for by inspection, registration, and license fees.[79]

Apart from this the Government has made policies for the promotion of the biotech Parks: The DBT will promote and support at least 10 biotech parks by 2010. In the biotech parks, concession will be given to the biotech companies located in biotech parks like tax holiday U/S 10B of Income Tax Act 1961, duty free or import of equipments, instruments etc. The Government has devised industry friendly policies without compromising safety aspects of biotech products, incentives like customs duty exemption equipments and consumable required for modern biotechnologies tools will further boost infrastructure capability of Indian biotech industry.
The Drug Policy Control Order 2006 declared that bulk drugs developed by Indian companies would be exempt from price control for five years or, in the case of new drugs, 10 years. Goods developed in India and patented in the U.S., Japan or E.U. enjoy a three-year waiver from excise duty, and companies get a 10-year tax holiday for income stemming from qualifying R&D.
Government is also working for legislation on the line of Bayh Dole Act, in which the academia, national labs and industry collaborate with each other and the IP generated pursuant to that is shared by those who contribute to the generation of IP.

Small Business innovation and Research Initiative (SBIRI) scheme has been launched by Department of Biotechnology to provide early stage funding to scientists in private industries for high risks, innovative product proposal. This scheme can be a big boost for early stage funding to scientists.

Ethical trials are very important. There are instances of litigation for unethical trials without requisite permissions, or on ill-informed patients. At the same time, regulatory officials announced stricter enforcement to international good clinical practice (GCP) and World Health Organization protocols. The DCGI also will conduct regular inspection of ongoing trial. The CDA will be responsible for increasing the criminal penalties for illegal clinical trials by a new law.[80]

The introduction of ethical guidelines for biomedical research on human subjects 2000, acceptance of good clinical practice (GCP) guidelines, revision of schedule Y (multicentric phase II and phase III trials) are increasing India's attractiveness a as place to conduct clinical trials. In the manufacturing area, an

[79] ibid;74

[80] National biotechnology development strategy. Department of Biotechnology. 2007 November.

amendment to the regulations, "Schedule M" of the Drug and Cosmetics Act, now specifies the good manufacturing practice (GMP) requirements for factory premises and materials, modeled after US FDA regulations.

Apart from these, the National Science and Technology Policy of the Government and the Vision Statement on Biotechnology issued by the Department of Biotechnology have directed notable interventions in the public and private sectors to foster life sciences and biotechnology.

Although looking at the recent reforms in drug regulations in India it is apparent that it has gained importance and been streamlined in efficient manner to attract more investment but still there is demand for 'Patent-Registration' linkage system. Pharma multinationals are now pushing the Government to introduce guidelines for linking drug registration for marketing approval to the patent system in the country. At present there is no provision under the drugs and cosmetics Act to establish patent linkage, where drug regulators checks the patent status of a drug before granting marketing approval to the company. The regulator gives marketing approval to the company. The regulator gives marketing approval after establishing its safety and efficacy. The patents are handled by ministry of commerce and industry. On the demand by the foreign companies 'Patent-Registration' linkage system has been proposed by the DGCI. Under which DCGI is preparing a document outlining a system to implement the linkage system. The Central Drugs Standard Control Organization (CDSCO) has planned for e-governance project to digitize all their records in a bid to ensure better co-ordination amongst their various offices in order to ensure better accountability and transparency. Such policy will prevent the infringement of patents at the initial stage which is generally sorted out after a long and time consuming judicial process. This is a good move of Government of India to gain confidence of the investors in Indian regulatory system.

It seems that very soon the weaknesses will be removed as the Government is working on the loopholes of the system. So, it can be said that in times to come the regulatory system will be quite efficient in order to attract foreign investment. Although it is hard to say that bureaucratic inefficiency which is the major problem of Indian system will be removed so easily or not.

3. Fiscal policies

Sound tax system, with moderate rates and a broad base, is an integral part of the prudent fiscal policy. According to Morisset and Pirnia[81], Tax policies are obviously capable of affecting the volume and location of FDI. Fiscal policy of a country comprise of mainly two kinds of taxes, direct tax and indirect tax.

[81] How Tax Policy and Incentives Affect Foreign Direct Investment: A Review; JACQUES P. MORISSET World Bank Group - Foreign Investment Advisory Service (FIAS)NEDE PIRNIA World Bank November 30, 1999World Bank Policy Research Working Paper No. 2509

Direct Taxes

Corporate tax is a form of direct tax, which refers to a tax imposed by various jurisdictions on the profits made by companies or associations. The tax rate may, however, vary between jurisdictions. In India, corporate tax rate for a company depends on the origin of that particular company. A company based in India will have to pay a flat tax rate of 30%. However, for a foreign company, the tax rate is dependent on a variety of factors. The companies that are domicile to India pay taxes based on the criteria of global income, whereas the foreign companies in India are taxed on the basis of their income generated out of Indian operations.

Domestic Corporate Income Taxes Rates		
	Tax Rate	Effective Tax Rate with surcharge
Domestic Corporations	30%	30%

Foreign Companies Tax Rates		
	Withholding Tax Rate for non-treaty foreign companies	Tax Rate for US companies under the treaty
Dividends	20%	15%1
Interest Income	20%	15%2
Royalties	30%	20%2
Technical Services	30%	20%2

Note :- A surcharge of 10% of the income tax is levied, if the taxable income exceeds Rs. 1 million. All companies incorporated in India are deemed as domestic Indian companies for tax purposes, even if owned by foreign companies.

Source : Finance Act 2008-09

There is controversy with regard to the higher corporate tax levied on the foreign corporation than Indian companies. It has been alleged that despite of the various tax treaties which India has made with a large number of countries the corporate tax on foreign companies are higher. As per the foreign multinational companies the non-discrimination clause provides that a foreign enterprise in India will not be subjected to

any taxation which is more burdensome than the taxation to which Indian enterprises are subjected to under similar conditions.

Despite the above internationally accepted position explanation to Section 90 of the Income-tax Act provides that the charge of tax in respect of a foreign company at a rate higher than the rate at which a domestic company is chargeable, shall not be regarded as less favourable charge of levy of tax in respect of such foreign company.

The aforesaid non-discrimination clause is on the lines of an article contained in the UN Model of tax treaties, which reads as under: Nationals of a Contracting State shall not be subjected in the other Contracting State to any taxation or any requirement connected therewith which is other or more burdensome than the taxation and connected requirements to which nations of that other State in the same circumstances are or may be subjected. This provision shall, notwithstanding the provisions of article 1, also apply to persons who are not residents of one or both of the Contracting States.

On the issue of discrimination by imposing higher rate of tax and India commitment to the International tax treaties made with other sovereign states, it is interesting to discuss recent case judgment in this regard. In Chohung Bank vs Deputy Director of Income-tax[82] Korean Chohung bank which had a branch in India filed a case claiming that the tax rate as applicable to Indian companies carrying on similar business should be applied for the Chohung bank too relying upon article 26 of the Agreement for Avoidance of Double Taxation between India and Korea. Accordingly, the foreign bank income was taxed at higher rate of 48% instead of at the rate applicable to a domestic company i.e. 35%. . The branch (called assessee-company) was involved in normal banking activities including financing of foreign trade and foreign exchange transactions.

The ITAT Mumbai after considering Section 90 [83]of the Income-tax Act 1961 and the non-discrimination clause in the Tax Treaty with Korea, ultimately held that the provision of non-discrimination has nothing to do with the rate. Looking at the decision of the case and other incentive provisions of Income tax Act 1961 it can be said that the judgement of the Mumbai tribunal is justified as foreign companies in invest and do businesses which are not available to domestic companies. For example, foreign exporters are generally not

[82] Chohung Bank vs Deputy Director of Income-tax (2006) 102 ITD

[83] AGREEMENT WITH FOREIGN COUNTRIES. (1) The Central Government may enter into an agreement with the Government of any country outside India - (a) For the granting of relief in respect of income on which have been paid both income-tax under this Act and income-tax in that country, or (b) For the avoidance of double taxation of income under this Act and under the corresponding law in force in that country, or (c) For exchange of information for the prevention of evasion or avoidance of income-tax chargeable under this Act or under the corresponding law in force in that country, or investigation of cases of such evasion or avoidance, or (d) For recovery of income-tax under this Act and under the corresponding law in force in that country, and may, by notification in the Official Gazette, make such provisions as may be necessary for implementing the agreement. (2) Where the Central Government has entered into an agreement with the Government of any country outside India under sub-section (1) for granting relief of tax, or as the case may be, avoidance of double taxation, then, in relation to the assessee to whom such agreement applies, the provisions of this Act shall apply to the extent they are more beneficial to that assessee.

liable to tax if the sale is concluded abroad and the proceeds are received when they have business connection or permanent establishment or any activity in India. Also, a foreign corporation is not liable to tax on operations confined to the purchase of goods in India for the purpose of business. This could be an incentive if a foreign biopharma company were planning on purchasing raw ingredients in India for making of the Hepatitis A Vaccine for distribution in India.

There is another issue with regard to higher corporate tax in India which is a cause of reluctance for the foreign companies to do business in India. India charges the second highest corporate tax from foreign companies, next only to the US. "India and Japan retain the second and the third highest corporate tax rates in the world. India taxes foreign companies at a maximum rate of 42 per cent while Japan levies a corporate tax of 41 per cent. New York City imposes the highest corporate tax of 46.2 per cent. This is a barrier to establish business in India which needs to be addressed efficiently.

Now coming to indirect taxation, in indirect tax customs tariffs, excise duties are the prominent ones. In order to know the exact amount of the applicable customs duty on a product, it is therefore necessary to add: the basic customs duty surcharge + countervailing duties. As mentioned before that Government imposed tax and tariff raise the price of the life saving drugs specially the combined tax and tariffs imposed on drugs is 55% which is quite high which needs to be addressed . We will see the recent effort of Government of India to reduce the same.

The Union Budget 2008- 09 has reduced of customs duty on raw materials for ELISA kits to 18.72 percent and select vaccines and select bio-therapeutics to 9.36 percent. An 8 percent reduction in export duties from 16% to 8% along with export duty exemption for indigenous life saving drugs and 5 percent from 10% customs duty reduction for imported Life Saving Drugs will certainly reduce drug prices. Many vaccine companies will also benefit due to reduction in custom duty. This will benefit many MNC who are importing the various combination vaccines into the country. As in case of all drugs (formulations), excise duty rate has been reduced to 8 percent. This is good for biopharmaceutical manufacturers in the country. In general, the budget is a very good sign.

This is a better way to address healthcare costs rather than drug price control. Perhaps the most important tax benefit announced for the sector is the 125 percent weighted average tax deduction on outsourced R&D, which sends a strong signal of the potential that discovery research holds for the Indian pharma and biotech industry.

Despite of all incentives to pull foreign investment still medical technology is left as an industry, which is reeling under unprecedented tax burden (36 percent). There was no special mention made for the industry and no reduction in custom duties for the Import of medical equipments/ devices. The government has not given any incentives like capital grants and subsidies for local manufacturing of medical devices as well.

The Finance Minster has proposed to increase its healthcare allocation by 21.9 percent and has extended a 5 year tax holiday for setting up hospitals in non- urban cities, but this however will not reduce the cost of healthcare in the country, until the cost of medical equipments are reduced. Health of the common man has been neglected and so has been the government's attitude to the Indian medical equipment manufacturer

More incentives are needed for R&D as 10 year holiday of 200 percent weighted tax deduction for both in-house and outsourced R&D is desired to boost investment for R&D and move up the value chain.

Although there is general decline of customs tariffs within the framework of their WTO participation but still India remains one of the countries where the customs duty is the highest. There are 4 basic rates: 5%; 15%; 25% and 35. To these basic duties, a 10% surcharge can be added. India also applies some "countervailing duties" to compensate for the loss of excise duty, which it would have earned on raw materials, components and ingredients if the product had been made in India.

Also despite of India proposal of a six-year phase-out to the WTO for removing quantitative restrictions on imports of some 2,700 items, including consumer goods, which have been maintained since the 1950's on balance of payments grounds. Import licenses are still required for most pharmaceuticals and chemicals, and products reserved in India which serves as an effective ban on importation. India's strict trade policy and complicated import polices and licensing could be limiting factors in an effective policy making process. India's import policy is administered by the means of a negative list. The negative list would make export of pharmaceuticals difficult, as certain pharmaceuticals and medicines could fall into the gray area or restrictive items.

Thus, we have seen that Indian trade policies and tariffs including import duties, and tax structure etc. have been rationalized and liberalized in tune with the WTO requirements in order to make them attractive to attract more investment but still the tariff levels are very high by international standards.

But still there are issues, which bring varying degrees of business risks for biopharma multinationals to invest which are discussed above. It is within the context of these business risks that abovementioned fiscal impediments need to be eliminated in order to have better flow of foreign investment at the same time also efficiently addressing the public health concern such as maintaining lower tax rates for the life saving drugs.

Conclusion:

As mentioned earlier, technology and technical know-how are essential for improving productivity, promoting export growth and attaining the development aspirations of countries. Therefore, technology transfer is seen as an important tool to narrow the growing technological gap between developed and developing countries, for integrating developing countries into global economy and enabling developing

countries to meet their international obligations. TRIPs Agreement contains statements about the importance of technological innovation and the role of transfer of technology along with the stronger patent protection. So, according to TRIPs text, intellectual property protection has a direct link with technology transfer (Article 7). Foreign direct investment can be an important means of transferring technology to developing countries [84] it is widely recognized that both policy makers and analysts require a better understanding of the effect, if any, that a developing country's system of intellectual property rights protection has on the transfer of technology.

The biotech sector is reliant on a strong partnering model. Partnership model is all about using cost arbitrage to deliver value arbitrage. Mounting costs of drug discovery and development, extended timelines for bringing new drugs to market, fierce competition, pricing pressure and funding challenges have combined to prompt pharma companies in the developed countries to look to countries beyond their own borders on multiple fronts. This places India at a particular advantage. At the same time, there are certain factors which need to be strengthened in order to attract foreign investment specially on regulatory front. As per John Dunning's[85] ownership location and internalisation (OLI) approach ownership specific location, location specific and internalisation specific ownership advantage create monopolistic advantages which can be used to prevail in market abroad. The paradigm shows that market size and structure, prospect for market growth and degree of development, the cultural, legal, political and institutional environment and Government legislaton and policies of the host country governs the decision of foreign investors to invest. The paper has evaluated the government IP policies and pother drug legislations which governs the foreign investment as well as strength of other stimulant factors. This analysis evaluates current scope of patent policy along with drug regulations and fiscal policies to attract foreign investment in biopharmaceutical sector for the new drugs innovation as well as providing accessibility of the same to the needy. Based on this analysis, the paper concludes that optimal design of patent for biopharma innovaton in India should confine to trade off between patent length and breadth taking into account the flexibility provisions of TRIPs. The fine tuned patent policy can be achieved by allowing broader biotech patents to set incentive to attract investment for the innovation, as patents with longer lives allow the patent holder to set a higher market prices for the patented product, patents with longer lives allow patent holders to obtain revenues for longer period of time. Larger breadth makes it more difficult to imitate or improve upon the protected invention, whereas increasing the duration of patent protection enhances the incentives to improve the invention [86]by increasing R&D investment for the innovation of biopharmaceutical drugs in general and neglected diseases drugs through foreign investment in particular carrot in terms of data exclusivity and higher form of patent protection should be given along with the stick of properly framed compulsory licensing provision and parallel importation to balance the need of the access that are

[84] Blomstrom, M., and E. Wolff. 1989. *Multinational Corporations and Productivity Convergence in Mexico*. C.V. Starr Center for Applied Economics, New York University.

[85] Dunning.J (1979); Explaining changing pattern of international production:In defence of Eclectic theory,41 Oxford Bulletin of econometric statistics,269-275.

[86] ibid;20

applicable to the. In biotechnology, the surge in innovation, notably by start-ups, benefited greatly from the possibility of obtaining patent protection, which attracted the capital needed in this area. At the same time, Government subsides can directly promote the development of biopharma technologies. Government's funds significant research and development through basic grants for medical research. Governments also seek to spur innovation indirectly, especially in the environmental and occupational health and safety fields, through regulatory reforms.

While the crisis of access to medicines in poor countries has multiple determinants, intellectual property protection leading to high prices is well-established as one critical element of the access gap. The study believes that one of the major causes of high price of life saving drugs is Government posed taxes and tariffs as the combined taxes and tariffs on imported medicines are quite high. Higher intellectual property protection can not be blamed solely for the high prices of the drugs. At the same time an 8 percent reduction in export duties along with export duties exemption for indigenous life saving drugs and 5 percent customs duty reduction for imported life saving drugs by the budget of 2008-09 will definitely make the drugs price lower. In fact this is a better way to address drugs costs rather than drugs price control. Given the current international political climate, systemic, Government driven reform of intellectual property protection seems unlikely in the near term.

The main hurdle for putting money for the research and development of the neglected diseases drugs is control exercised on essential drugs by the Drug Price Control Order (DPCO) whereas non essential drugs are left to the market forces. Therefore, this paper suggests policymakers to consider targeted policies for neglected diseases drugs innovation such as early stage research grants and clinical development tax credits. They would address the funding gap and above average development risks associated with neglected diseases. Most notably, in May 2006, the World Health Assembly passed resolution HA59.24, which created an intergovernmental working group to develop a global plan of action on intellectual Property, innovation, and public health. While this is undoubtedly a useful initial step, true reform of intellectual property protection can only be achieved through domestic, government driven reform or binding international agreements along the lines of the TRIPS regime. Therefore, the study proposes India should adopt a modest balanced policy that works within existing patent law and drug development paradigms in order to proactively circumvent both biopharma drug innovation and access.

Thus it can be said that if the patent, regulatory and fiscal policies are framed on a model balancing both the interest groups and implemented properly, then it can be said for sure that TRIPs agreement leads to greater technological innovation and transfer of technology for the mutual advantage of producer and user of technological knowledge in a manner conducive to the social and economic welfare too.

Table: 1

Drug patent expiration in US

Drug patent expirations (2007-2009)

Brand name	Generic name	Manufacturer	Patent expiration
Lotrel	Amlodipine and benazepril	Novartis	Jan. 31, 2007
Norvasc	Amlodipine	Pfizer	Jan. 31, 2007
Actiq	Fentanyl transmucosal	Cephalon	Feb. 5, 2007
Aceon	Perindopril	Solvay	Feb. 21, 2007
Alocril	Nedocromil	Allergan	April 2, 2007
Imitrex	Sumatriptan	GlaxoSmithKline	June 28, 2007
Geodon	Ziprasidone	Pfizer	Sept. 2, 2007
Coreg	Carvedilol	GlaxoSmithKline	Sept. 5, 2007
Meridia	Sibutramine	Abbott Laboratories	Dec. 11, 2007
Mavik	Trandolapril	Abbott Laboratories	Dec. 12, 2007
Tequin	Gatifloxacin	GlaxoSmithKline	Dec. 25, 2007
Zyrtec	Cetirizine	Pfizer	Dec. 25, 2007
Clarinex	Desloratadine	Schering-Plough	2007 (Generics expected 2008)
Fosamax	Alendronate	Merck	Feb. 6, 2008
Camptosar	Irinotecan	Pfizer	Feb. 20, 2008
Effexor/XR	Venlafaxine	Wyeth	June 13, 2008
Zymar	Gatifloxacin	Allergan	June 25, 2008
Dovonex	Calcipotriene	Bristol-Myers Squibb	June 29, 2008
Kytril	Granisetron	Roche	June 29, 2008
Risperdal	Risperidone	Janssen	June 29, 2008
Depakote	Divalproex sodium	Abbott Laboratories	July 29, 2008
Advair	Fluticasone and salmeterol	GlaxoSmithKline	Aug. 12, 2008
Serevent	Salmeterol	GlaxoSmithKline	Aug. 12, 2008
Casodex	Bicalutamide	Bristol-Myers Squibb	Oct. 1, 2008
Trusopt	Dorzolamide	Merck	Oct. 28, 2008
Zerit	Stavudine	Bristol-Myers Squibb	Dec. 24, 2008
Lamictal	Lamotrigine	GlaxoSmithKline	Jan. 22, 2009
Vexol	Rimexolone	Alcon Labs	Jan. 22, 2009
Avandia	Rosiglitazone	GlaxoSmithKline	Feb. 28, 2009
Topamax	Topiramate	Johnson & Johnson	March 26, 2009
Glyset	Miglitol	Pfizer	July 27, 2009
Acular	Ketorolac tromethamine	Allergan	Nov. 5, 2009
Xenical	Orlistat	Roche	Dec. 18, 2009
Valtrex	Valacyclovir	GlaxoSmithKline	Dec. 23, 2009
Avelox	Moxifloxacin	Bayer	Dec. 30, 2009

Source: Express Scripts and Generic Pharmaceutical Association

Table: 2 International examples of Compulsory Licensing

Country	Year	Detail
Argentina	18 Oct 2005	Argentina announced intention to grant CL for Tamil Flow (Oseltamivir) It later found that the patent was never granted in Argentina
Brazil	6th July 2007	Brazil grants CL for Abott's Kaletra
Brazil	4 May 2007	Brazil grants CL for Mercks HIV/AIDS drug Efavirenz
Equador	2003	Petitions by local manufacturer (Acoomax) for CL for Combivir Lamivudine and AZT) refused, appealed and refused again. GSK agrees to supply drug at a discount
Eritrea	5th June 2005	Eritria issues CL for importation on Eritria of generic HIV / medicines.
Zimbabwe	May 2002	Zimbabwe declares Period of emergency which enables it to ignore antiretroviral drug patents for 6 months via a CL. In 2003 the period of emergency was extended by 5 years (Untill 31st Dec 2008)
Thailand	April 2007	After weeks of negotiations and public debate (and statements about with drawing drugs from Thailand, abbott agrees to provide discounted AIDs drugs (Kaledtra /Aluwin) to Thailand
Thailand	Feb 2007	Thailand announced two

		compulsory licenses on Plavix (heart diseases drug) made by BMS and Sanofi-Aventis and Kaletra for HIV by Abott
Thailand	Dec 6 2006	Thai Government issues CL on Merks AIDS drugs Efavirenz.
Zambia	21st 2004	CL for Lamitudire, Slavudine and Nevivapine
Ghana	Oct 2005	CL for the importation into Ghana of Indian generic HIV/AIDS medicines
Guinea	18th April 2005	CL for importation on patents on drugs to treat HIV –AIDS
Indonesia	5th Oct 2004	Indonesia issues act to manufacture generic versions of Lumi vidine and nevirapine (both Hive /AIDS) drugs)
Israel	Jan 1942	Cl to manufacture Bop Hep B under Biogen patent. Biogen's appeal was unsuccessful. The patent expired in 1999 before the SC ruled on the dispute.
Italy	21 march 2007	Italy grants CL in relation to Finas teride and related generic drugs for two years prior to the 2009 expiration of patent monopoly
Republic of Korea	June 2002	Korea rejects application for CL of Novartis Glivec
Malaysia	29th Sept 2004	Cl to import from India dida nosine (ddl) Zidovudine (AZT) and Lamivudine (Combivir)

Rwanda	19th July 2007	Rwanda becomes the I country to notify the WTO that intends to use the paragraph 6 system (of DOH A Declaration). Paragraph 6 is designed for those countries that do not have the facilitates to manufacture pharmaceuticals and also allows importations
Mozambique	5th April 2004	CL for Lamivundine, Slavudine and Nevirapine
Canada	4 Oct 2007	The WTO received from Canada on 4th Oct 2007, the first notification from any Government that it has authorized a company to make a generic version of patented medicine for export under special WTO provisions agreed in 2003. The triple combination AIDS therapy drug, Tri Avir, Can now be made and exported to Rwanda, which is unable to manufacture the medicine itself. Earlier on 17th July, Rwanda informed the WTO that it intentends to import 260,000 packs of Tri Avir – a fixed dose combination product of Ziol Ovudine, lamivudine two years. The drug so to be made in Canada by Apotex the and is called Apo Triavir by the manufacture
Canada	14th May 2004	Canada amends its patent law to allow Canadian manufacturer to export to countries which lacks the ability to manufacture

		pharmaceuticals but only in respect of drugs listed in schedule, of the Act which include, Lamivudine Nevirapine Zidovudin tablets etc.
Canada	Oct 18 , 2001	CL in relation to the Bayers ciprofloxacin and authorized generic manufacturer to build manufacturer to build stockpiles protection against and attack and anthrax

Source: Based formation collected from various sources