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CASE ANALYSIS OF NOVARTIS AG V UOI. PATENT V PATIENT MR. RAHUL JOSHI*

"Drawing the line between improper attempts at evergreening and legitimate incremental innovation is a broad and difficult problem in patent law." [1]

Abstract

The pursuit for development and better life standards in the present world is ever increasing. These needs are fulfilled by continuous development in science and technology. But what motivates the person to put great endeavour to make the lives of other people better? According to the incentive theory people are pulled toward those things that offer positive incentives.[2] If the people are rewarded for their hard work others will also be motivated and ultimately they will come out with better quality of commodities which will eventually make the life better. So in science and technology field the people are awarded by various means. One such method is to give an exclusive right of a particular (new) thing to its inventor, so none could take advantage of his hardwork. This right is termed as patent.

A patent is a monopoly right granted to the person who has invented a new and useful thing or an improvement of a new article or new process of making an article.[3] The patent law story in India begin in by Act No.6 of 1856. Then came the Indian Patents and Designs Act in 1911. In order to reconsider the patent law the government of India formed two committees, *Bakshi Tek Chand* in 1948 and *Justice Ayyangar Committee* in 1957. The former's aim was to make the patent system positive to the national interests. The latter one revealed the shortcomings of the then enforced act and was more vital as it formed the ground for the present Patent Act of 1970 (hereinafter referred to as the act). In 2005 this act was further amended to make it compliance with the TRIPS agreement.[4]

The amendment of 2005 introduced Section 3(d) in the act. This Section provided a negative definition for the patents i.e. it defined what are not patents. A negative definition concept was considered so as to remove ambiguity from the text.[5] After this amendment the mailbox procedure[6] was not followed and the patent applications which were accumulated during the past decade were taken into consideration. One such application in the mailbox system was

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[1] *Biotechnology Research and the Patent Paradox*, available at (http://shodhganga.inflibnet.ac.in:8080/jspui/bitstream/10603/26002/12/12_chapter%202.pdf)
[2] Kendra Cherry, *The Incentive Theory of Motivation*, http://psychology.about.com/od/motivation/a/incentive-theory-of-motivation.htm
[3] P. NARAYANAN, PATENT LAW, (3rd ed.1998).
[4] *India-Patents (Amendment) Act, 2005 (Act No. 15 of 2005)*, Available at (http://www.wipo.int/wipolex/en/details.jsp?id=2407).
[5] Geo Miller and Co. Pvt Ltd. and Ors v State of M.P. and Ors. AIR 2004 SC 3552.
[6] It's a term that denotes a system which reserves the patent applications in those (developing) countries that wished to benefit from the TRIPs transitional period by not considering the patents application for pharmaceutical products until 2005.But Exclusive Marketing Rights could be granted.

by the Swiss drug company *Novartis*[7] for the grant of patent of anti-leukaemia drug Glivec[8] which is the beta crystalline form of Imatinib Mesylate.[9] This application grabbed attention of law framers and most importantly pharmaceuticals companies as it involved a patent of a vital cancer drug.

This paper will attempt to look into the reasoning of the Supreme Court in the case of *Novartis AG v UOI*[10] which prima facie involved the patent of an anti-cancer drug but the decision would impact the patentability of other drugs also. Finally the paper will reveal that how the judgement is beneficial for short term but in long term it will hinder growth of pharmaceutical industries. The case involved the patent of an anti-cancer drug Glivec.[11] Novartis applied for a patent in the Madras Patent Office on 17th July, 1998 for Imatinib Mesylate in "*Beta Crystalline*" form. In 2003 the Novartis was granted Exclusive Marketing Rights by the virtue of Article 24(a) of the then enforced act.[12] The application was put in the mailbox procedure till 1st January 2005 and was taken into consideration only after the Indian patent system was made in compliance with the TRIPS Agreement.[13]

Facts and Judgement

The case involved the patent of an anti-cancer drug Glivec.[14] Novartis applied for a patent in the Madras Patent Office on 17th July, 1998 for Imatinib Mesylate in "*Beta Crystalline*" form. In 2003 the Novartis was granted Exclusive Marketing Rights by the virtue of Article 24(a) of the then enforced act.[15] The application was put in the mailbox procedure till 1st January 2005 and was taken into consideration only after the Indian patent system was made in compliance with the TRIPS Agreement.[16]

Novartis appealed to the Madras Patent Office that patent should be granted on grounds of enhanced efficacy with respect to the better flow properties, thermodynamic stability, and most importantly 30% increased bioavailability[17] of the respective product. Before the application was taken five pharma companies filled pre-grant opposition to the application. The office upheld the pre-grant oppositions claims and rejected the application of Novartis for the reason that the said product does not pass the test of obviousness to a person skilled in the art and novelty and could be considered as an invention as per Section 3(d) of the act(hereinafter referred as Section 3(d)). The company then appealed to Madras High Court. The company contented that Section 3(d) was unclear, ambiguous, violated Article 14

[7] Application No. 1602/MAS/1998.
[8] Glivec is the brand name for Imatinib Mesylate. Also known as Gleevec.
[9] The Mesylate salt of Imatinib, a tyrosine kinase inhibitor with antineoplastic activity. Its chemical structure is 4-[(4-methyl-1-piperazinyl) methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl] amino]-phenyl] benzamide methane sulfonate. See (http://www.cancer.gov/drugdictionary?cdrid=37862)
[10] AIR 2013 SC 1331
[11] *Supra n 9*.
[12] *THE PATENTS ACT*, 1970(39 OF 1970). Available at (http://ipindia.nic.in/ipr/patent/patact1970-3-99.html)
[13] India introduced an amended version of patent laws to make it compatible with the TRIPS agreement.
[14] *Supra n 9*.
[15] *THE PATENTS ACT*, 1970(39 OF 1970). Available at (http://ipindia.nic.in/ipr/patent/patact1970-3-99.html)
[16] India introduced an amended version of patent laws to make it compatible with the TRIPS agreement.
[17] Bioavailability refers to the proportion of the pharmaceutical product which is absorbed into the blood during circulation and thus is an indicator of its efficiency, Available at (http://www.merckmanuals.com/professional/clinical_pharmacology/pharmacokinetics/drug_bioavailability.html).

of the Indian Constitution and was not in harmony with the TRIPS agreement and most importantly for the reversal of judgement granted by the patent office. In 2007 the High Court rejected the application but the application was transferred to the Intellectual Property Appellate Board (IPAB). The Appellate Board also denied the patent. Finally in 2009 Novartis filed a Special Leave Petition in the Supreme Court of India against the order of IPAB.[18] The Supreme Court not considering any of the above judgements started the hearing afresh.

The first issue encountered by the Apex Court was that whether the beta form of Imatinib Mesylate was an invention or not. Invention according to the act[19] means a new product or process involving an inventive step[20] and capable of industrial application.[21] The Court concluded that the beta form of Imatinib Mesylate is not an invention as it found it obvious to the person skilled in the art or having knowledge about *Zimmerman* patent[22] as it teaches how to make beta form of Imatinib Mesylate from Imatinib. The Court neither considered Imatinib Mesylate as well its beta form as an invention nor being patentable. This attracted Section 3(d) of the act into the case. Section 3(d) says "*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. Explanation -For the 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*". The Court gave the judgment that the product does not satisfy the Section 3(d) as the beta form of Imatinib Mesylate do not possess any enhanced efficacy (which the Court took here as only therapeutic efficacy) over Imatinib or Imatinib Mesylate. The Supreme Court finally rejected the application of Novartis and stated that their claim for patent for beta crystalline form of Imatinib Mesylate appeared as an attempt to obtain a patent for Imatinib Mesylate by just modifying the (crystalline) form of substance. Neither the derivation of beta form of Imatinib Mesylate could be considered as invention (as the Court considered it as obvious) nor did it possess any enhanced therapeutic efficacy.

Comment

This part of the paper will analyse the reasoning adopted in the judgement. The author objects the approach of the Supreme Court in the judgement.

The Section 2(1) (l)when read along with Section 2(1)(j) of the act one would get the definition of invention and when it is read with Section 3(d) one would get an idea on what inventions could not be patented. Section 2(1) (l) and 2 (1) (j) states that a new invention is that which has not been disclosed in any publication and that which involves an inventive

[18] *See* Article 136 of the Indian Constitution.
[19] See Section 2(1) (j) of the Patents Act 1970.
[20] *See* Section 2(1) (ja) of Patents Act 1970.
[21] *See* Section 2(1) (ac) of Patents Act 1970.
[22] An application for grant of patent for the Zimmermann invention (Pyrimidine Derivatives and Processes for the Preparation thereof) was filed in the United States of America on April 2, 1993, by Ciba Geigy (US Patent Application No. 08/042, 322).

step. In the present case the issue is that whether the beta form of Imatinib Mesylate is an invention or not. And if it is an invention could it pass the test according to Section 3(d). The Apex Court held that the compound do not qualify as invention because of two reasons firstly as the key substance of this compound i.e. Imatinib already existed in *Zimmerman* patent and secondly being the compound details published in a journal named '*Cancer Research*' in 1996. So this compound cannot be regarded as an invention because it was obvious for a person skilled in the art to make beta form of Imatinib Mesylate from *Zimmerman* patent and prior publication.

The author disagrees with the reasoning of Court in the said issue and contends that the compound is non-obvious with respect to its publications and *Zimmerman* patent. First consider the meaning of obviousness in context of patent laws, it means very plain[23] or on the face of it. But looking into the process involved to make beta form of Imatinib Mesylate from Imatinib do not appear as or on the face of it. The *Zimmerman* patent contained thirty seven derivatives of Imatinib.[24] The author agrees that the making of Imatinib is completely obvious, but selecting one single derivative from thirty seven compounds and then performing seven to ten complex steps in a two stage process[25] to make beta form of Imatinib Mesylate does not sound obvious. The Court opted for a very subjective test of obviousness by claiming a process obvious which first involves selection of single derivative from thirty seven derivatives (here Imatinib) and then deriving its methane plain sulfonic acid addition salt i.e. Imatinib Mesylate, and then proceeded to develop the alpha form and then beta crystalline form of the of Imatinib Mesylate.[26]

The second argument that the compound was not obvious is that as Novartis took more an eight years to develop the beta form of Imatinib Mesylate from Imatinib. The *Zimmerman* patent was applied in 1992.[27] Whereas Novartis applied application for beta form of Imatinib Mesylate in 2000. So as quoted by Justice *Herschell* in *Siddell v Vickers*[28] the test of obviousness is whether the thing under consideration was so obvious that it could occur at 'once' to anyone acquainted with the subject. No pharmaceutical companies will take more than eight years to develop a path breaking anti leukaemia drug that could bring a lot of profit if it was so obvious. The fact that Novartis took considerable amount of time to develop beta form of Imatinib Mesylate from Imatinib combined with the test in *Siddell vs Vickers*[29], connotes that the process was not obvious. The tests of obviousness laid down in *Winsurfing v Tabur*[30] should be taken to grasp the issue better. The case laid down four tests for obviousness. The first test is to identify an inventive concept in the specification of the product under consideration. So here the inventive concept are the complex steps adopted by the company to change Imatinib into beta form of Imatinib Mesylate. The second and important test is that the product is obvious to a normally skilled but an 'unimaginative'

[23] The General Tire & Rubber Company v The Firestone Type and Rubber Company Ltd [1972] R.P.C. 457
[24] *Pyrimidine derivatives and processes for the preparation thereof,* see (http://www.google.co.in/patents/US5521184)
[25] *Supra n. 10.* See para 7
[26] *Supra n.24*
[27] See European Paten website at (http://worldwide.espacenet.com/publicationDetails/inpadocPatentFamily?page=0&FT=D&CC=US&locale=en_EP&DB=&NR=5521184A&date=19960528&ND=&KC=A).
[28] 1890 (7) RPC 292.
[29] *Ibid.*
[30] 1985 RPC 59 CA.

person. Here unimaginative refers to a person will not conceptualize the product further. So to derive the beta form of Imatinib Mesylate from Imatinib one has to envision the scientific steps going to be involved. The third test is to identify the difference between matters citied as known with the alleged invention. The Apex Court mentioned that the article in Cancer research journal made the invention obvious, but still the author completely agree with the claim of appellant's attorney that the Imatinib Mesylate was discussed in the article it was not disclosed in it. though the author believes that this amounts to publication but the article only discussed " discussion about the anti-tumour properties of Imatinib and its methane sulfonate salt, i.e., Imatinib Mesylate"[31] but it did not actually revealed the process of making Imatinib Mesylate and that too in its beta form. So the test that was supposed to be adopted was that of whether the article disclosed the method of making beta form of Imatinib Mesylate or not. A mere discussion about the properties or even the product itself cannot be an indication of its obviousness. The test of obviousness relates to the technicality of the considered product[32], the beta form formation involves some unusual technical aspects. Even if there is a partial disclosure regarding the making of the product to such extent that it could not be prepared then also it cannot be considered to make the product publicly known. The author does not deny the probability of the journal being an introduction to the product but it actually did not disclosed the method of preparation. The last test is that if the knowledge of invention was not there to the skilled person could he derive at the invention or whether the deriving to the invention involved any inventive steps. As the fact that developing beta form of Imatinib Mesylate from Imatinib took many years to form and to be used as a drug involves complex methods so to reach the beta form there would require some inventive steps. And even if one assume that the beta form of Imatinib Mesylate differ marginally from Imatinib or was a technique of evergreening of a patent but regarding the question of obviousness and inventive steps it certainly involved inventive steps and research and it was not obvious to produce beta form of Imatinib Mesylate from Imatinib. So it is submitted that the reasoning applied for the test of invention and obviousness by the Supreme Court was rather a weak one.

The author also object the interpretation of Section 3(d) in the judgement. Although the Apex Court was absolutely correct to reject the claim of applicants with respect to non-applicability of Section 3(d). Beta form of Imatinib Mesylate being a polymorph[33] of Imatinib Mesylate directly invites Section 3(d) which also includes salt, ester etc. So on the face of it relates to Section 3(d). The term 'known efficacy' means that the product efficacy was known and well established beyond doubt. The matter regarding the therapeutic properties of Imatinib and Imatinib Mesylate were already known or proven beyond doubt as both the products were granted patent in USA so the efficacy was determined. The defence taken by the appellants that the known efficacy was not widely or publicly known do not stand good as it requires that mere known to persons who were engaged in pursuit of knowledge of patented product[34] would constitute that efficacy was proven or known beyond doubt.

[31] *Supra n10.* See Para 127.
[32] Dyson v Hoover [2002] RPC 22.
[33] The condition in which a solid chemical compound exists in more than one crystalline form; the forms differ somewhat in physical and, sometimes, chemical properties, although their solutions and vapours are identical. See (http://www.britannica.com/EBchecked/topic/468806/polymorphism).
[34] Monsanto Company v Coramandal Indag Products AIR 1986 SC 712.

But the author objects the interpretation of the Section 3(d). According to Section 3(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance will not be considered as an invention. Consequently, the Court concluded that in the case of a medicine that aims to cure an illness, the test of efficacy could only be "therapeutic efficacy", i.e. the capability of the medicine for beneficial change and its healing property. The dictionary meaning of efficacy is the ability to produce a desired or intended result.[35] But the Court unfortunately adopted a subjective interpretation approach. The Court concluded that the properties of more beneficial flow, better thermodynamic stability, and lower hygroscopicity[36] would result only in its physical efficacy not its therapeutic efficacy.

The interpretation of term 'enhanced efficacy' matters here since the Court took efficacy as only that element which directly enhances the ability of healing. The author is of the opinion that the properties of more beneficial flow, better thermodynamic stability, and lower hygroscopicity are those which on the very face of it do not give the product any therapeutic efficacy but are those which hold or retain the therapeutic properties. The thermodynamic stability refers to the product being capable to withstand variation of temperature. If the drug is more stable then it means that its therapeutic effect is preserved. So a new version being capable to preserve the therapeutic efficacy longer than the previous one is itself an indicator that the efficacy is increased. Hygroscopicity refers to the property of a substance by which it readily takes up and retains moisture. The claim of Novartis was not even considered by the Court and directly attributed it to physical efficacy of the product. The characteristic of not absorbing moisture itself is indicator of preserving the therapeutic efficacy being diminished. Although being physical properties they are important to maintain the therapeutic efficacy. So they give an indirect therapeutic efficacy to the referred compound.

The Court did not adopted the method of equitable construction of meaning for Section 3(d). Here the Court only interpreted the definition as such that only properties leading to direct enhancement of the therapeutic efficacy would be considered but excluding those properties which are required to hold the respective therapeutic effect. The other consideration that the Apex Court ignored was that the basic rule for interpretation of statute is that they must prima facie be given their ordinary meaning.[37] The case of *Gurudevdatta v. State of Maharashtra*[38], is a landmark judgment with respect to interpretation of statutes, it states that when words of statute are clear and plain then Court bound to give effect to that meaning 'irrespective' of consequences but The Court in Novartis case interpreted the meaning of Section 3(d) as looking in reference to the intention for which the statute was formed[39] i.e. they give the meaning by looking into the Ayyangar Committee report [40]which suggested that the patent power of the government has to be restricted with respect to pharmaceutical products[41] so as to promote national interest rather than boosting individual

[35] See Oxford dictionary definition of Efficacy.
[36] Hygroscopy is the ability of a substance to attract and hold water molecules from the surrounding environment. See definition at (http://www.merriam-webster.com/dictionary/hygroscopic).
[37] Gurudevdatta VKSSS Maryadit & Ors.v State of Maharashtra & Ors. (2001) 4 SCC 534.
[38] *Ibid.*
[39] Utkal Contractors and Joinery Pvt Ltd. and Ors. v. State of Orissa 1987 AIR 1454.
[40] See Ayyangar Committee Report. Available at (http://spicyip.com/wp-content/uploads/2013/10/ayyangar_committee_report.pdf).
[41] *Supra n.10.* See Para 41.

research.[42] The word themselves best declare intention of law. So by taking the dictionary meaning, the Section just talks about 'enhanced efficacy', so if the efficacy is increased substantially either by direct or indirect mechanism, the Court should consider it. Simply by taking the definition of efficacy it can submitted that enhanced efficacy also encompasses the physical properties of the drug which indirectly increases their ability to produce the desired (therapeutic) effect. And if the Section would have said enhanced efficacy only with respect to the purpose the product aims to serve then the Supreme Court was justified to give the meaning of efficacy as therapeutic efficacy.

So it is concluded that these factor do not directly connected to the therapeutic efficacy but they are indirectly related to therapeutic efficacy by preserving it and hence indirectly increase efficacy by making the healing property of medicine last longer.

Conclusion Analysis

The Intellectual property is a property created by law. Unlike the tangible properties (like land, money) which already existed before the formation of property laws, Intellectual property is a recent thing. So the law framers came up with the concept of granting recognition to Intellectual Property. The aim is to preserve an individual's (intangible) property, to offer the rights associated with it, and offer a reward for their research and hardwork which will ultimately provide an inducement to infuse more investment. In cases of inventions it gets patented under Intellectual property laws and this patent gives the inventor exclusive rights over his product.

The new financial year of 2013-2014 began with a landmark judgment by the Supreme Court in *Novartis AG v UOI* which will have far reaching impacts on the pharmaceutical sector. The Apex Court concluded that the beta form of Imatinib Mesylate does not satisfy the test of 'enhanced efficacy' as per Section 3 (d) of the Patents Act, 1970 and hence cannot be granted patent. The author is of the opinion that the reasoning used by the Supreme Court was a weak one. The invention of beta form of Imatinib Mesylate was not obvious either to a person skilled in the art of *Zimmerman* Patent or by its publication in '*Cancer Research*'. Following a technical approach the author submits that the present case did not satisfies the tests of obviousness laid down in *Siddell v Vickers* and *Winsurfing v Tabur*. Regarding the question of enhanced efficacy the author submits that the Apex Court restricted the meaning as only to therapeutic efficacy. The term efficacy means the ability to produce a desired result. So the ability to produce healing effect of Imatinib Mesylate is enhanced by its beta form, as its therapeutic efficacy is made to last longer. If the product is not stable its efficacy can't be utilised. The properties of beta form did not increased the healing efficacy but it indirectly increased its efficacy as the healing properties were preserved.

But still patent law is a very ambiguous area of law. The question is whether one consider patent law as a right given to the inventor so he would be motivated and would carry out such research and development activity with the same zeal in future or whether one consider it as to support the national interest and one should not enjoy a monopoly right on particular product. This question becomes more intense when it comes to essential pharmaceuticals. The companies who have a patent over a particular essential patent enjoys a

[42] *Supra n.10*. See Para 36.

monopoly over the market. It charges high prices from the customer which they justify as a yield from their hardwork research and investment. This high yield from one patented invention motivates other invention and thus accelerates the inventing activeness among the public which in turns creates a desire among the public and ultimately generate new products and process which lead to the growth of the country. The advantage of not granting a patent is that the drug will be manufactured by generic drug companies which charges extremely low as compared to their patented versions.

The Novartis case could be considered as a short term benefit judgement. The cost of the treatment with patented Glivec tablets would be around three and half lacs per month but now as the patent is not granted) one month treatment will costs only thirteen thousand.[43] But is this difference of amount would substitute the loss that our country could face as a result of such restricted patent laws. In the long term these restricted laws will prevent the pharma companies to support research programs for better quality drugs and putting their investment on risk. But the dilemma of Court is to reward incremental innovation and at the same time preventing the ever greening of a product. The author believes that the Beta form of Imatinib Mesylate has only slightly different structure and properties. But considering the law it should have granted a patent. It could be an attempt to evergreen the patent but the efficacy of new product was increased so it is submitted that the product should have been granted patent.

The legislature should consider the patent laws again and aim to strike a balance between promoting research and development and keeping monopoly rights at minimum for essential commodities. When analysing the evolution of patent laws one could say that the laws were made in hurry so as to make it TRIPS complaint before the deadline. So the legislature should have given proper time and consideration in formation of laws so as to make them clear and unambiguous. In Section 3(d) which was introduced by the 2005 amendment act, the legislature should have given specific guidelines for interpretation of the text. So the author suggests that the legislature should reconsider the patent laws especially Section 3(d). The author is of the opinion that 'enhanced efficacy' in Section 3(d) should include any kind of increased efficacy which either directly or indirectly raises the ability of the product to produce the desired effect.

[43] Gardiner Harris and Katie Thomas, *Low-Cost Drugs in Poor Nations Get a Lift in Indian Court*, New York Times, April 1, 2013. Available at (http://www.nytimes.com/2013/04/02/business/global/top-Court-in-india-rejects-novartis-drug-patent.html?pagewanted=all&_r=0).