ANALYSIS OF SECTION 3(D) OF PATENT AMENDMENT ACT, 2005 AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY WITH ESPECIAL REFERENCE TO NOVARTIS CASE

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INTRODUCTION

Glivec case is remarkable because it has gone beyond the specific technical and legal issues surrounding patents and has put the matter in a much larger political and economic perspective. What the judgment says and what it implies has tremendous significance for the patent regimes in developing countries beyond the secondary patenting issues.

Judgment of *Novartis* case has raised many questions of international law and the compatibility of the Indian Patents (Amendment) Act, 2005 with Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs agreement) of the World Trade Organization (WTO).[1]

HISTORICAL BACKGROUND: PATENT AND PHARMACEUTICAL INDUSTRY

Patent has been in progress in India since a long time. The discussion on having a law to protect inventions goes back to as early as 1832.[2] After a number of failed attempts, the first Patents Act of India was enacted finally in 1856. This was really a copy of the British patent law of 1852. This was soon replaced with Act No. XV of 1859. Then followed a series of laws in 1872 and 1883 and finally they were all consolidated in the Inventions and Designs Act of 1888. Consequent on major changes in British law, a new Patents & Designs Act was enacted in 1911, again adapting the British law. This, with minor amendments from time to time, remained the patent law of India until 1970.[3]

The ostensible purpose of any patent system is to motivate an innovative culture, but as brought out by the Patent Enquiry Committee, in 1950. The Indian patent system (of the pre-Independence period) has failed in its main purpose, namely, to stimulate invention among Indians and to encourage development and exploitation of new inventions for industrial purpose in the country, so as to secure the benefits thereof to the largest section of the public[4]

The long period of more than 110 years of patent protection as per the norms of an industrialized country resulted in a tottering pharmaceutical industry and one of the poorest medical care systems in the world. Justice N. RajagopalaAyyangar Committee in September 1959, who had studied the Indian patents system and the pharmaceutical industry for well over three years. It was the diagnosis of the problems of the Indian pharma industry by this Committee as well as its recommendations that paved way for the Patents Act of 1970. This Committee rightly observed, after studying the growth of Indian pharmaceutical industry under the colonial period and post colonial period but under a colonial Patent law, that India was not in a position to afford product patents in the field of drugs, chemicals and food items.[5]

After establishing Patent Act of 1970 it was working smoothly without any interruption till 1995; during this period, numbers of patents were granted by the Patent Office annually. But it declined in 1994-95. The number of pharmaceutical companies also increased in 1992-1993 comparing to an estimated 16,000 in 1969-70. The Federation of Indian Chambers of Commerce & Industry (FICCI), in a report prepared for the National Manufacturing Competitiveness Council (NMCC) in March, 2005, assessed the market share of Indian companies, in 2003 as 72.77 per cent and observed the Indian pharmaceutical industry, with over 20,000 units, was meeting 95 % of the country's pharmaceutical needs.[6]

It was to this scenario of dominance of the Indian drug market by the Indian pharma companies that the changes obligated by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) were introduced in the Patents Act, 1970. A series of three amendments were brought in from 1999 onwards. The

[1] K.D. Raju, "Interpretation Of Section 3(D) In The Indian Patents Act 2005:A Case Study Of Novartis", Cited In, Http://Www.Nalsar.Ac.In/Ijipl/Files/Archives/Volume%201/2.Pdf, Visited At 17/4/13 At 1:13 A.m.
[2] *Report of the Patent Enquiry Committee* (1948-50), p.11.cited in, T.C. James, (2003), "Patent Protection and Innovation section 3(d) of patent Act and Indian Pharmaceutical Industry.
[3] T.C. James, (2003), "Patent Protection and Innovation section 3(d) of patent Act and Indian Pharmaceutical Industry.
[4] Ibid.
[5] Supra note 4 at 3.
[6] Ibid.

final one was in 2005 when section 5 of the Patents Act, which prevented product patents in the fields of drugs, chemicals and food items, was deleted, thus paving way for product patents in all fields of technology. The impact of the expansion of the scope of product patent regime on public health, however, became a matter of serious concern of the parliamentarians. The government felt that it would not be TRIPS compatible to restrict the patentability criteria thus, though it promised to set up an Expert Group to study the issue in-depth. Thus the Mashelkar Committee was set up. The government, however, introduced certain additions to Section 3 (d) which it felt were necessary to prevent bad patenting and the phenomenon of ever greening.[7]The development of patent in brief is mentioned below:

1. **1856:** The Act 6 of 1856 on protection of inventions based on the British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
2. **1859:** The Act modifies as Act 15; Patent Monopolies called exclusive privileges (making, selling and using inventions in India and authorizing others to do so far 14 years from date of filing specification).
3. **1872:** The Patents and Design Protection Act
4. **1883:** The Protection of Invention Act.
5. **1888:** Consolidated as the Invention and DesignAct.
6. **1911:** The Indian Patents and Design Act.
7. **1972**: The Patent Act (Act 39 of 1970) came in toforce on 20-04-1 972.
8. **1999:** The Patents (Amendment) Act, 1999 camein to force from 01-01-1995.
9. **2002:** The Patents (Amendment) Act, 2002 came in to force from 20-05-2003.
10. **2005**: The Patents (Amendment) Act, 2005 came into force from 01-01-2005.

DEFINITION:

Patent refers to grant of some privilege, property of authority made by the Government or the Sovereign of the country to one or more individuals. The instrument by which such grant is made is known as 'patent'.[8]

A patent is a set of exclusive rights granted by a sovereign state to an inventor or their assignee for a limited period of time, in exchange for the public disclosure of the invention. An invention is a solution to a specific technological problem, and may be a product or a process. Patents are a form of intellectual property.[9]The Patents (Amendment) Act, 2005 defines patent under section 2(m) as – "patent" means a patent for any invention granted under this Act.

The word pharmaceutical comes from the Greek word 'Pharmakeia'. The modern transliteration of 'Pharmakeia' is 'Pharmacia'.Thepharmaceutical industry develops, produces, and marketsdrugsor pharmaceuticalslicensedfor use as medications. Pharmaceutical companies are allowed to deal in generic and/orbrandmedications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs[10]

THE CONTROVERSY ABOUT PATENTS FOR PHARMACEUTICALS

Patents provide legal protection for inventors in order to prevent other people from making use of their ideas. However, when the ideas that are being protected are medicinal drugs, this can be very controversial. Much of the controversy over pharmaceutical patents relates to the provision of drugs in the developing world, but there are also issues over the ownership of rights to medicines derived from traditional remedies.

Pharmaceutical companies often maintain that patent protection for drugs ensures that they are able to invest billions of dollars into the development of new products, by making sure that they will be able to take advantage of the sales. The other side of the argument suggests that this is not appropriate when the lives of many people may depend upon access to a new drug, which they can only afford if it is available in a cheaper, generic form.[11]

Patent protection for pharmaceutical products in the developing world can help to encourage the development of new medicines for diseases that affect these countries, by providing protection for the investments that need to be made by the pharmaceutical companies. However, patents on drugs can also make it more difficult for developing countries to afford the medicines they need.

[7] Supra note 3 at page 3.
[8] Dr. B.L. Wadehra, "Law Relating To Intellectual Property, Universal Law Publication Co. (2007) p. 4
[9]URL: http://en.wikipedia.org/wiki/Patent, accessed on 18/4/2013 at, 4:16 pm.
[10]URL:http://en.wikipedia.org/wiki/Pharmaceutical_industry, accessed on17/4/2013 at 3:13 pm.
[11]URL:http://www.fedcirc.us/the-controversy-about-patents-for-pharmaceuticals.php. Accessed on 17/04/2013 at 11:15 pm.

Creating a new medicine can take a lot of time and money. It can involve many years of research and clinical testing, which can be very expensive. If pharmaceutical companies are going to make this kind of investment into a new product, then they want to know that they will be able to protect their intellectual rights and ensure that they will be able to profit from the new drug. However, this could result in many important drugs being unavailable to poorer countries and people. It could also make pharmaceutical companies less likely to invest in medicines that are mainly needed in the developing world by encouraging them to focus on the most profitable investments and ignoring less profitable diseases. However, even with patent protection, these types of diseases are likely to be ignored since they will be less profitable than the diseases affecting rich nations.[12]

Pharmaceutical companies may offer cheaper versions of their drugs to developing countries, with some medications even being provided free of charge. However, pharmaceutical companies have also pursued legal action because of patent infringement. An attempt was made by 41 companies to sue South Africa because of its legislation to allow the importation and production of generic drugs for the treatment of AIDS. However, following an outcry around the world this case was dropped.[13]

Another controversial topic in the patenting of pharmaceutical products is the use of medicines that are derived from plants. There has been a lot of debate over who should profit from the use of drugs derived from plants that may already have been used as herbal medicines in certain parts of the world, with many people arguing that the pharmaceutical companies should compensate the communities from whom they have taken their inspiration. The pharmaceutical industry is not the only one to be affected by patent regulations, although it is one of the most controversial.

ANALYSIS OF SECTION 3(D) OF INDIAN PATENT AMENDMENT ACT, 2005

Section 3(d) of Indian patent Act has been a source of rising debate especially when pharmaceutical companies are considered. There aretwo important points pertaining to the analysis of section 3(d) with respect to products Glivec and Erlotinib i.e., Novartis case. While the inclusion of section 3(d) by the way of an amendment in 2005 of the Indian Patent Act supports humanitarian aspect like affordable drug prices but is not very encouraging from business perspective.

The very objective of having Section 3(d) as an amendment clause to Indian Patent Act was to prevent the "ever-greening" of patents. It was addressed at the Federation of Indian Chambers of Commerce and Industry (FICCI) round table on 29th March 2010 that removal of section 3(d) would result in "ever greening" and delays in the entry of generics, thereby affecting public health[3]. This was especially to keep a check on patenting of trivial modifications of current patented inventions to extend its monopoly regime. This section sought to prevent ever-greening by disallowing the patenting of a known substance unless it results in an 'enhancement of the efficacy of that substance'. By making derivatives with added efficacy patentable, section 3(d) encourages sequential developments of existing products or technologies that help bring in improved products to the market.[14]

Section 3 (d) says what are not inventions and it reads as follows:

> *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant".*[15]

Explanation: For purposes of this clause, 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.[16]

The basic principle behind section 3(d) is as follows:

1. Unless a new form of an existing substance depicted increased efficacy, it was not patentable. If it does demonstrate increased efficacy, then it is treated as an altogether "new substance".
2. The "mere new use" of a known compound cannot be patented.[17]

NOVARTIS CASE

[12]Ibid.
[13] Supra note 11 at page 7.
[14]Dr. Dhanalakshmi Iyer (2012), " Analysis of Section 3(d) of Indian Patent Act" http://www.ipfrontline.com/depts/article.aspx?id=26756&deptid=4. Accessed on 18/4/2013 at, 10:45 pm.
[15]Section 3(d) of Indian Patent Act, 1970.
[16] Ibid.
[17]http://www.ipfrontline.com/depts/article.aspx?id=26756&deptid=4 visited on 17. 4. 13at 1238 pm.

The case has appeared before the Madras High Court, the IPAB and now, before the Supreme Court, where the court had "*rejected pharma giant Novartis AG's plea to preserve its patent over life saving cancer drug, Glivec."*[18]Wherein the main point of objection is that the invention is a "*mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance".*[19]

Fact of the Case: Novartis A.G, a pharmaceutical company based in Switzerland, filed a patent application in the Chennai Patent Controller office for the beta-crystalline of imatinibMesylate, brand name Glivec on the ground that it invented the beta crystalline salt from (imatinibmesylate) of the free base, imatinib. But his claim was rejected by the Patent Controller Office (Chennai). After being rejected by the Indian Patent Office (Chennai) under Section 3(d), Novartis moved the Madras High Court in 2006 challenging the decision. It challenged the grounds on which the IPO rejected the application as well as Section 3(d) arguing that the Section contravenes TRIPS as well as Article 14 of the Indian Constitution.[20]

The High Court, in 2007, decided to split the two challenges, deciding to continue to deal with the validity of the Indian law but referred the appeal challenging the grounds on which the Indian Patent Office (IPO) rejected the patent application to the Intellectual Property Appellate Board (IPAB).

Before The High Court: On the matter of constitutional validity, Novartis stated that Section 3(d) violates Article 14 of the Constitution as the terms such as "enhancement of known efficacy" and "differ significantly in properties with regard to efficacy" are not accompanied by guidelines to define its scope, hence rendering the section vague and arbitrary, and as a result, conferring unfettered power to IPAB which violates the concept of equality enshrined in Article 14 of the Constitution.[21]

The High Court, deciding on the validity of Section 3(d) held that Section 3(d) is constitutionally valid. It correctly noted -

"*The argument that the amended section must be held to be bad in Law since for want of guidelines it gives scope to the Statutory Authority to exercise its power arbitrarily, has to be necessarily rejected since, we find that there are in-built materials in the amended section and the Explanation itself, which would control / guide the discretion to be exercised by the Statutory Authority. In other words, the Statutory Authority would be definitely guided by the materials to be placed before it for arriving at a decision*."[22]

Additionally, as *obiter dicta,* the Court tried to define the scope of the term "efficacy" and took the aid of a medical dictionary to conclude that "efficacy" would mean "*therapeutic* efficacy". This scope of "efficacy" was unclear as to whether bio-availability would count as therapeutic efficacy, since bio-availability might mean that a dosage of a certain medicine with side effects is reduced to a smaller dosage with no side-effects, thus making it therapeutically effective. The question was to whether bio-availabity would make the beta-crystalline form therapeutically efficacious was to be decided by the IPAB.[23]

Before the IPAB: In 2009, when the appeal challenging the grounds on which IPO rejected the application was heard before IPAB, IPAB held that though the claim covering the beta crystalline version of ImatinibMesylate is both novel and inventive, it failed the test under section 3(d), which requires a demonstration of "significantly enhanced efficacy".

To this, Novartis showed that the beta-crystalline form of imatinibmesylate showed enhancement due to its 30% bio-availabity; however, this evidence was rejected by the IPAB which iterated that the evidence did not conclude the enhancement sought under Section 3(d). It stated that section 3(d) is a heightened inventive step standard and that the only kind of efficacy that would satisfy section 3(d) is *therapeutic efficacy*. It said that Novartis's beta-crystalline version may possess improved bioavailability, thermodynamic stability, improved flow properties and lower hygroscopicity, but this does not amount to an increase in "therapeutic efficacy". The IPAB did not provide detailed reasons as to why it thought the beta-crystalline form lacked efficacy.

Appeal to Supreme Court: Novartis, in 2009, appealed to the Supreme Court against this decision of IPAB. The Supreme Court recently rejected the plea of Novartis AG for patent protection of its anti-cancer drug

[18] The Times of India, "SC Rules For Cheap Cancer Drug", Tuesday April 2 2013, At P. 8.
[19]Supra note 12 at page 7.
[20]Equality before law.
[21]*V.K. Unni (2012),* "Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health", *Presented in March 2011 at the University of the Pacific, McGeorge School ofLaw Symposium on The Global Impact and Implementation of Human RightsNorms.*
[22]URL:http://indiapatents.blogspot.in/2011/12/rustling-section-3d-in-novartis-glivec.html. accessed on 13/4/2013 at 10:30 pm.
[23]Supra note18 at page 9.

Glivec. The Supreme Court judgment (pages 22 -26) quite extensively quoted the adverse effects of product patents and positive effects of its abolition in the pharma industry in India.[24]

Comment: As a result of this judgment the anti-cancer drug will become more affordable. In future, thanks to this judgment and the simple but strict criterion of efficacy, it will be more difficult to get patents for new forms of old drugs. Hence these will be more affordable. But all the drugs which are under product patents and will be so in future will be high priced unless compulsory licenses are given to non-patentees to manufacture and sell these. Which we had seen in the Novartis's case.

In India, there is also the very critical problem that because of factors like low incomes, poor public health and inadequate insurance facilities, access to essential drugs, including those which are not patented, is very low. Thus to ensure proper health care much more needs to be done.

IMPACT ON PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is one of three technology-based industries in which the patent virtually equals the product. The others are the chemical industry (including agricultural chemicals) and the biotechnology industry, whose innovations span the spectrum from engineered plant varieties to human pharmaceutical therapies. These three industries are much different than other patenting industries such as computers and electronics. Most importantly, unlike industries which produce products requiring expensive and complex manufacturing infrastructures, the patented products of pharmaceutical companies can be easily and cheaply replicated by copiers with little capital investment. Since capital investment in the pharmaceutical industry disproportionately is directed to laboratory research and clinical trials rather than the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment. The pharmaceutical industry is heavily regulated by government agencies to assure the safety and efficacy of products which will be sold to consumers. The tolerance for a "buyers beware" philosophy in the pharmaceutical industry is extremely low compared to other industries.[25]

The product is now on the market in India and is available to asthma sufferers in that country at a price they can afford.14 Similar commercialization activities involving new therapies for leprosy, HIV and cancer are in development as a result of partnerships between CISR and private Indian pharmaceutical companies such as Cadila Pharmaceuticals, Ltd.[26] Following are the main issues in the Pharmaceutical world which is mentioned below:

1. ***Product Patents and Prices of Medicines***

The debate on impact of product patents on the pharmaceutical industry in India[27] has centered on the issues of price of the patented product and their accessibility. The positive association is observed between stronger protection and prices of the drugs, also the prices declined with the expiry of patent. The adoption of process patents along with the domestic regulations that restricted the role of Pharmaceutical Industry of India has reached a position of near self-sufficiency in formulations. After long experience of having a negative balance of trade in pharmaceutical products, India started enjoying positive balance of trade from the late 1980s. In production volume India accounts for 8% of world's pharmaceutical production and is the fifth largest in the world.[28]

The price control along with the amendment of patent laws in early 1970s resulted in a declining impact on prices. In India three factors have contributed to the lower cost of production: 1) the process development capacity of the units; 2) severe competition among the firms and 3) relatively lower cost of production. The comparison of patented drugs introduced elsewhere in the world shows that prices of the drugs had increased manifold after the protection. In the other side, developing countries may not be affected by the increase in the price of the drug due to low participation of patented drugs, because dynamic domestic players in India have managed to introduce substitutes of the patented products within four or five years after their appearance in the world market.

2. ***Impact of Weak Protection Regime***

[24]URL:http://www.rediff.com/business/interview/interview-novartis-ruling-is-not-an-anti-patent-judgement/20130410.htm. accessed on, 23/4/13 at 2:20 pm.
[25]S.B. Puranik, MamataSangamesh And Mona Golshan.S, Patent Laws In India And Its Impact On Pharmaceutical Industry International Journal of Pharma and Bio Sciences V1(2)2010. URL: http://www.ijpbs.net/issue-2/117.pdf. Accessed on 17/4/2013 at 11;15 pm.
[26] Ibid.
[27] Supra note 25 at 14.
[28] Ibid.

One of the major advantages of the universal system is that, it would facilitate access to new medical products. While welfare loss due to possible price increase in the post WTO regime is high lightened in the most of the studies, the welfare loss due non introduction of new patented drugs in India due to the weak protection regime is not discussed adequately. In this context, one of the advantages of the product patents is that the stronger patents will provide access to the latest inventions in the drugs, which the developed world will not shy away from introducing in India. The drug prices in India were brought under control based on recommendations of Hathi Committee, which observed that since the drugs industry has a social responsibility, it should operate much above the principles of trade for profit.

3. Product Patents and Research and Development

One of the advantages of the universal patent regime is that private venture capital firms become willing to invest in technology based start-up companies; technical knowledge flows more rapidly from university laboratories to the market place and local firms become willing to devote substantial resources to internet search. The higher cost of the Research and Development proves to be an effective entry barrier for new firms and hence only firms with large flow of funds become responsible for industrial inventive activity.

1. The market structure and prices
2. The growth of the Indian generic companies,

In the product patent regime, the prices of the new drugs would depend on:

1. What prices the MNC's holding the patents would charge
2. What steps can be taken to regulate such prices.
3. What prices (and manufacturing decisions) the MNC's will take for the new patented drugs.
4. What extent they will introduce them in India and other developing countries in the first place, are still not clear.

CONCLUSION:

In light of the above, It can be concluded that India should continue to maintain its present stance on Section 3(d) which is a statutory provision taking care of public interest and preventing ever-greening of patents. Just like Supreme Court of India in a historic judgment of Novartis Case has rejected the plea of Novartis and says – *"ways and means should therefore be thought out for making these drugs available to the masses at affordable prices".*[29]We can also say that there is no confirm evidence to show that without a strong patent protection regime innovations cannot occur, that minor innovations in the pharmaceutical sector do not require patent protection and that section 3(d) of the Patents Act is not a bar for patenting of significant innovations. What is required is more genuine innovations leading to development of drugs for diseases which still pose a challenge to humanity and not minor cosmetic modifications on existing drugs.

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[29] Supra note 15 at page 7.