PATENT PROTECTION AND DRUG PRICING IN HEALTHCARE SECTOR

Mahak Rathee & Disha Yadav

***Abstract**: This paper will deal with patenting in healthcare industry and will primarily focus on Indian scenario. Patent is a right given for an invention, which can either be a product or a process that provides a new way of doing something , or offers a new technical solution to a problem. Healthcare sector being one of the most sensitive one. In the health sector, intellectual property rights can provide an important stimulation for the development of new drugs and medicines. This paper will also discuss the Novartis case and how it has proved to be a landmark judgment. In this case Supreme court denied patent of a cancer drug which was a merely modified from its previous version by adding a compound. It was held that improvement in performance should be seen as compared to older version to make it patentable. Of all the goods and services traded in the market economy, pharmaceuticals are perhaps the most contentious. Though produced by private companies, they are a major constituent of public good. Controlling the price of life- saving drugs is a major issue on the policy agenda of most modern governments. Granting a patent on life saving drug means the company has sole monopoly to control the price of that drug and price of such patented drugs is out of reach of common masses. It is the duty of the government to regulate the price of such life- saving drugs so as to make them available to public at affordable rates.*

"I knew that a country without a patent office and good patent laws was just a crab and couldn't travel anyway but sideways and backwards…. " - Mark Twain

Intellectual property is frequently referred to as 'the novel products of human intellectual endeavour'[1]

Subject to the provisions of paragraphs 2 and 3 of Article 27 of TRIPS agreement , patents shall be available for any inventions ,whether products or processes, in all fields of technology ,provided that they are new ,involve an inventive step and are capable of industrial application . Subject to paragraph 4 of article 65,paragraph 8 of article 70 and paragraph 3 of article 27 ,patents shall be available and patent rights enjoyable without discrimination as to the place of invention ,the field of technology and whether products are imported or locally produced . [2]

Basically a patent is a right given for an invention, which can either be a product or a process that provides a new way of doing something , or offers a new technical solution to a problem. The basic obligation in the area of patents is that, invention in all branches of technology whether products or processes shall be patentable if they meet the three tests of being new involving an inventive step and being capable of industrial application.

The exclusive right to market a product during the life of a patent allows the holder to recoup some or all of their initial investment, by charging more for the product. This in turn has an impact on price, which affects access to medicines. Although price is only one of the factors that determine access, it is a highly significant one. [3]

In the health sector, intellectual property rights can provide an important stimulation for the development of new drugs and medicines. However, a significant proportion of the world's population, especially in developing countries, have yet to derive much benefit from innovations that are commonplace elsewhere. The reasons range from weak supply systems to unaffordable prices. The factors that drive innovation are often biased against conditions that disproportionately affect the populations of developing countries.[4]

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[1] Hector MacQueen, Contemporary Intellectual Property, Pg 40 , Oxford University Press ,Second edition
[2] Daniel Gervais , The Trips Agreement : Drafting History and Analysis, Pg no 93 , Thomas Reuters(Legal) Limited (2008) third edition
[3]Intellectual property rights, http://www.who.int/trade/glossary/story055/en/,last seen at September 7 2014.
[4] Intellectual property rights, http://www.who.int/trade/glossary/story055/en/,last seen at September 7 2014

The policy option in this sector mainly lies in the development of low cost medicines in the country itself with an eye on bringing more and more rural poor under modern medical facilities.

It is important to state that patents are only one among a range of institutions and issues affecting drug development on the one hand and access to drugs on the other.[5]

Reconciling the needs of patients and patent-holders is a challenge to efforts to improve access to essential health care. Given the potential impact of intellectual property rights on price, there has been a growing interest in mechanisms designed to bring about the most favourable pricing for developing countries. Relaxed patent requirements, tiered pricing, voluntary licensing, compulsory licensing, bulk purchasing and corporate donations have each been evaluated as potentially effective mechanisms to achieve the most favourable pricing of patented medicines in developing countries.

HISTORY OF PATENT LAWS IN INDIA

India's drug industry has a unique history. For more than 30 years, the country did not recognised pharmaceutical patents. Domestic firms became masters at copying medicine and making it cheaply available to the masses. There was a change in this situation after India joined the World Trade Organisation (WTO) in 1995 as it had to change its patent policy. But its new system, in place since 2005, includes special protections for both patients and generic manufacturers.

Till 2005 drugs were not patentable for medical purposes in India. Therefore, it was apprehended that this switch from the non-patent regime to the patent regime would not be a smooth one and India will face many problems in future . Though India has high technical expertise and infrastructure to manufacture medicines, even then, almost 60% of Indian population is not under the reach of modern medicines and depend on local treatments or

[5] Smita Shrinivas, Intellectual Property Rights, Innovation and Healthcare, http://www.columbia.edu/cu/tclab/pdfs/srinivas_intellectualpropertyrights.pdf,last seen at September 8 2014.

herbal formulations. The reasons behind this low coverage of the modern medicine are due to low earnings, poor accessibility of medical facilities and low awareness or education among the mass. In the last few years, the price of many medicines which also includes essential antibiotics have raised constantly and this is due to organized efforts of the manufacturing firms and monopolistic conditions existing in the drug industry. Since the profit margin on low cost medicines is not considerable, many pharmaceutical companies avoid venturing into that sector.

Considering these circumstances, it will not be wrong to expect a price rise for many of the medicines in India. Comparing the price for same medicine among countries with and without patent regime for medicines, it was found that in some countries with patent right, the drug price was higher up to 41 times than in India prior to 2005 (with no drug patents).[6]

The origin of Indian patent law can be traced to 1856, when a law was enacted in India to grant certain exclusive privileges to inventors for a period of fourteen years. Since the 1856 law did not had a prior sanction of the British Queen, many experts opined that it is beyond the authority of the Legislative Council of India to pass it. The reason given behind this was that since the grant of patents in India rested with the Crown, hence any patent law passed by the Indian legislature required the prior permission of the Crown or its representative.

This Act of 1856 was repealed when the Indian Legislative Council passed Act IX of 1857; Act IX was followed by a new law enacted in 1859 that granted inventors the exclusive privilege to make, use, and sell their invention in India. The main purpose of this legislation was to help British patent holders in gaining control over the Indian markets, and the law contained major restrictions on the importation of technologies and inventions. As a consequence, importation of technology became highly complex and prohibitively expensive.[7]

After independence, the government appointed to committees taking into consideration the relative inaccessibility and unaffordability or even non-availability of essential life saving medicines . These committees were : the Tek Chand Patents Enquiry Committee (1948-50)

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[6] Pardeep Kumar and Deoki Nandan, Intellectual Property rights and healthcare, http://medind.nic.in/hab/t09/i1/habt09i1pi.pdf, last seen at September 9 2012.

[7] Unni VK,Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health, http://connection.ebscohost.com/c/conference-papers/89892735/indian-patent-law-trips-redrawing-flexibility-framework-context-public-policy-health,last seen at September 9 2014.

and the Ayyangar Committee (1959). After taking account of the reports submitted and recommendations made by these committees the Indian Patent Law was amended in 1970. The Patents Act, 1970 abolished product patents for food, pharmaceuticals and chemicals and restricted grant of patents in these fields only to process patents.[8]

Indian Patent Act 1970: The objective of this act was to foster the development of an Indian pharmaceutical industry and to guarantee that the Indian public had access to low-cost drugs . The Patent Bill was first introduced in Parliament in 1967, but the Patent Act, 1970 came into force only in 1972.New processes for around 107 drugs were developed by Indian scientists . Indian companies are now among the world leaders in the production of bulk drugs from basic stages. Today, the prices of drugs in India are very economic as compared to many other nations. [9]

The Patents Act, 1970 incorporated very well-thought out, highly effective, safe-harbor provisions were incorporated by the Patents Act , 1970 which was though considered controversial in the global context for early generic introductions of patented New Chemical Entities (NCEs) in India and essential life saving medicine based on them.

The flexibility for pharmaceutical patents, has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. This enhancement was put into practice in 2003 with a decision which enabled countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory license. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement. [10] The minimum standards which were required by TRIPS resulted in losing capacity to regulate pharmaceutical patents and cost of medicines in developing countries , however the agreement left some flexibility for them to take measures to protect public health.[11]

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[8]Gopakumar G Nair,Impact of TRIPS on Pharmaceutical industry, http://nopr.niscair.res.in/bitstream/123456789/2029/1/JIPR%2013(5)%20432-441.pdf ,last seen at sepetmber 10 2014.

[9]Sarda Rohit R, Ladkat Nilesh B,The Indian Phramaceutical industry:Evolution of regulatory system and present scenario, http://www.irjponline.com/admin/php/uploads/1164_pdf.pdf, Last seen at sepetmber 5 2014.

[10] Damanjeet Ghai, Patent Protection and Indian Pharmaceutical industry, http://www.globalresearchonline.net/journalcontents/Volume3issue2/Article%20008.pdf.

[11] Intellectual property and access to medicines,http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/msh_2012._intellectual_property_and_access_to_medicines_chapter_3.pdf, last seen at September 7 2014.

DRUG PRICING v. PATENTS

The pharmaceutical industry faces legal and regulatory environment. Government, drug companies and advocacy groups are always in a conflict , the question to which is over the type of patent rights that will be available to industry.

Controlling the price of life- saving is a major issue on the policy agenda of most modern governments. The reasons behind this are quite clear. Modern states are generally assumed to have a duty to provide at least a minimum level of healthcare services for their citizens.
A major portion of population in a country like India and other developing and under developed countries does not have access to basic health care facilities. So it is the responsibility of government to make basic facilities as well as life- saving drugs within the reach of these people.

Talking about patents, they no doubt make local markets more attractive, they also convey control over launch decisions to multinational firms with global interests. It is upon the discretion of multinationals which may delay or even avoid launching drugs in lower-priced countries because they are concerned about the implications for pricing in *other* markets.[12]
Since monopolists set higher prices for consumers who are more price-insensitive, hence if there is no price regulation mechanism then pharmaceutical firms will presumably charge very high prices for their on patented drugs. .[13]

Of all the goods and services traded in the market economy, pharmaceuticals are perhaps the most contentious. Though produced by private companies, they are a major constituent of public good, both because they can prevent epidemics and also because healthy people function better as members of society than sick ones do. [14] Hence price regulation is very important in this sector as this has a direct effect on functioning of the economy.

[12]Jean O Lanjouw, Patents price control and access to new drugs: How policy affects global market entry, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=997353, last seen at September 5 2014.
[13]Nicholas Bloom and John Van Reenan,Regulating drug pricing: where do we go from here?, http://web.stanford.edu/~nbloom/PPRS.pdf,last seen at September 6 2014.
[14] The new drugs war.The Economist,http://www.economist.com/news/leaders/21592619-patents-drugs-are-interests-sick-well-industry-protection-should-not,Janaury 4 2014.

The Drugs Price Control Order (DPCO), 1995: This order was issued by the Government of India under the Essential Commodities Act, 1955 to regulate the prices of drugs. The Order provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions among other things. For the purpose of implementing provisions of DPCO, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (NPPA). DPCO doesn't cover patented drugs.[15] Hence leaving price regulation in the ambit of multinationals .

Drug pricing is a one of the major issue in India. The Indian government believes that the prices of life saving drugs shouldn't be set by market forces. In a country where very few people have health insurance, 70% of Indians pay for healthcare expenses out of their own pockets and who can't afford to pay for high priced patented drugs . The problem is more acute in case of cancer drugs. There is no way that people in India can pay even a fraction of the cost for drugs that can be priced at $50,000/year in the West.[16] Patents play a key role in the availability and affordability of medicines in era of increasingly globalised trade pharmaceutical. When a patent is grantes to a company then it enforce monopolies over drug distribution and also it is discretion of the companies to charge whatever price they want. Usually the price set by these companies is so high that only a small proportion of population can afford it and the needy and the poor cannot get access to such life saving drugs.

DRUG PRICING IN CONTEXT TO NOVARTIS CASE

Novartis case is one of the landmark judgement for intellectual property cases in India ,where a large number of patented drugs are unaffordable for a major portion of 1.2 billion people . It is a clear indication by India after allowing generic versions of these three drugs to flood its

[15] Sarda Rohit R, Ladkat Nilesh B,The Indian Phramaceutical industry:Evolution of regulatory system and present scenario, http://www.irjponline.com/admin/php/uploads/1164_pdf.pdf, Last seen at sepetmber 5 2014

[16] John LaMattina, India's solution to drug costs: ignore patents and control priceshttp://www.forbes.com/sites/johnlamattina/2013/04/08/indias-solution-to-drug-costs-ignore-patents-and-control-prices-except-for-home-grown-drugs/, last seen on September 5 2014.

market that pharmaceutical manufacturers outside its borders will not be able to control price at their will over its market of 1.2 billion people. Questions are being raised after India's denial of patent protection, regarding the pharmaceutical industry's ability to make a profit in the world's second-most populous country — and another important aspect which comes in light is that whether pharmaceutical industry's obligation to provide access to life-saving drugs should outweigh its drive for profits. Also this ruling in Novartis case will help India in maintaining its role as provider of most inexpensive medicines in the world, which is critical in the global fight against deadly diseases.[17] This will provide access to lifesaving drugs to needy and poor .

[17] Gardiner Harris and Katie Thomas, Low cost drugs in poor nations get a lift in Indian courts, The New York Times,http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?pagewanted=all, April 1 2013.

In this case , Novartis applied for a patent in the Madras Patent Office in 1998 for Imanitib Mesylate in Beta crystalline form . The Indian Patent regime was in a transitional phase during 1995 to 2005 , as per the TRIPS Agreement . Therefore , the Patent application filed by Novartis remained dormant in the "Mailbox Procedure". It was taken up for consideration only after amendments in compliance with the TRIPS Agreement were made in 2005.

It was contended that a product patent should be granted to Novartis on grounds of enhanced efficacy. The Supreme Court gave a detailed and comprehensive judgment in the instant matter ,taking into account the history of patent laws in the country. The reports of Justice Ayyangar, which ultimately led to the the framing of the Indian Patent Act 1970 was discussed to demonstrate the evolution of patent laws in India. Owing to the Constitutional obligations of the State towards its citizens , the national interests outweigh the interests of an individual inventor. Here , "national interest" refers to the easy accessibility of life saving drugs to the masses.

Novartis' application for patent was rejected.[18]

Supreme Court ruled that the patent that was sought by Novartis for Gleevec was not a true. Without taking into consideration the fact that India's 2005 patent law was passed under international pressure, India passed patent law for the first time allowed for patents on medicines for the first time , but only for drugs discovered after 1995. In 1993, Novartis patented a version of Gleevec that it later abandoned in development, but the Indian judges held that the early and later versions were not different enough for the later one to be granted a separate. Hence, India has refused protection for Glivec on the grounds that it is not a new medicine, but an amended version of a known compound. Critics described the ruling as being unjust to manufacturers, saying it was further evidence that India does not respect the intellectual property rights of pharmaceutical companies

The Indian Parliament's decision which was supported by the Supreme Court, that Indian consumers should only pay for expensive patented products when there is some improvement in those products over their older versions ,mere change in one ingredient of that product is not the sufficient condition for granting a new patent , there should be a considerable improvement in performance as compared to its older version . This decision of Supreme

[18] Ananya Kumar singh and Vatsal joshi,The Novartis case: precedence to social welfare over inventor's rights,http://www.ilnuejournal.org/pdf/judgment/Case%20Note%20%20-%20Novartis%20Case.pdf, last seen at September 8 2014.

Court should not be misunderstood that a new form of a compound can never be patented, also it did not say that improving the bioavailability characteristics of the drug may never result in enhanced efficacy. The question which was raised was regarding enhanced efficacy whether it only refers to curative effect, or has a broader meaning which includes an improvement in safety profile and reduced toxicity.[19]

"The intellectual property ecosystem in India is not very encouraging," Ranjit Shahani, managing director of Novartis India Ltd told reporters after the ruling.[20] Healthcare activists have raised their voice against high price of patented drugs and have asked the government to make such lifesaving medicines cheaper in a country where many patented drugs are too costly for most people, 40 percent of whom earn less than $1.25 a day, and where patented drugs account for under 10 percent of total drug sales.[21]

After Supreme Court's ruling against patent claim of Novartis for cancer drug Glivec a clear message is being sent by India to other generic drug companies to keep life-saving drugs at an affordable price to common masses. Supreme court was extra conscious in taking this decision as it understood the sensitivity of this sector and a minute error of judgement in this case would have put life-saving drugs beyond the reach of common masses not only in India rather in other developing and underdeveloped countries which are dependent on India for generic drugs.

Supreme's court verdict on Novartis case is in right direction as it if patent was allowed on that drug then it would have unfair and unjust to patients right of having life saving medicines at affordable cost . This judgement of Novartis case is largely welcomed as this judgment has paved way for accessibility of the drugs in India at reasonable prices. We shall also keep in consideration the positive impact on affordability and accessibility of medicines this judgment will have. Thus basically, the Supreme Court in interpreting Section 3(d) is saying is that consumers should not be forced to pay higher prices on a drug just because it is chemically a new drug unless there is a therapeutic benefit of that drug . On contrary note

[19] Frederick M Abbott, Inside views: The judgment in Novartis v India, http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/,last seen at September 6 2014.
[20] KAUSTUBH KULKARNI AND SUCHITRA MOHANTY, Novartis loses landmark India cancer drug patent case , http://in.reuters.com/article/2013/04/01/us-india-novartis-patent-idUSBRE93002I20130401, last seen at September 8 2014
[21] KAUSTUBH KULKARNI AND SUCHITRA MOHANTY, Novartis loses landmark India cancer drug patent case , http://in.reuters.com/article/2013/04/01/us-india-novartis-patent-idUSBRE93002I20130401, last seen at September 8 2014.

when a patent is given on a drug then it will exclude others from producing and marketing it, which will lead to inhibition of competition and hence setting up of higher prices and hence less access to such drugs.

This judgement does not reject the importance innovation of innovation impact. It is only saying that in cases where the innovation impact is absent or trivial or is limited to certain extent then the consumers should not be forced to pay a higher price and hence patents should not be granted.[22] Taking into consideration the Novartis case it is important to keep in mind that there is a significant price gap between the patented version of Glivec and its generic copy, as a monthly dose of the former can cost as much as USD $5,000 in the U.S., whereas a monthly dose of the latter can be purchased for just USD$200 in India.[23] Also there was not a considerable improvement in new form as compared to older one.

This case is a landmark case because it represents critical issues related to intellectual property protection and access to medicines, which will impact how multinational pharmaceutical companies conduct business in India in the future, as well as India's role as the "Pharmacy of the Developing World".[24] The Novartis case sets an important precedent for access to medicines by putting the pharmaceutical industry on the reach of patent law. The ruling puts social justice over commercial interests by keeping in view the common masses who could not afford such life- saving drugs and also helps India's own domestic industry.

CONCLUSION

Healthcare sector is one of the most sensitive sectors among all and Pharmaceutical industry occupies an important place in Indian economy as it is research- oriented and research based industry. Various new challenges and opportunities for this sector have been brought by

[22] Indrani Roy, 'Novartis case: Supreme Court ruling wise and balanced'http://www.rediff.com/business/interview/interview-novartis-ruling-is-not-an-anti-patent-judgement/20130410.htm, last seen at September 9 2014.
[23]Ravinder Gabble and Jillian Clare Kohler, "To patent or not to patent? the case of Novartis' cancer drug Glivec in India" http://www.globalizationandhealth.com/content/pdf/1744-8603-10-3.pdf ,last seen at 9 september 2014.
[24] Ravinder Gabble and Jillian Clare Kohler, "To patent or not to patent? the case of Novartis' cancer drug Glivec in India" http://www.globalizationandhealth.com/content/pdf/1744-8603-10-3.pdf ,last seen at 9 september 2014

Trade related aspects of Intellectual Property Rights (TRIPs) and it is very essential for the researchers to properly analyse all the factors responsible for successful gains from this market . The Indian Pharmaceutical industry's success and survival will depend on how effectively it will face the upcoming challenges and opportunities in this sector. On one hand the developing countries are still in need of the most basic health care facilities , whereas on other hand many new medical scholars are making such developing countries as their target with promising profits for medicines in lifestyle diseases .Also one common trend noticed is that the awareness about Intellectual Property Rights is relatively low in India as compared to other developing countries . Proper awareness should be spread regarding this among entrepreneurs, researchers ,technocrats and concerned persons through mass media and seminars along with strengthening legal base in this field .

Impact of Drugs Price Control Order 2013 will always be double coined as on one hand it will it will prove boon to common man as it is a ray of hope for needy and poor who are deprived of basic healthcare facilities as continuous availability of medicines is assured by government whereas on other hand, this new policy deems unfit to the other category of the market which plays a significant role in manufacture of these medicines and which makes them available to public as this policy will effect their profit to a large extent and will also affect their growth in the global market. Government should take all neccessary steps to make life saving drugs available to the masses and multinational companies should not be given sole monopoly to regulate the prices of their products as they only take into consideration their profits and due to this such life saving drugs become unaccesable to general public and only the higher income groups can afford such medicines.