HUMAN RIGHTS VIS-A-VIS PATENT PROTECTION: A CASE STUDY OF NOVARTIS AG V. UNION OF INDIA

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Abstract

The Indian Supreme Court's (SC) decision in Novartis v Union of India (UOI) was enough to drastically affect the booming and vibrant pharmaceutical industry and developed the goals which are focusing more on the public health in India. "Novartis" a pharmaceutical company produced GLIVEC (IMATNIB MESYLATE). In 2006 after putting the controversy before IPAB, the board refused "GLIVEC'S" patent under section 3(d) by arguing that it was only a modified version of an existing drugs therefore the drug was not an innovative one.

Section 3 of the Patent Act identifies the cases of inventions which are not patentable and its letter (d) as amended in 2005.The interpretation of Supreme Court for the above section was simply to limit the pharmaceutical companies in order to obtain secondary patents on the life saving drugs and to improve their availability focusing on a goal that the public health interest supersedes the commercial interest. Novartis battled the litigation with the Indian government but the foremost and final outcome of Supreme court in 2013 was that the new form of known substance is not eligible for patent because of lack of 'enhanced efficacy' and hence defined it as 'therapeutic efficacy'. The core problem is the controversy surround section 3(d) which shows the paradoxical nature of the above section in three different aspects which are the main issues of the case. Firstly, because it imposes a requirement of enhanced efficacy over a prior art before a patent on reformulation of an original pharmaceutical compound can be obtained. Secondly, the above section has limited itself and is exhaustive only upon pharmaceutical product. Thirdly, the narrow interpretation of the word "therapeutic efficacy". Moreover the decision affects the interpretation of article 27 of TRIPS Agreements.

This paper includes the multidisciplinary notion to answer the well suited questions raised by the Novartis AG with an analysis of TRIPS agreement and social–economic impact of different

interpretation as there is complex game that results in tension between the global trade commitment and domestic public health concern.

Keyword: Novartis, Patent, Therapeutic Efficacy, Pharmaceutical industry, Invention, TRIPS Agreement

Introduction

Countries in order to attain development while taking care of the needs of its citizens must go through a paradigm shift, now more than ever. And in order to maximize achievements of developmental goals, health is a parameter of utmost importance; healthy citizens can lead to overall growth of an economy. India is till present categorized as a developing nation owning a naïve Intellectual Property Law regime in contrast to a swiftly germinating population- ranked second largest globally. But this disparity does not settle the classic case of commercialism *versus* larger public good in the form of human rights. The Indian law since long followed a 'process' patenting system which was brought to a stop with TRIPS Agreement of the World Trade Organization (WTO) in 1995 that made 'product' patenting mandatory; thus opening a disputable area in India between the giant pharmaceutical sector and the larger goal of public health.

The Supreme Court's judgment in *Novartis A.G V. Union of India*[1] whereby it dismissed the patent application filed by Novartis for a drug used to treat a type of blood cancer, was a much awaited decision that seriously affected the pharmaceutical industry. This ended an eight year- long litigation at different forums for Novartis for grant of patent. Apparently, there was immense pressure on the Supreme Court in order to satisfy "*competing interests; encourage scientific innovation and making life –saving drugs available to the world's neediest citizen.'*[2] Though the central point of debate in this case was Section 3(d)[3] of the Indian Patent Act, 1970 dealing with *'the secondary patent on the life saving drugs.*'[4], the Hon'ble Court went on to pronounce a decision considering a much wider political and economic perspective. "*For once court is urging on promoting the scientific research and development by affording monopolistic protection to the producers of novel drugs in order to keep the obligation under*

[1]*Novartis Ag V. Union Of India & Others*, AIR(2013)SC 1311
[2]Kevin Tarsa,*Novartis Ag V. Union Of India: Why The Court's Narrow Interpretation Of Enhanced Efficacy Threatens Domestic And Foreign Drug Development,* Boston College International And Comparative Law Review,Vol.39 Http://Lawdigitalcommons.Bc.Edu/Cgi/Viewcontent.Cgi?Article=1764&Context=Iclrs
[3]*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 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 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."*
[4]*Novartis Ag V. Union Of India & Others*, AIR(2013)SC 1311,Para18

the International treaties and on the other hand they are promoting public health interest by protecting the generic drug producers in order to maintain the status of India as pharmacy of the world".[5]

As much interesting it is to study this historical decision, the importance of discussing particular aspects like the term 'enhanced efficacy' or the need to offer protection to India's generic drug industry also cannot be ignored. India provided for compliance with Article 27 of TRIPS by amending Section 3(d) of the Patent Act, 1970 but whether or not it is sufficient is discussed herein. Authors through this paper at studying a landmark judicial achievement seek a better understanding of the term 'enhanced efficacy' and effects of the same on a larger public access to medicines. Lastly, authors pursue an argument for widening the ambit of 'enhanced efficacy' in order to achieve a holistic development.

Historical Framework of Pharmaceutical Patents laws in India:

India's first patent law i.e. Act VI of 1856 on protection of inventions was based on the *British Patent Law of 1852* giving the inventor an opportunity to be protected for 14 years. With the number of modifications this law transformed into '*Inventions and Designs Act of 1888'*. India was beginning to leap towards industrialization but the pharmaceutical industry was still in its infancy, looking at which in 1911, the British replaced it *with 'The Indian Patents and Design Act'*. The 1911 Act established India's first patent administration[6] but was later reviewed by two committees namely the Patent Enquire Committee[7] and the Patent Revision Committee[8] on whether the Indian patent regime was consistent with national interests. Keeping in line with such considerations the *Patents Act, 1970* came into existence repealing the act of 1911. Major priority of the then established domestic patent regime was to focus on country- specific goals rather than western goals and resultantly, the Act of 1970 had a noteworthy impact on the yet budding pharmaceutical industry. The act provided patent on the processes for making the pharmaceutical compound. Thus, it can be concluded that the basic motive behind the 1970 act was to vitalize a procrastinating Indian economy by manufacturing of drugs domestically.[9]

[5] *Supra* note 3
[6] William J. Bennett " *Indian Pharamceutical patent law and the Effects of Novartis AG v UOI*", Washington University Global Studies Law Review, Vol. 13,2014, (Accessed on 09.07.2017) http://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1500&context=law_globalstudies
[7] Headed by Justice BakshiTek Chand
[8] Headed by Justice N.RajagoplaAyyangar
[9] Shri Justice N. RajagopalaAyyangar ,REPORT ON THE REVISION OF THE PATENTS LAW, September, 1959 www.ipa-india.org/static-files/pdf/publications/resources/Nov%202009.pdf

Evolution of the generic drug industry provided a boom to the Indian economy and benevolent to the general public, a large portion of who would have not been able to afford expensive drugs. This earned India the nickname 'pharmacy of the world' for its flourishing generic pharmaceutical industry and related exports.[10]. Further, India enacted the *Patent (Amendment) Act of 2005* in compliance with the TRIP's agreements and enabled the patenting of pharmaceutical products accordingly. The case decided by the Supreme Court against *Novartis Ag*[11] revolved around Section 3(d) of the *Patents Act, 1970* and a term '*minimum efficacy*' derived by the Court, the definition of which was not to be found anywhere in the Act. *Supreme Court itself observed that efficacy means "the ability to produce a desired or intended result".* After this decision India broke free from the 'draconian' patent law regime in place since the time of British colonial era and was able to prosper and contribute to the growth of the country's 'indigenous scientific and technological capacity'.[12]

The Chronological Order of the facts of Novartis AG

a) On July 17, 1998, the pharmaceutical company Novartis filed a patent application at the Chennai Patent Office for the "*beta-crystalline form of ImatinibMesylate* which *was sold in the market with name of GLIVEC.*"[13] At the time when Novartis had filed an application for grant of patent a 'mail box' process was followed for the acceptance of applications. Novartis' application was pending in the mailbox till 2005 and India on the other hand had introduced the product patent regime falling in line with the requirement of TRIPS.

b) The time during which the application was pending through the process of mailbox which was the requirement under TRIPS Agreement and the Act, Novartis was granted exclusive marketing rights under section 24A of the Act[14] which was in line of the TRIPS Agreement.

c) In the year 2005 India proceeded to amend the Patents Act, 1970 and introduced the regime of product patent simultaneously amending Section 3(d)[15] of the Act. The above section put the constraint on granting a patent on any product manufactured by using an already known substance by merely changing the chemical formula. The criterion of 'enhanced efficacy' laid down by the amended legislation was included in section 3(d)

[10]Dorothy, Du. "*Novartis Ag V. Union of India: 'Evergreening,' Trips, And 'Enhanced Efficacy'*" Under Section 3(d)' (2013-2014)21 J. Intell. Prop. L., 223 , Journal Of Intellectual Property Law, Vol.21, (Accessed on 09.07.2017), http://heinonline.org/HOL/Page?handle=hein.journals/intpl21&div=13&g_sent=1&collection=journals
[11]*Novartis Ag V. Union Of India & Others*, AIR(2013)SC 1311
[12]*Ibid*
[13]*Ibid*
[14] Indian Patent Act, Sec 24 A
[15] Substituted by the Patents (Amendment) Act,2005 (15 of 2005),S.3, for cl. (d) (w.e.f. 1-1-2005)

which would finally decide the patentability of the product. The major motive for this was to prevent ever greening and grant of frivolous patent.

d) Before Novartis's patent application was taken up for examination there were five pre-grants opposition which were filed by the Cancer Patient Aid Association, Cipla Limited, NATCO Pharma, Ranbaxy Laboratories and Hetro Drugs.

e) The Assistant Controller of Patents and Designs at the Patent Office dismissed the patent application of Novartis on the ground that it lacked novelty, was obvious and was not an invention as per section 3(d) since an older version of the molecule was used in the new product, hence making the new product fall off the criteria.

f) Resultantly, in May 2006 Novartis filed writ petitions under Article 226 of the Constitution of India before the Madras High Court against the Union of India, the Controller General of Patents & Designs ("Controller") and Opponents.Novartis contended that:[16]

- *Section 3(d) of the 2005 violated Article 14 of the Constitution of India and was not in compliance with requirements of TRIPS;*
- *The Controller erred in interpreting the enhanced efficacy standard imbibed in Section 3(d) with regard to product;*
- *The Controller disregarded the in-house laboratory test performed by Novartis' scientists on rats to show that a 30% increase in bioavailability between Imatinib and Imatinib Mesylate was adequate to meet up the enhanced efficacy*[17] *benchmark of section 3(d).*

g) There were two questions before the Madras high court, firstly as to whether Section 3(d) violated Article 14 of the Constitution of India, and secondly whether the Patent Office was correct in not granting Novartis's new product with a patent on the grounds it applied.

h) Thereafter, Madras High Court took up the question of constitutional validity while sending the question regarding obviousness and lack of novelty of the product to the Intellectual Property Appellate Board (IPAB). The court reserved it's right on the issue of constitutional validity and held that Section 3(d) did not violate Article 14 of the Constitution of India against which no further appeal was filed by Novartis.

i) On the question referred to the IPAB by the High Court, IPAB reversed the decision of the Controller on the issues of anticipation and obviousness. It was held that the subject

[16]Ajay Chandru & Gowree Gokhale, "Novartis Indian Supreme Court judgment: what is efficacy for pharmaceutical invention?",Manupatra Intellectual Property Reports (MIPR), Vol.2,2013 http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Articles/MIPR_Novartis.pdf
[17]*Novartis Ag V. Union Of India & Others*, AIR(2013)SC 1311

matter was barred from patentability under the concerned Section therefore rejecting the patent but allowing the process patent.

j) In 2009, Novartis filed a Special Leave Petition under Article 136 of the Indian Constitution before the Supreme Court of India against the said IPAB order.

k) In 2013, The Supreme Court delivered a judgment against Novartis Ag.

Analysis off the term '*Efficacy':*

The Indian Supreme Court in *Novartis AG* has given three different interpretations of 'enhanced efficacy'. The first interpretation is that enhanced efficacy is subsumed completely within India's "inventive step" and "industrial application" requirements. The second interpretation is that enhanced efficacy refers broadly to any improvements on the functioning of a pharmaceutical as a treatment. The third is that enhanced efficacy means therapeutic efficacy only, as narrowly defined by the Madras High Court and the IPAB. Each interpretation has its own attendant consequences for ever-greening, public health, and innovation, and there are tradeoffs to each.

A. Inventive Step or Industrial Application Requirement

One interpretation of Section 3(d)'s enhanced efficacy requirement is that it is merely a re-articulation of the inventive step or industrial application requirement in the context of pharmaceutical product patents. Section 3(d) would be least likely to contravene TRIPS Article 27.1 under this interpretation of enhanced efficacy. Inventive step and industrial application are already required in India as a result of TRIPS Article 27.1.[18] According to Section 2(1)(j) of the 1970 Act, an "invention" is a new product or process that involves an inventive step and is capable of industrial application.[19]

Many practitioners believe that Section 3(d) to be no- more than an explanation of the inventive step or industrial application requirement in the field of pharmaceutical products. Thus, Section 3(d) is essentially not an enhanced efficacy requirement and does not add any additional barrier to patentability. Some says that Section 3(d) as "just another form of saying that something is non-obvious in a more concrete way."[20]According this view, the patent office could just demand higher

[18]Agreement on Trade-Related Aspects of Intellectual Property Rights, Art.27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round Vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS]

[19]Ranjan Matthew, Lakshmi kumaran&Sridharan, *Patentability requirements in India* (2011), http://www.lakshmisri.com/Uploads/MediaTypes/Documents/L&SWebsite IPRFeaturedRanjan.pdf.

[20]Ranjan Matthew, Lakshmi kumaran&Sridharan, *Patentability requirements in India* (2011), http://www.lakshmisri.com/Uploads/MediaTypes/Documents/L&SWebsite IPRFeaturedRanjan.pdf.

efficacy even without Section 3(d) and the inventive step and industrial application requirements themselves require some level of increased efficacy above the prior art in order to obtain a patent.

By this it may be assumed that Section 3(d) creates a doctrine analogous to the United States' "obvious to try" doctrine that has experienced recent revival in cases like *KSR v. Teleflex, ExparteKubin,* and *Pfizer v. Apotex.*[21]If we assume that US patent law is consistent with TRIPS, which we recognize is itself an assumption for the sake of argument,[22] then Section 3(d) can be construed as consistent with TRIPS by analogy. Although *KSR* was about a mechanical and electronic device, not a pharmaceutical, it nevertheless shifted the overall tone of the courts towards using "obvious to try" to supplement the "teaching, suggestion, or motivation test."[23] In *KSR,* the U.S. Supreme Court commented that the Federal Circuit had "concluded in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try."[24]

Following *KSR,* the court in *Pfizer v. Apotex* found a patent obvious because the prior art had already narrowed down the potential combinations for an effective drug to fifty-three besylates.[25] Further, in *Exparte Kubin,* a biotechnology case, the Patent Board reaffirmed the use of obvious to try, citing *KSR.*[26] Under the "obvious to try" test, if the prior art narrows down a finite set of particular and predictable combinations that are obvious for a person of ordinary skill in the art to try, then those combinations fail the non-obviousness requirement.[27]Section 3(d) could merely embody a legislative judgment that a reformulation or "slight" modification of a chemical compound is per se obvious to try.

As for Section 3(d) being an elaboration of industrial application in the pharmaceutical sphere, then it can be said that Section 3(d) "is meant to prevent the patenting of stereoisomers that were accidentally discovered." The provision simply requires that the isomer actually *does something.* In other words, Section 3(d) is India's answer to the specific utility or substantial utility requirement that constitutes one requirement of Section 101 in the United States. Like specific utility or substantial utility in the United States, Section 3(d) may simply require that patent applicants state

[21]Andrew V. Trask, *'Obvious to Try":A Proper Patentability Standard in the Pharmaceutical Arts?, 76,* FORDHAM L. REV. 2625 (2008),http://ir.lawnet.fordham.edu/flr/vol76/iss5/9.
[22]*Ibid*
[23]KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).
[24]*Ibid*
[25] Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1364-69 (Fed. Cir. 2007).
[26]*Supra* note 23
[27]*Ibid*

a sufficiently well-defined use for the new drug or demonstrate a real-world benefit to the public at the time of filing, respectively.

B. More than Inventive Step and Industrial Application

Alternatively, the Indian Supreme Court in *Novartis AG* could have found, as the lower courts did, that Section 3(d)'s enhanced efficacy requirement demands more than on inventive step and industrial application to obtain a pharmaceutical product patent. On such an interpretation of the term Enhanced Efficacy various arguments has been raised, firstly that under any such interpretation of enhanced efficacy, Section 3(d) is not TRIPS compliant, secondly on the restriction of the enhanced efficacy requirement to a narrow therapeutic efficacy requirement and finally on India's use of patent law theory to justify actions much more consistent with a "social welfare" theory.

Noncompliance with TRIPS: The Indian Supreme Court has interpreted enhanced efficacy in Section 3(d) to mean medically significant efficacy that is fundamentally different from the inventive step and industrial application requirements. This interpretation departs from U.S. conceptions of pharmaceutical patent protection.[28] If the US is assumed to be a good benchmark of compliance with TRIPS, [29] then by creating an additional barrier to patenting drugs, Section 3(d) contravenes TRIPS.

The plain language of Article 27.1 is ambiguous, but if anything, it suggests that inventive step, industrial application, and novelty are to be the only requirements for patentability.[30] As stated above, the first part of TRIPS Article 27.1 says that patents shall be available in "all fields" of technology if they are "new, involve an inventive step and are capable of industrial application."[31]According to a well-known semantic canon of statutory construction, *expressiouniusestexclusioalterius,* the explicit mention of items in a list gives rise to an inference that all other items are excluded.[32]Logical reasoning about the nature and purpose of TRIPS leads to the same conclusion. If TRIPS was meant to guarantee Intellectual Property Rights (IPRs) or at least minimum IPRs in all members of the WTO, especially developing countries that lacked such rights,

[28]See LokSabha Debates (March 22,2005),http://164.100.47.132/LssNew/psearch/result14.aspx?dbsl=1866
[29]Andrew V. Trask, *'Obvious to Try":A Proper Patentability Standard in the Pharmaceutical Arts?, 76,* FORDHAM L. REV. 2625 (2008),http://ir.lawnet.fordham.edu/flr/vol76/iss5/9.
[30]Bhaven N. Sampat, Kenneth C. Shadlen & Tahir M. Amin, *Challenges to India's Pharmaceutical Patent Laws,* 337 SCIENCE 414, 414-15 (2012).
[31]Art 27 of TRIPS
[32]People v. Smith, 393 Mich. 432, 436, 225 N.W.2d 165, 166 (1975).

then to allow such countries to append additional requirements onto the list of requirements set forth by TRIPS would render the provision a nullity. A developing country could circumvent the spirit of TRIPS by simply erecting extra barriers to patenting wherever it believed it would benefit. The second part of Article 27.1, the non-discrimination clause, only strengthens the argument that Section 3(d) violates TRIPS by clarifying that the named requirements should not be applied differently to different fields of technology.[33]

Throughout *Novartis AG,* the courts on every level have invoked the importance of the generic drug industry to India's economy, which raised the question of whether Section 3(d) is being used prejudicially against pharmaceutical patent holders, which tend to be foreign MNCs.[34]

The courts *in Novartis AG* have "listened more to the Indian drug market than to the other side" and various "NGOs, legal aid societies put pressure on the court to consider the survival of the generics industry."[35] On these facts, Section 3(d) may violate the spirit of Article 27.1 to promote free and fair trade if it is interpreted so strictly as to preclude the patenting of a large portion of pharmaceutical drugs that foreign companies apply for, to the benefit of generic drug manufacturers.

Analysis of an Additional Enhanced Efficacy Requirement Generally: Despite noncompliance with TRIPS, the Supreme Court has adopted an interpretation of Section 3(d) that demands more than inventive step and industrial application. The main benefit of requiring enhanced efficacy is straightforward-although it would have no effect on promoting access to generic medicines for the reasons described in Part III, Section 3(d) would keep out patents on useless and relatively harmless products.[36]

However, an enhanced efficacy requirement does create the possibility of blocking the patenting of genuine innovation. As "The issue the pharmaceutical industry is currently facing is that it is difficult to demonstrate 'enhanced efficacy' at the time of patenting, even if the reformulated

[33]Art 27.1 of TRIPS
[34]*More Foreigners than Indian's receiving Patents in India,* ECON. TIMES (May 22, 2011, 12:45 PM), http://ardes.economictimes.indiatimes.com/2011-05-22/news/29571273_patents-act-patent-protection-utility-models.
[35]Swiss Govt. Not to Take Novartis Case to WTO, Bus. STANDARD (Aug. 8, 2007),http://www.business-standard.com/article/economypolicy/swiss-govt-not-to-take-novaris-case-to-wto-1 07080801003 1.html
[36]Sharmnad Basheer& T. Prashant Reddy, *The 'Efficacy" of Indan Patent Law: Ironing out the Creases in Section 3(d),* 5 SCRIPTED 232, 255 (2008).

products in fact possess enhanced efficacy."[37] The Madras High Court's opinion seems to assume that it would be easy to procure efficacy data, if enhanced efficacy exists.[38] If the patent office and courts decide, post- Supreme Court decision, that Section 3(d) demands proof of efficacy in the regulatory sense-that is, statistically significant clinical trials demonstrating efficacy-at the time of patenting, then many efficacious drugs may fail under Section 3(d).[39] Pharmaceutical companies typically seek patents up to several years before they are able to sell a commercially viable drug.[40]A patent provides the incentive to perform the clinical trials to get efficacy data by (1) guaranteeing the drug company a right to exclude others from exploiting then eventual fruits of its labor[41]and (2) protecting companies from having their own clinical data used as prior art against their future patent applications.[42]If the Supreme Court requires a high level of proof of efficacy too early in the long and arduous[43] process of drug development, it might put the cart before the horse.[44]

Narrowing the Interpretation of Efficacy to Therapeutic Efficacy only: If the true purpose of Section 3(d) is to separate minor modifications from genuine innovation, as proponents of Section 3(d) claim, the Supreme Court should have selected a broad interpretation of enhanced efficacy that blocks secondary patents on treatments that do not improve patient outcomes while permitting the patenting of valuable new iterations of drugs. A narrow interpretation of enhanced efficacy would not reward innovation in accordance with patent law theory; it cannot be justified on the principle of preventing pharmaceutical companies from extending monopoly protection on their drugs without producing valuable changes to drugs.

A different theory that justifies the distinction created between "therapeutic" and other types of "efficacy" would be required. The theory could simply be that India should limit pharmaceutical patenting whenever it benefits India to do so, balancing increased access to affordable medicines and loss of incentives to innovate, rather than the nature and extent of innovation in a patent application. The straightforward benefit of disallowing secondary patents under this social welfare-

[37] *Ibid*
[38] *Ibid*
[39] *Ibid*
[40] Edmund W. Kitch, *The Nature and Function of the Patent System,* 20 J.L. &EcON. 265, 276 (1977)
[41]Sharmnad Basheer& T. Prashant Reddy, *The 'Efficagy" of Indan Patent Law: Ironing out the Creases in Section 3(d),* 5 SCRIPTED 232, 255 (2008).
[42]Jane Larkindale, *Why Does It Take So Long to Go from Mouse to Man,* QUEST (Jan. 1, 2012, 3:11 PM), http://quest.mda.org/article/why-does-it-take-so-long-go-mouse-man .
[43] *Ibid*
[44]Shamnad Basheer& T. Prashant Reddy, *The 'Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d),* 5 SCRIPTED 232, 255 (2008).

oriented theory is that it undeniably allows India's large population of poor patients to access generic drugs sooner.

India could have altruistic social welfare reasons to block the patenting of even genuine improvements on drugs. A patent, however innovative the product, is still a monopoly. If the only commercially approved version of the drug is the one on which the pharmaceutical company seeks a secondary patent, granting the patent would indeed block generic companies from producing the commercially approved drug until the secondary patent expires.[45] As a result of which generic companies face high regulatory barriers for making a second tablet with the same active compound inside. The moment they do a different form to avoid the secondary patent, they are facing regulatory barriers because now they have to show bioequivalence [to the MNC's approved drug].[46] Considering Indian pharmaceutical companies' current model of reverse engineering rather than doing original research and development, few domestic companies would be up to the challenge.[47] In the meantime, India's large population of poor patients would be denied access to relatively inexpensive generics.

Analysis of IPAB Judgment on Enhanced efficacy

IPAB considers the definition of Efficacy according to 'Dorland's Illustrated Medical Dictionary (Dorland's)' i.e. "the ability of a drug to produce the desired therapeutic effect, independent of potency", without looking into the history of the term "efficacy" and intention of the legislature. "*On this basis, the board concluded that enhanced efficacy cannot merely be a change in the amount or dosage needed to treat the illness, but rather, it requires something they call therapeutic efficacy, which they left undefined*".[48]In this way the plain language of the statute suggest a narrowing of the term "efficacy" from its ordinary meaning by putting the qualifier 'therapeutic' in the statute.

Further the IPAB stated that "bio-availability and therapeutic efficacy are not the same"[49]as determinative of whether the increased bioavailability offered by the beta crystalline form of

[45] If a patent covers the commercialized product, the patentee can legally prevent others from "making, using, offering for sale, selling or importing for those purposes that product in India." The Patents Act, 1970 § 48(a), No. 39 of 1970, INDIA CODE (1993), http://Indiacode.nic.in.
[46] Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical innovation,* 68 U. PITT.L. REV. 491, 495, 536-37 (2007)
[47] *Ibid*
[48] MIPR2009(2)345
[49]Novartis AG v. Union of India (IPAB June 26, 2009), http://www.ipal.tn.nic.in/Orders/100-2009.htm.

imatinibmesylate fulfills the requirement of therapeutic efficacy. Increased bio-availability alone is not always sufficient to lead to increased therapeutic effect, it can be a contributing cause towards achieving increased therapeutic effect or it can be said that changes in bioavailability can have clinical significance. If a substance already has therapeutic effect, increasing its bio-availability would of course enhance its therapeutic effect if all else is held equal. Enhanced therapeutic efficacy can follow naturally from enhanced bioavailability.

IPAB's order also seems to stem from its fear that an inventor could use a broad definition of efficacy in order to patent different dosages of the same essential drug by claiming that using a higher dose causes the drug to have enhanced efficacy.[50]Yet, the facts of the instant case are far from this imagined stratagem.

Here, Novartis is effectively claiming that a *lower* amount of the drug would have the same therapeutic effect.[51] The patent application does not claim that the beta crystalline form of imatinibmesylate is more effective than imatinib free base because it contains a higher concentration of the active molecule; the patent claims a salt, not an amount or concentration.[52]Rather, the claimed salt is stated to be more effective because the active molecule has been chemically altered through its reaction with methansulfonic acid and a subsequent crystallization process to be more thermodynamically stable, less hygroscopic, and possess superior flow properties.[53]

Moreover, the polymorph of imatinib claimed in the patent is actually the only form that is *usable*in a form administrable to patients. As counsel Tehmtan R. Andhyarujina argued on behalf of Novartis, it is only the beta crystalline form of imatinibmesylate that is used in Glivec[54]. If a drug cannot be administered, its chemical potency in vitro arguably has no therapeutic effect. In that

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[50]*C.* Godugu et al., Approaches to Improve the Oral Bioavailability and Effects of Novel Anticancer Drugs Berberine and Betulinic Acid, PLOS ONE, Mar. 10, 2014, Vol. 9 Issue 3, at *1,* http://www.plosone.org/article/info%/3Adoi%/.

[51]*Ibid*

[52]Novartis AG v. Union of India, A.I.R. 2013 S.C. 1311, at 7 (India),http://supremecourtofindia.nic.in/outtoday/patent.pdf.*Cf*International Patent Application WO 99/03854, page 22, file:///C:/Users/ddu/Desktop/personal/9006361800b35af.pdf or http://patenscope.wipo.int/search/en/detai.jsf?docld=W01999003854&recNum=1&maxRec=1&office=&prevFilter=&sortOption=Pub+Date+Desc&queryString=FP%3A%2899%2FO3854%29&tab=PCT Description.

[53]Novartis AG v. Union of India, A.I.R. 2013 S.C. 1311, at 85, 88, 94 (India), http://supremecourtofindia.nic.in/outtoday/patent.pdf.*Cf.* International Patent Application WO99/03854, pages 3, 8, file:///C:/Users/ddu/Desktop/Personal/9006361 800b35af.pdfor http://patentscope.vipo.int/search/en/detail.jsfdocldWO1999003854&recNum=1&maxRec=1&office=&prevFilter=&sortOption=Pub+Date+Desc&queryStrong=FP%3A%2899%2F03854%29&tab=PCTDescription.

[54]Lawyers Collective HIV/AIDS Unit, *supra* note 86; *Gleevec,* DRUGS.COM, http://www.drugs.com/pro/gleevec.html

respect, imatinib free base or even imatinibmesylate in general lacks therapeutic effect; it is only the beta-crystalline form of imatinibmesylate that has any therapeutic effect.

Reinterpretation on Enhanced Efficacy by Supreme Court.

On appeal, Novartis lost for the essential reason that the Supreme Court of India affirmed the IPAB's interpretation of efficacy as therapeutic efficacy, using the IPAB's definition of the term. If the Supreme Court had instead construed enhanced efficacy to require some type of improved efficacy, but interpreted efficacy broadly, Novartis' application would have fulfilled Section 3(d)'s demands. Finally, if the Court had decided to read enhanced efficacy into the inventive step and industrial application requirements, *aforiori,* Novartis's patent application would have survived Section 3(d). The differing outcomes under these three interpretations exemplify the problem Section 3(d) poses to the future of pharmaceutical innovation and operations in India. Below, I argue that the Supreme Court's interpretation of Section 3(d) wrongfully precludes the patenting of a pharmaceutical like Glivec in *NovartisAG.*

First, if there exist cases in which a drug company deceives the public into demanding the latest version of a drug though the new version works no better than the old, such is not the case in *Novartis AG.* Novartis was not trying to deceive patients into demanding imatinibmesylate, when imatinib free base or some other salt was just as effective. Whereas other salts and forms of imatinib were not stable enough to be encapsulated and administered as a cancer treatment, the beta crystalline form of imatinibmesylate claimed in Novartis's rejected application was.[55]Glivec, which uses this form of imatinibmesylate, has been widely recognized as a breakthrough drug for treating chronic myeloid leukemia (CML) by both Novartis's supporters and detractors.[56]

Second, demand for Glivec by generics and NGOs like Lawyers Collective has been extremely high.[57] Considering that Indians are more price sensitive and many cannot afford branded versions of expensive drugs, the fact that Glivec has been commercially successful and patients prefer

[55]Novartis AG v. Union of India (IPAB June 26, 2009), http://www.ipab.tn.nic.in/Orders/100-2009.htm ("Because of the advantageous properties, beta-crystal form is superiorto the alpha form with respect to the manufacture of pharmaceutical preparations in solid dosages."). Claim 11 of the rejected application was "[a] pharmaceutical composition, comprising a form of the methanesulfonic acid addition salt of a compound of formula *1" Novartis AG.*
[56] Leslie A. Pray, *Gleevec: The Breakthrough in Cancer Treatment,* NATURE EDUCATION (2008), http://www.nature.com/scitable/topicpage/gleevec-the-breakthrough-in-cancer-treatment-565.
[57]Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and* Novartis AG v. Union of India, 23 BERKELEY TECH. L.J. 281, 281 (2008).

Glivec suggests that Glivec has enhanced efficacy above the prior art. That is, imatinibmesylate in beta crystalline form and not imatinib free base is what saves lives. Those, who do not believe the innovative leap from imatinib to imatinibmesylate in beta crystalline form qualifies Novartis for a new patent have yet to identify an alternative salt or polymorph of imatinib that could be used in a commercial drug.

Third, the secondary patent demanded wouldin this case preclude the sale of generic Glivec after the expiration of a hypothetical patent on imatinib free base, [58]but this is due to the nature of the secondary patent as the specific usable form in this case. It is not because the secondary patent would extend patent protection over the original invention, which it would not. Novartis's 1993 patent on imatinib did not disclose or enable the use of a usable anticancer drug.[59] Rather, the invention of the beta crystalline form of imatinibmesylate and the discovery of its anticancer properties and amenability to storage in solid dosage required much additional research, which the IPAB opinion recognized.[60] IPAB further conceded that Glivec satisfies the other requirements for patentability, including inventive step and industrial application.[61] It is inconsistent to argue, then, that the invention of Glivec took little effort and ingenuity above the prior art.

Last and relatedly, it is the invention of imatinibmesylate, not imatinib free base that society should aim to incentivize with its patent laws. A patent on imatinib alone could still incentivize the development of a commercial drug that utilizes it, since there would be no way to profit from imatinib unless and until a commercially viable drug was developed. However, that incentive would be more incidental than targeted towards the true invention.

Perhaps India's true objection to pharmaceutical patents is that patent protection for pharmaceutical products is too strong and the term too long, considering that many Indian patients cannot afford the sticker price for lifesaving drugs like Glivec. If that is the case, it may be legitimate under a social welfare theory. However, as noted in the arguments of the case, these arguments should be made explicit so that the international dialogue and related litigation can focus on what the debate is truly about-the fact that India wants an exceptional patent provision because it believes its social and economic conditions are exceptional. Until India acknowledges its social welfare theory of patent protection, it cannot expect TRIPS and other international treaties to be modified according to its needs.

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[58]*Ibid*
[59]Sanofi-Synthelabo v. Apotex, Inc., 492 F. Supp. 2d 353, 384 (S.D.N.Y. 2007).
[60]Novartis AG v. Union of India (IPAB June 26, 2009),http://www.ipab.rn.nic.in/Orders/100-2009.htm
[61]*Ibid*

Conclusion

Progress is as important in crowded forms of art as compared to those which in the pioneer stage and such progress is usually made by small increments.[62]Every coin has two sides and same is the case after the analysis of this landmark judgment. A question that rightly arises is whether the 2005 amendment to the Indian Patents Act, 1970 is a boon or a bane. When amended and brought into force, the change was favorable to the pharmaceutical companies however there was less vision towards its future repercussions. Likewise, the judgment has a good and a bad side; though public interest is of paramount consideration over commercial benefits, there is a significant impact on the health of multi-national companies by disallowing secondary patents on very important drugs thereby affecting the public at large.

The reason India was bequeathed the title of is that the companies involved in manufacturing and selling of generic drugs at a nominal price are not equipped enough to invest in R&D as it is ridiculously expensive. India's developing demography demands and justifies the need of a economical generic drug market. While on one hand there is hardly a doubt that the Supreme Court set an example in this case by placing public health over commercial manufacturing of drugs and has laid down an important precedent, on the other hand the undesirable repercussions were not foreseen. There was a widespread discouragement amongst MNCs against participation in the Indian market that led to obstacles in essential pharmaceutical innovations and which surely did not have a remedial effect on the economy as a whole.

Often it happens that our intentions have a benign goal but they do not necessarily take off and land at the desired platform. That may have happened with Honorable Supreme Court which considered several aspects while deciding this case, including the disadvantages however ultimately failed to strike a fair balance between public health and pharmaceutical innovations. Of the many examples set by this case, a very important one is as to how naïve India's intellectual property laws' foundation is. Our country is continually pressed to oblige to the many global requirements with the presence of a necessity to ensure considering public interest. There is a palpable tension between our global trade commitment and public health concern. At this juncture is good to be reminded of what the Supreme Court opines of our country *"India is a welfare state governed by the constitution which holds the pride of place in the hearts of its citizens. It lays special emphasis on the protection and*

[62] In re Hummer,44 CCPA 814,241 F2d 742,112 USPQ 66(1957).

wellbeing of the weaker sections of society and seeks to improve their economic and social status on the basis of constitutional guarantees spelled out in its provision."[63]

This decision settles down many questions, the answers to which shall accordingly keep changing and shaping the future of pharmaceutical sector in India. A reading of the decisions of the Honorable Supreme Court and High Court as well as IPAB provides an understanding that the term 'enhanced efficacy' is generally desired "to curb pharmaceutical patenting, although the courts have declined to embrace the rationale." Further, our analysis shows that if the general rule of treaty interpretation is considered in the context of TRIPS a new world is set to open where the analysis of the welfare effects of IPRs may gain a prominent role. Talking in the Indian context, public interest and welfare is the highest goal eyed by the Government which would therefore balance it against a private interest by allowing small diminution of the right in question. Hence even if the results are in conformity with goals of achieving social welfare, the reason behind this judgment has been flawed. The decision reflects Indian society's value judgments and economic interests more than the technicalities of patent law. It is in concurrence with the constitutional obligation to promote social welfare and balance interest of stakeholders within the limited resources available with the country. It is also in consonance with Bentham's view that law must aim at maximizing the amount of pleasure and minimizing the amount of pain.[64]

[63]VikramDeo Singh Tomar V. State of Bihar,AIR 1988 SC 1782.
[64] Jeremy Bentham,*An introduction to the principles of Moral and Legislation,*Dover Publication(2007).