PHARMACEUTICAL PATENTS: INDIA AND BEYOND

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"The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."

– Mrs. Indira Gandhi at the World Health Assembly in 1982

I. INTRODUCTION

Probably the most controversial aspect of India becoming the member of the WTO has been the advent of product patents in the field of pharmaceuticals. The Indian pharmaceutical industry flourished under the Patent Act, 1970 which provided only for process patents of drugs. The industry achieved remarkable progress during this period and is now a source of low cost generic drugs to the entire world. The role of private investment in the field of research and development of pharmaceutical drugs cannot be denied. Moreover, it is easy for small firms to reverse engineer the drugs and enjoy the fruits of someone else's work and millions spent on the research and development (R&D) of such drugs. Thus, economically it is not viable for research firms to develop new drugs without the provision of adequate patent protection.

Patent protection to new innovations is based on the concept of *quid pro quo*. The innovator is given exclusive right to use or exercise and commercially exploit an invention for a certain period and in consideration he discloses the information about the invention to the world at large which becomes a public property once the patent period is over. Patent protection not only stimulates future innovators but also promotes investment in the innovation and allows it to be made into a commercial product.

The Indian pharmaceutical industry has special significance in the case of pandemics such as AIDS. The Antiretroviral (ARV) drugs marketed by firms from developed countries, which offer product patents on drugs, are

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priced exorbitantly. The Indian generic drug manufacturers, on the other hand, are offering these drugs at 5% of that price. This difference in price while maintaining similar quality of the drugs made India the pharmacy of the developing world.

The scenario in India changed with the Patent (Amendment) Act, 2005, which was enacted to comply with the provisions of TRIPS Agreement. TRIPS Agreement aims at establishing minimum standards for Intellectual Property Rights for the WTO member countries. The members have to provide for product patent protection for all the products including pharmaceuticals within the specified time period. This created a lot of hue and cry. The general feeling being that this will lead to pharmaceutical companies charging exorbitant prices for their patented drugs and this in turn will lead to public health crisis in the developing countries which rely heavily on the cheap generic copies of the patented drugs produced in India. Although a lot of policy changes are being brought about due to the pressure being put by various NGOs on the governments but it is still uncertain if these are going to be of any major help. This paper provides an outline of the Indian patent law related to the pharmaceutical drugs along with the amendments brought about by the TRIPS agreement. It analyses the implications of the controversial law and what could be its long-term effects in the developing world. It goes on to analyse the ways available in the TRIPS agreement itself to go around this problem.

II. History of The Indian Patent Law

Patent laws were first promulgated in India in 1856, a year before her first war of independence in 1857. These laws were modified from time to time, and more stable patent and design laws were enacted in 1911. At that time the patent laws were the same as followed in England and therefore were at par with the laws of most advanced countries. These laws were revisited after India got her independence in 1947 and it was decided that the laws required some changes in order to meet the social and economic needs of the country, with a large population of poor people who did not have easy access to medicines and other advancements of science. At the same time there was the desire to be self-reliant in many areas of technology and this led to serious efforts towards nurturing science and technology in India. The patent laws were revised and the Patent Act, 1970 was enacted,

which did not allow patenting of substances emanating as a result of chemical reactions. Product patents were allowed except in respect of drugs, chemicals and food items. However, process patents are granted for drugs, food items and chemicals.

The Patent and Design Act,1911 provided for product patents of drugs but were excluded from the 1970 Act. This exclusion was introduced to secede India's dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry.

III. The Effect Of Patent Act, 1970

The Indian Patent Act of 1970[1] came into force in 1972. At that time, the national sector was very small, estimated at less than 25% of the domestic pharmaceutical market. Of the top ten firms by retail sales, only two were Indian firms and the rest were subsidiaries of multinationals. Much of the country's pharmaceutical consumption was met by imports. The Act specifically excluded patent coverage for pharmaceutical products and only admitted process patents for a period of 5 or 7 years. In essence, the India Patents Act gave only very limited protection to research-based pharmaceutical companies. Imitating firms only had to avoid patented processes to copy a newly developed drug. It is, however, in most cases very easy to modify or circumvent a patented process in order to avoid infringement. Without product patents, protection of new drugs was very limited. Moreover, because of the various restrictions related to process patents, protection was even further reduced. As a result, the number of patents granted per year fell by three-quarters[2] over the following decade, from 3,923 in 1970-71 (of which 629 were to Indian applicants, 3,294 to foreign applicants) down to 1,019 in 1980-81 (349 Indian, 670 foreign). Supported by the regulatory environment, such as created by Drug Price Control Order (DPCO, 1970), by 1991, Indian firms accounted for 70% of the bulk drugs and 80% of formulations produced in the country. Of the top ten firms by 1996 pharmaceutical sales, six were now Indian firms rather than the subsidiaries of foreign multinationals. Domestic firms produced about

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1 Available at: http:// www.patentoffice.nic.in

2 Peoples' Commission on Patent Laws for India, Report of the Peoples' Commission on Patent Laws for India, New Delhi: Centre for Study of Global Trade System and Development, 2003.

350 of the 500 bulk drugs consumed in the country. Employment in the pharmaceutical sector was estimated to have reached almost half a million by 1995.

IV. The Trips Agreement

A. How it came into being

The World Trade Organization (WTO) and the TRIPS Agreement were created in the framework of the General Agreement on Tariffs and Trade (GATT) and agreed upon in 1994. The TRIPS Agreement is undoubtedly the most significant development in intellectual property, together with the creation of the World Intellectual Property Organization (WIPO) at the 1968 Stockholm Conference[3]. TRIPS, which set the minimum standard for IPR protection among the WTO members, became final after many negotiations between 1986 and 1994. The first proposal that had similarities with the final TRIPS Agreement was tabled by the EC in March 1990, and was entitled "Draft Agreement on Trade-Related Aspects of Intellectual Property". The US closely followed with a very similar draft, which also carried the same title. Consultations between the two had probably preceded the tabling of both documents. Many countries disagreed with the proposals in full or in part, filing additional proposals. What the developing countries were especially concerned about was the inclusion of pharmaceutical products in the agreement.

In June 1990 the Chairman of the negotiations put forward a draft called "Chairman's draft" or "Composite draft text", which included and combined all of the suggested proposals. Developing countries opposed an all-encompassing agreement on intellectual property, especially as they felt that the proposal by the Chairman adopted an overall structure that was very similar to that of the EC and the US proposals. During further discussions it was clear that the question of protection of pharmaceutical products through patents was one of the major issues to be resolved. However, with a new draft of TRIPS presented by the Chairman, the reactions were mainly positive and although pressure still existed for changes,

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[3] Mirza, Zafar WTO/TRIPs, Pharmaceuticals and Health: Impacts and Strategies, The Society for International Development, SAGE Publications, 1999: http://www.sagepub.co.uk/journals/Details/issue/sample/a010932.pdf

few amendments were made before the final TRIPS Agreement was adopted at Marrakech in 1994. Regarding pharmaceutical patents, the two parties mainly opposing the agreement were India and the American pharmaceutical industry. Although it was not a party to the Agreement, the American pharmaceutical industry was a powerful lobbyist. The industry felt that it was not receiving the immediate protection it wanted because of the transition rules, which stretched the transition periods for least developed countries (LDCs) even further. India was, and still is, concerned about restrictions on compulsory licensing of patents, found in TRIPS, Article 31. It seems evident that the two could not have found a draft with which they were both satisfied[4].

It is commonly known that TRIPS was formulated when the industrialized countries, as a result of pressure from the pharmaceutical, software and phonogram industrial lobbies, forced the agenda to have the standard of protection for IPRs universalised and recognised as a trade issue.

The Preamble to the agreement recognises that IPRs are private rights. But it also recognises the underlying public policy objectives and the special needs of the developing countries to have flexibility in implementing the provisions of TRIPS. The protection of the rights of the patentees however is not the sole concern of TRIPS. TRIPS provide flexibilities for governments to fine-tune the protection granted in order to meet social and economic goals. Article 7 of TRIPS on *Objectives* speaks of the mutual advantage of both producers and users of technological knowledge and stresses the need for a balance of rights and obligations. TRIPS recognises in Article 7 that the protection and enforcement of IPRs should be "conducive to social and economic welfare." Again Article 8 on *Principles*, empowers the member countries to adopt measures to "protect public health and nutrition, and to promote the public interest in sectors of vital importance ..." and "to prevent the abuse of intellectual property rights by right holders." Such measures are however required to be consistent with the provisions of TRIPS.

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[4] TRIPS, pharmaceuticals and public health: http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

B. TRIPS Agreement and the Indian pharmaceutical patents

India, as a member of the World Trade Organization (WTO), has to comply with the provisions set forth in the TRIPS Agreement. The main provisions of TRIPS as they relate to pharmaceutical patents can be summarized as follows[5]: Among the general obligations, Articles 3 and 4 of TRIPS require member governments to apply the principles of national treatment, i.e. equal treatment of nationals and non-nationals, and most-favored-nation (MFN) treatment, i.e. equal treatment of foreigners regardless of their country of origin. With respect to patents, Article 27.1 of TRIPS states that "...patents shall be available for any invention, whether products or processes, in all fields of technology...," which clearly encompasses pharmaceutical products. Moreover, "...patents shall be available... whether products are imported or locally produced," which means that importation counts as working the patent. Article 31 addresses the use of patented subject matter without the authorization of the rights holder, e.g., through compulsory licenses. Although it ties such unauthorized use to specific conditions, legal interpretations of Article 31 vary and it has been argued that national governments have some leeway in designing rules regulating the grant of compulsory licenses. Article 33 sets a uniform minimum term of patent protection of 20 years counted from the filing date. Article 34.1 specifies that the burden of proof in case of process patent infringement rests with the defendant, i.e. the party accused of patent infringement. Finally, Article 41.1 requires member governments to "...ensure that enforcement procedures... are available under their national laws so as to permit effective action against any act of infringement of intellectual property rights..." and Article 62.2 obligates members to "...ensure that the procedures for grant or registration ...permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection."

The provisions of TRIPS became applicable to all signatories by the beginning of 1996. However, Articles 65.2 and 65.4 of the TRIPS Agreement entitle developing countries to a four-year transition period in implementing all obligations (except for obligations pertaining to national and

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[5] The WTO website's gateway to TRIPS: http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

MFN treatment) and an additional five-year transitional period for product patents in fields of technology that were not protected at the date of application of the Agreement. Accordingly, India had to amend its patent law to allow for the grant of pharmaceutical product patents by 2005. Article 70.3 does not require member countries to extend protection to subject matter in existence before the introduction of a new law, i.e. patent protection would not apply retroactively. Articles 70.8 and 70.9, however, also specify that members should "...provide ...a means for which patents for [pharmaceutical and agricultural chemical products] can be filed" (this 'means' is often referred to as a 'mail-box'). Moreover, for such 'mail-box' applications "...exclusive marketing rights shall be granted ...for a period of five years after obtaining market approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that ...a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member." To that extent the exclusive marketing rights related to 'mail-box' applications and exclusive rights conferred by a regular patent title are practically the same, Articles 70.8 and 70.9 effectively offset the transition period with regard to pharmaceutical product patents.

Thus India went through three stages to comply with the TRIPS provisions[6]:

1) Introduction of a "mail box" facility from January 1, 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications were not processed for the grant of a patent until the end of 2004. But Exclusive Marketing Rights (EMRs) could be obtained for those application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.
2) Compliance, from January 1, 2000 with other obligations of TRIPS, namely, those related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof and so on, and

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[6] Sudip Chaudhuri, *Trips Agreement And Amendment of Patents Act In India*, EPW, August 2005.

3) Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mail box are also required to be taken up for examination from January 1, 2005.

C. Apprehensions to TRIPS

A number of new medicines that are vital for the survival of millions are already too costly for the vast majority of people in poor countries. In addition, investment in R&D towards the health needs of people in developing countries has almost come to a standstill. Developing countries, where three-quarters of the world population lives, account for less than 10% of the global pharmaceutical market. The implementation of TRIPS is expected to have a further upward effect on drug prices, while increased R&D investment that aims at addressing health needs in developing countries, despite higher levels of intellectual property protection, is not expected. One-third of the world population lacks access to the most basic essential drugs and, in the poorest parts of Africa and Asia, this figure climbs to one half[7].

Access to treatment for diseases in developing countries is problematic either because the medicines are unaffordable, have become ineffective due to resistance, or are not sufficiently adapted to specific local conditions and constraints.

Many factors contribute to the problem of limited access to essential medicines. Unavailability can be caused by various factors such as logistical supply and storage problems, substandard drug quality, etc. Despite the enormous burden of disease, drug discovery and development targeted at diseases in poor countries has virtually ground to a standstill because drug companies in developed and developing nations simply cannot recoup the cost of R&D for products to treat diseases that abound in developing countries. Of the 1,223 new drugs approved between 1975 and 1997, approximately 1% (13 drugs) specifically treats tropical diseases[8].

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[7] R. Chaudhuri, B. Chatterjee and P.S. Mehta, *TRIPs and Pharmaceuticals: Implications for India*, Consumer Unity & Trust Society (CUTS) Briefing Paper: http://www.cuts-india.org/1997-8.htm#Pharmaceutical%20 Industry%20in

[8] Brown, Eric. *TRIPS: India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*. European Journal of International Law (1998). Nov, 2002: http://www.ejil.org/journal/ Vol9/No1/sr1f.html

Medecins sans Frontieres (MSF), together with other non-governmental organizations (NGOs), formulated the following concerns related to TRIPS[9]:

- Increased patent protection leads to higher drug prices. The number of new essential drugs under patent protection will increase, but the drugs will remain out of reach to people in developing countries because of high prices. As a result, the access gap between developed and developing countries will widen.
- Enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend.

It is unlikely that TRIPS will encourage adequate R&D in developing countries for diseases such as malaria and tuberculosis, because poor countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry.

Developing countries are under pressure from industrialized countries and the pharmaceutical industry to implement patent legislation that goes beyond the obligations of TRIPS. This is often referred to as "TRIPS plus." TRIPS plus is a non-technical term which refers to efforts to extend patent life beyond the twenty-year TRIPS minimum, to tighten patent protection, to limit compulsory licensing in ways not required by TRIPS, or to limit exceptions which facilitate prompt introduction of generics.

Industrialized countries and World Intellectual Property Organization offer expert assistance to help countries become TRIPS-compliant. This technical assistance, however, does not take into account the health needs of the populations of developing countries. Both of these institutions are under strong pressure to advance the interests of large companies that own patents and other intellectual property rights.

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[9] *A Matter of Life and Death: The Role of Patents in Access to Essential Medicines.* MEDECINS SANS FRONTIERES CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES. Nov, 2002: http://www.accessmedmsf.org/upload/ReportsandPublications/291020011614133/dohacol.pdf

V. Indian Pharmaceutical Industry And Its Role In The Third World

The highly organized Indian pharma industry is in the forefront of scientific industries, with a wide range of capabilities in the technological and drug manufacturing fields. The Indian pharma industry is estimated to be worth about $10 billion, with an 8-9% annual growth rate. It is one of the leading industries among the Third World countries, and is highly respected for its quality, technology, and range of drugs manufactured and supplied at competitive prices. Export markets primarily propel the growth of the Indian pharma industry. India exports its drugs to more than 65 countries[10].

According to *McKinsey*,[11] Indian pharma exports contribute US $3.2 billion out of the annual turnover of $5 billion, with the industry further assured to grow at $25 billion by 2010. Indian pharma industry's share in value terms in the global market is estimated to be at 1% (13th rank), while in volume terms, it is 8% (4th rank). India also has the largest number (74) of US Food & Drug Administration (USFDA) approved drug manufacturing facilities outside the US. There were 126 Drug Master Files (DMFs) filed by Indian companies, which was higher than the combined DMFs of China, Italy, Spain and Israel. Indian companies, on an average, account for 35% of all DMF applications in the US. The Indian companies' share in the domestic market has witnessed continuous growth from nearly 20% in 1970 to 70% in 2005. In terms of revenue, Ranbaxy Laboratories leads the Indian pharma companies, while Cipla and Dr. Reddy's Laboratories stand second and third respectively[12].

The ability of the Indian firms to produce generic versions of the modern drugs is a boon to the developing and least developed countries. Many of the third world countries do not have the technology and the

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[10] *Indian Pharma Revenues to Touch $25 Billion by 2010,* The Economic Times, 1 May 2001.

[11] *Four Opportunities in India's Pharmaceutical Market,* The McKinsey Quarterly, No.IV, 1996.

[12] Jean O Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering'?,* Yale University, Economic Growth Center, Center Discussion Paper No. 775, August 1997.

economic capacity to produce these drugs. Indian generics account for almost half of the ARVs used in the developing world[13]. Thus, there is a lot on stake for these countries. Exporting of generic drugs to third world countries is already a low profit activity, now with the new patent laws these exports, using the concept of compulsory licensing, are bound to become extremely difficult and costly, if not altogether impossible. The drugs, which acquired patent before January 1, 1995 do not come under the effect of the product patent regime brought about by the amendment in the patent law of India. This means that the Indian pharmaceutical firms for the time being can continue manufacturing the generic versions of those drugs and supply to the third world countries that are in dire need of those drugs. The problem will escalate later when resistance to the current drugs will be developed and the law will prevent production and export of the generic versions of the subsequent generations of these drugs including ARVs and it will be in the hands of the firm with the patent of that drug to decide the price, which will not be low considering there will be no competition from the generic drug manufacturers.

VI. Concept Of "Ever-Greening"

Ever-greening, in one common form, occurs when a brand-name manufacturer literally "stockpiles" patent protection by obtaining separate 20-year patents on multiple attributes of a single product. These patents can cover everything from aspects of the manufacturing process to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolized by the patient. When ever-greening through patent strategies, the originator manufacturer simply keeps adding patents to the product, which may not be legitimate even, essentially forcing the generic manufacturer to wait for all the patents to expire[14].

Ever-greening of pharmaceutical drugs is prevented under section 3(d)[15] of the Indian Patent Act of 1970:

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[13] Shadlen, Ken, DESTIN, *Patents, India, and HIV/AIDS treatment*, LSE, LSEAIDS, Update 4, April 2005

[14] Andrade, Chittranjan, Nilesh Shah and Sarvesh Chandra, *The new patent regime: Implications for patients in India,* March 2007: http://www.indianjpsychiatry.org/article.asp?issn=0019-5545;year=2007; volume=49; issue=1;s page=56; epage=59; aulast=Andrade

Section 3- What are not inventions. The following are not inventions within the meaning of this Act, -

[...]

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of the substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

Explanation. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolities, pure form, particle size, isomers, mixture 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;

Thus, the Indian law does not grant patents to incremental innovations although there is a huge pressure on the government to allow ever-greening. The argument is that molecules are patented very early during the process of drug discovery, but unique clinical characteristics or benefits are not discovered until much later, when clinical trials are conducted, if at all. Therefore, it is unreasonable to ask that unique characteristics of a slightly altered molecule be described at the time of the application for the patent, itself.

A government-appointed committee on patent laws, headed by R.A. Mashelkar[16], a former chief of the Council for Scientific and Industrial Research, favored the grant of patents to all incremental innovations made to a drug, but not to frivolous ever-greening. The report was widely interpreted to permit most forms of ever-greening. The report was withdrawn in February 2007, after it was discovered that a part of the report was lifted, without acknowledgement and verbatim, from a paper published by a UK-based organization which had been funded by the pharmaceutical industry.

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[15] *Supra.* n.1.

[16] MASHELKAR COMMITTEE REPORT available at: http://www.patentoffice.nic.in/ipr/patent/mashelkar_committee_report.doc

Some excerpts from the report:

> [...]
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> Granting patents only to NCEs or NMEs and thereby excluding other categories of pharmaceutical inventions is likely to contravene the mandate under Article 27 to grant patents to all 'inventions'. Neither Articles 7 and 8 of the TRIPS Agreement nor the Doha Declaration on TRIPS Agreement and Public Health can be used to derogate from this specific mandate under Article 27. (5.6)
>
> Article 1 of the TRIPS Agreement requires compliance to the provisions of the Agreement, while TRIPS plus provisions are optional. This would mean that limiting grant of patents to pharmaceutical substances to new chemical entities only, and excluding new forms of crystals, polymorphs, etc., if they satisfy the criteria of patentability, is not consistent with TRIPS Agreement. (5.7)
>
> [...]
>
> It is important to distinguish 'ever-greening' from what is commonly referred to as 'incremental innovation'. While '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. Therefore, such incremental developments ought to be encouraged by the Indian patent regime. (5.10)

Interestingly, according to the submissions of various Indian pharmaceutical industries in the report, such as Ranbaxy, it would be in the long-term interest of Indian companies, which have far less resources, to go in for early commercialization of their incremental innovations[17].

A. Novartis Case

From 1995 to 2005, when the "mail-box" and exclusive marketing rights (EMRs) provisions were in force in India, contrary to the apprehensions, only a few applications for EMR were filed in India. But the one granted to an MNC, Novartis, for an anti-cancer drug, imatinib mesylate (Novartis' brand name: Glivec) created a

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[17] *Ibid.*

controversy[18]. Under Article 70(3) of TRIPS, a WTO member country has no obligation to provide protection (through patents or EMRs) for any subject matter which has fallen into the "public domain" before WTO came into being, i.e., before 1 January, 1995. Patent information published in the US FDA Orange Book shows that Novartis' patent for the new chemical entity, imatinib mesylate was granted in USA before 1995.A number of Indian companies have been manufacturing and marketing generic versions before the EMR was granted to Novartis in November 2003. Compared to the price of Rs 120000 per month for the Novartis's product, generic versions cost between Rs 9000 and Rs 12000. The EMR sought and granted to Novartis is for modification of the crystal form of imatinib mesylate (beta-crystal form). Novartis' EMR relates to this modified form for which it got patent and marketing approval in Australia during 2001-03. Novartis filed suits against the generic companies in the Madras High Court. The latter passed an interim order restraining six Indian companies from manufacturing and marketing imanitib mesylate. What was basically being contested was whether secondary patents obtained after 1995 for a new chemical entity patented before 1995 can be used to prevent generic companies from producing the drug. After 2005 deadline, when the mail-box applications came to be reviewed by the patent office, the patent to Novartis AG's Glivec was rejected in January 2006 under section 3(d) of the Act. Novartis challenged the rejection of patent to Glivec as well as the legal provision that allowed for this contending that the said section was not compliant with the WTO's TRIPS agreement and violated the Indian Constitution as it was "vague" and gave arbitrary powers to the patent authority[19].

On August 6, 2007 the court dismissed Novartis petition and observed that the relevant section was neither "vague or ambiguous", nor did it give the patent authority arbitrary powers. The section has "in-built material" to guide patent authorities to take a decision on an application. The judges said when the TRIPS itself provides for a dispute settlement mechanism, the courts have no jurisdiction to decide whether the amended section violates Section 27 of the agreement.

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[18] Sudip Chaudhari, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY (New Delhi: Oxford University Press; 2005).

[19] Novartis Glivec patent case information center:http://www.novartis.com/newsroom/india-glivec-patent-case/index.shtml

The court's decision was cheered by health activists and patients groups as a landmark decision that would ensure the availability of cheap generic or off-patent drugs. Tido von Schoen-Angerer, director of MSF Campaign for Access to Essential Medicines, said, "This is huge relief for millions of patients and doctors in developing countries who depend on affordable medicines from India."[20]

B. Roche Controversy

Recently, the Chennai patent office in India granted a patent to an anti-HIV drug, valganciclovir, to F Hoffman-La Roche Ltd, a Swiss drug maker, without hearing groups opposed to monopoly protection given to the medicine. A Mumbai-based NGO, Lawyers Collective that works for AIDS patients' access to medicines in India, plans to file a case against the patent controller of India and the Chennai patent office.

Lawyers Collective had filed a pre-grant opposition to the valganciclovir patent application of Roche in 2006 on the ground that the drug was a pre-1995 molecule. Valganciclovir, which was invented by Roche in 1994, was patented first in Switzerland the same year. The drug, sold by Roche as Valcyte internationally, nevertheless, was granted the India patent. Roche charges about $9,900 for a three-month treatment for valganciclovir and has reduced the price to $1,800 for NGOs and customers in Sub-Saharan African and LDCs[21].

The patent will prevent Indian generic drug maker Cipla Ltd, which is currently developing a generic version of the said drug. There are no other generic copies of the drug, used by HIV patients to ward off infection.

C. South African Dispute

Responding to the alarming growth of HIV infections in the country, South Africa passed a law in 1997 giving the government "blanket powers to...produce or import cheap alternatives to the brand-name drugs for HIV and other diseases." Since producers of generics do not need to invest money in research, they can sell at a fraction of the cost of patented drugs. This

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[20] *Court rejects Novartis challenge of patent law, Glivec Case*, MINT, August 7, 2007.

[21] *Lawyer group to challenge patent for Roche's anti-HIV drug*, Pharma Controversy, MINT, September 26, 2007.

fraction can be as little as six percent. Thirty-nine pharmaceutical companies raised a court challenge to prevent South Africa from implementing the law. John Barton, former chair of the UK Commission on Intellectual Property Rights, observes that this move "became a public relations debacle for the industry." A multitude of NGOs, including Oxfam and Medecins Sans Frontieres (MSF), sharply criticized the pharmaceutical companies for attempting to restrict health access. With pressure mounting, the companies eventually dropped their challenge, "after threats that the amount of public support for the development of the relevant drugs would be publicized in the hearings." Despite the victory, the South African government has been criticized for moving too slowly on resolving its AIDS epidemic since then.

D. Brazilian Example

In 1996, the Brazilian government began offering free ARV therapy to people with AIDS. As the costs of this program grew, the government expanded its health budget and increased its production and import of generics. Brazil also used the threat of compulsory licensing – authorizing companies to produce generic copies of patented drugs – to force patent-holders to cut prices. As a result, drug prices in Brazil were much lower than other countries and the government succeeded in cutting AIDS mortality rates by 50 percent. In response to Brazil's actions, the US filed a complaint with the WTO in early 2001, accusing the government of violating TRIPS.

As in the case of South Africa, the move backfired. In April 2001, all members of the UN Human Rights Commission except the US supported a Brazilian resolution asking nations not to "deny or limit equal access for all persons to preventive, curative or palliative pharmaceutical or medical technologies used to treat pandemics such as HIV/AIDS." The US withdrew the complaint in June 2001, saying it would pursue the issue in bilateral talks[22].

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[22] Jayashri Kulkarni, *Brazilian Pharma Market: A Veritable Goldmine for Generic Players?* www.pharmabiz.com, August, 2004.

VII. Flexibilities In TRIPS

A. Eligibility for patenting

Government can refuse to grant patents for three reasons that may relate to public health[23]:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health (Article 27.2)
- diagnostic, therapeutic and surgical methods for treating humans or animals (Article 27.3a)
- certain plant and animal inventions (Article 27.3b)

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not unreasonably conflict with the normal exploitation of the patent (Article 30).

B. Compulsory licensing

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In current discussion, this is associated with pharmaceuticals, but it could also apply to patents in any field.

The agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term compulsory licensing does not appear in the TRIPS Agreement. Instead, the phrase "other use without authorization of the right holder" appears in the title of Article 31. Compulsory licensing is only part of this since other use includes use by governments for their own purposes. Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder. For example[24]: Normally, the person

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[23] WTO, September 2006, *TRIPS and Pharmaceutical Patents*, Fact Sheet, Geneva: World Trade Organization.

[24] Coriat, Benjamin and Fabienne Orsi, *Pharmaceutical Patents, Generic Drugs and Public Health Under The TRIPS Agreement*, DRUID summer conference, Copenhagen June, 2003.

or company applying for a license must have first attempted, unsuccessfully, to obtain a voluntary license from the right holder on reasonable commercial terms (Article 31b). If a compulsory license is issued, adequate remuneration must still be paid to the patent holder (Article 31h).

However, for national emergencies, other circumstances of extreme urgency or public noncommercial use (or government use) or anticompetitive practices, there is no need to try for a voluntary license (Article 31b). Compulsory licensing must meet certain additional requirements[25]. In particular, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and usually it must be granted mainly to supply the domestic market.

The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. In Article 31, it does mention national emergencies, other circumstances of extreme urgency and anti-competitive practices but only as grounds when some of the normal requirements for compulsory licensing do not apply, such as the need to try for a voluntary license first. (Doha declaration 5(b) and (c)).

C. Compulsory license and data exclusivity

Pharmaceutical companies have to submit test and clinical data to the national health authorities to obtain marketing approval for a new drug. The national health authorities keep the innovator data confidential against " unfair commercial use" for a certain time period, thus barring generic manufacturers from using the submitted innovator data for the stipulated period.

Most often, companies use data exclusivity provisions to seek a period of monopoly in a country even if it does not have any patents on the product in the country. As such, data exclusivity provisions have considerable implications for developing countries like India. So far, India has not introduced provisions pertaining to data exclusivity in the three amendments to the Patents Act, 1970. India is now considering amendments to the Drugs

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[25] Jayashree Watal, *Introducing Product Patents in the Indian Pharmaceutical Sector: Implications for Prices and Welfare,* WORLD COMPETITION: LAW AND ECONOMICS REVIEW, 1996.

& Cosmetics Act, 1940 and the Indian Insecticides Act, 1968 incorporating provisions for data protection[26].

Once data exclusivity is introduced, generic companies would have to do their own safety and efficacy tests. The huge cost involved in this exercise could result in generic companies being barred from producing a generic version of a product for a period extending effectively beyond 20 years. It may also result in the ineffective use of a compulsory license due to data exclusivity provisions, were such a license issued to a generic manufacturer.

D. Parallel Imports

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

The legal principle here is 'exhaustion', the idea that once company A has sold a batch of its product, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch.

The TRIPS Agreement simply says that none of its provisions, except those dealing with nondiscrimination (national treatment. and most-favoured-nation treatment), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute.[27] In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. The Doha Declaration clarifies that this means that members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives. (Article 6 and Doha declaration 5(d)).

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[26] Prabuddha Ganguli, GEARING UP FOR PATENTS: THE INDIAN SCENARIO (Hyderabad: Universities Press (India) Ltd, 1998).

[27] Carlos Correa, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES. Geneva: South Centre, 2001.

E. "Bolar" Exception

Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval, for example from public health authorities without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the 'regulatory exception' or "Bolar" provision (Article 30). This has been upheld as conforming to the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms to the TRIPS Agreement in allowing manufacturers to do this. (The case was titled Canada Patent Protection for Pharmaceutical Products). Such experimental use of patented product had come into contention in the case of *Roche Product Inc* v. *Bolar Pharmaceutical Co Inc.*[28]

VIII. DOHA DECLARATION

Some governments were unsure of how these TRIPS flexibilities would be interpreted, and how far their right to use them would be respected. The African Group (all the African members of the WTO) was among the members pushing for clarification.

A large part of this was settled at the Doha Ministerial Conference in November 2001.[29] In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health by promoting both access to existing medicines and the creation of new medicines. They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries ability to use the flexibilities that are built into

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[28] 221 USPQ 937.

[29] The Doha Declaration on TRIPS and Public Health: http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm.

the TRIPS Agreement, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

On one remaining question, they assigned further work to the TRIPS Council to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. (This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in the separate Doha declaration on TRIPS and public health).

Importing under compulsory licensing ("paragraph 6" issue)

Article 31(f) of the TRIPS Agreement says products made under compulsory licensing must be predominantly for the supply of the domestic market. This applies to countries that can manufacture drugs, it limits the amount they can export when the drug is made under compulsory license. And it has an impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing. The legal problem for exporting countries was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.[30] When members agreed on the decision, the General Council chairperson also read out a statement setting out members shared understandings on how the decision would be interpreted and implemented. This was designed to assure governments that the decision will not be abused.

The decision actually contains three waivers:

- Exporting countries obligations under Article 31(f) are waived, any member country can export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries.
- Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.

[30] The 30 August 2003 decision on importing and exporting under compulsory licence: http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

- Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least developed countries at the time of the decision. That way, developing countries can make use of economies of scale.

Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. And they require governments using the system to keep all other members informed, although WTO approval is not required. At the same time phrases such as "reasonable measures within their means" and "proportionate to their administrative capacities" are included to prevent the conditions becoming burdensome and impractical for the importing countries.

India, along with several other potential exporting countries changed their laws and regulations in order to implement the waivers and to allow production exclusivity to exports under compulsory license. Section 92A (1)[31] of the amended Patent Act reads:

> *Section 92A(1)*- Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of patented pharmaceutical products from India.

IX. CONCLUSION

Serious effort is needed, from the governments and the NGOs, to prevent further escalation of the pandemics such as HIV/AIDS, Cancer, TB, Malaria, etc. It cannot be denied that TRIPS came into being because of the pressure from various Trans National Corporations through their governments. The developing countries are not yet ready for product patents in pharmaceuticals. Even in countries like Switzerland, Italy and Japan,

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[31] *Supra* n.1.

product patents in pharmaceuticals were introduced in the late seventies when the drug industry was fully established and developed there. The present scenario will adversely affect the public health in all the developing and least developed countries. Doha Declaration is a step in the right direction but it is still not clear if it will bring about the necessary results. Moreover, it does not cover all the aspects and the export and import of drugs under the compulsory license is still ambiguous. How much are the lives of people living in poor countries worth is a question worth discussing. The developing nations need to work together as a unit while the developed nations need to understand the implications of their own agendas.

India is a major force as a producer of cheap pharmaceutical drugs to be used domestically as well as in other developing countries. The provisions of the amended patent law of India makes it theoretically possible for it to continue playing the role it was playing prior to TRIPS, i.e. of the major producer of generic drugs for the developing world but what happens in reality remains to be seen. Moreover, the task is bound to become laborious in case of new chemical entities patented after January 1, 1995. Even in that case it must be made sure that the generics are made available in the market as soon as the patent expires and frivolous "ever-greening" should be avoided.

Flexibilities available in the TRIPS itself needs to be utilized to the fullest. The provision of compulsory license is a potent tool towards achieving the objective of access to medicine for all. Public health is a major issue and should not be left in the hands of those who only seek profit out of such misery.