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CRITIQUE OF THE NOVARTIS CASE: BROADENING THE HORIZON OF SECTION 3(D)

Authored By-Richik Dadhich

Introduction

2005 marked the beginning of an extraordinary new frontier for India's generic drug industry and drug-hungry population. For the first time in India's history, India recognized that pharmaceuticals, foods, and chemicals were patent-eligible and entitled to protection from infringers.[1] Thus, Section 3(d) of the Indian Patent Act introduced a new threshold of patent eligibility for pharmaceutical innovation that requires applicants to demonstrate enhanced efficacy of their products.

In 2006, the Indian patent office rejected a patent application covering Glivec. The rejection stemmed, inter alia, from a unique section in the Indian patent regime that prohibits the patenting of new forms of existing pharmaceutical substances that do not demonstrate significantly enhanced "efficacy". Failing to satisfy this Section 3(d) threshold, first at the Patent Office and later before the Madras High Court on appeal, Novartis' suit arrived at the Indian Supreme Court.

The judgment given by the two-judge bench of the Hon'ble Supreme Court of India in the case of Novartis AG V. Union of India[2] (hereafter **"the Novartis case")** is one the landmark judgments in India. In this case Novartis challenged the rejection of its patent application for Beta crystalline form of "Imatinib mesylate" wherein such challenge was rejected by the Supreme Court of India on the ground that the said drug did not produce an enhanced or superior therapeutic efficacy as compared to the known substance i.e., Imatinib mesylate means that the said drug did not involve an inventive step. One of the major reasons for rejecting the patent application of Novartis was to avoid ever-greening of already patented products by introducing minor changes.

[1] Janice 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, 529 (2007).
[2] Novartis AG v. Union of India, Nos. 2706-2716 of 2013.

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Now, this project will critically examine Section 3(d) of the Patent Act which would be followed by a critique of Novartis case in the context of protection of intellectual property of pharmaceutical companies. This is followed by concluding remarks which focuses on why the Indian legislature needs to draw a balance between social justice, intellectual property rights and scientific innovation.

Understanding The Nature Of Section 3(D)

It must be noted that much before the 2013 decision by the Indian Supreme Court, Section 3(d) had already been subjected to a mixed review.[3] Pharmaceutical companies condemned its higher threshold of patentability for fear of losing their extended market exclusivity. Scholars lauded its mechanism for preventing pharmaceutical companies from extending their market exclusivity strategies.[4]

Motivation And Context Of Section 3(D)

Evergreening is a term for corporate manoeuvring where a product manufacturer continues to extract patent protection on an originally patented product for successive designated periods on more than one attribute, even though such attributes can be linked to a single product.[5]

Section 3(d) was designed to prevent this, as the following discussion of the text and explanation of the statute would reveal. Section 3(d) reads as follows:[6]

"(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.

Explanation-For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other

[3] Dhanalakshmi Iyer, Analysis of Section 3(d) of Indian Patent Act, IP FRONTLINE (Apr. 9, 2012), http://www.ipfrontline.com/depts/printabletemplate.aspx?id=26756.
[4] Saby Ghoshray, 3(D) View of India's Patent Law: Social Justice Aspiration Meets Property Rights in Novartis v. Union of India & Others, 13 J. Marshall Rev. Intell. Prop. L. 719 (2014).
[5] Robert Chalmers, Evergreen or Deciduous? Australian Trends in Relation to the 'Evergreening' of Patents, 20 MELBOURNE U. L. REV. 29, 29 (2006).
[6] The Patents (Amendment) Act, No. 15 of 2005, Section 3(d).

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derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

Thus, Section 3(d) establishes an extra layer of deterministic criteria in the patent eligibility framework. This specific layer stipulates that, only those pharmaceutical derivatives that can be demonstrated to exhibit significantly enhanced efficacy are eligible for patent protection. This added layer would be a step towards real innovation as opposed to claiming innovation on minor enhancement. Therefore, this extra layer requiring enhanced efficacy would help in preventing fraudulent or superfluous patent applications that are routinely sought through evergreening or patent layering.

As each subsequent variant of a compound is structurally equivalent to the original, either in their naturally existing forms, or as known pharmaceutical substances, it is more likely than not that these structurally similar substances are functionally equivalent.[7] Therefore, Section 3(d)'s requirement of enhanced efficacy of the derivative is more effectively shown by observing its chemical interaction with other chemical compounds that offer the most significant reactivity.[8]

The statute for section 3(d) calls for a patent eligible product to be "efficacious," or have the attribute of enhanced efficacy over a prior known form, regardless of whether the invention is incremental or groundbreaking. It could be said that Section 3(d) creates a "floor" in demonstrating "efficacy," while charting a layered patentability framework for pharmaceutical products.[9] Therefore, in order to claim patent, the onus of proving enhancement-that of improved and enhanced functionality-would fall on the patent applicant. 100 Thus, imposition of this simple demonstrability barrier for claiming a patent should be recognized as a process or instrumentality of bringing improved chemical compounds to the market to make significant contributions as pharmaceutical agents. This efficacy step certainly can distinguish between patent applicants that arrive via evergreening and those that contain a rigorous inventive step. Therefore, by making it mandatory for derivatives of known substances to exhibit added efficacy, 3(d) encourages sequential development of improved products to address significant public health needs.

[7] Rajshree Chandra, *The Role of National Laws in Reconciling Constitutional Right to Health with TRIPS Obligations: An Examination of the Glivec Patent Case in India*, in INCENTIVES FOR GLOBAL PUB. HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MED (Thomas Pogge, Matthew Rimmer & Kim Rubenstein, eds., 2010).
[8] *Id.*
[9] *Supra* note 2.

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Compatibility With TRIPS

The core arguments of initial Novartis' challenge were centered on Section 3(d)'s lack of constitutionality and TRIPS incompatibility. TRIPS incompatibility has garnered significant coverage, an area on which the Madras High Court has refrained from ruling, citing jurisdictional grounds.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) framework sought to align global patentability regimes in line with predominantly U.S. standards, and the feasibility of achieving this was recognized early on. The resulting framework did not clearly define patentability criteria, nor did it articulate a bright line of distinction between invention and patentability. In many ways, the TRIPS agreement created a multi-layer exception paradigm that has taken into account the different starting points from which member States began their journey towards industrialization.[10]

Therefore, the only hurdle Section 3(d) might face is if under a broader WTO panel evaluation the efficacy barrier is eventually found to be in direct contravention of TRIPS.[11] Here, the deterministic benchmark would be to evaluate whether a required demonstration of efficacy invites one of the two outcomes-either imposing an undue burden on the innovator, or the patentability framework in the target jurisdiction is subject to arbitrary determination.

However, various scholars point out that given its clear articulation, well established legislative history, associated due diligence in its crafting, and a highly nuanced judicial deterministic paradigm, Indian patent regime's efficacy framework can no longer be recognized as narrowly construed for TRIPS violation.[12] Rather, it is of significant value to trace the flexibility guidelines provided within TRIPS in formulation of 3(d).

Article 27 of TRIPS endows a member State with the option to exclude certain inventions from patentability, if their commercial exploitation is contrary to the national interest or inconsistent with the settled law of the land. This exception allows flexibility to member States in crafting their patentability framework to be in line with their own interests. Moreover, members are also allowed to exclude various method patents that are consistent with providing essential

[10] Laurence R. Helfer, Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking, 29 YALE J. INTL. L. 1, 7 (2004)/
[11] *See supra* note 2.
[12] *Id.*

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health and human services to its citizens.[13] Thus, the TRIPS agreement embodies a commitment to public health and societal welfare.

In evaluating TRIPS compatibility of a member State's legal jurisdiction, we must bear in mind the fundamental precept-a member State has flexibility to create an individual paradigm that is resonant with its internal aspirations.[14] The TRIPS agreement has empowered its member States to craft their own patentability regimes that reflect their diverging starting points from an agrarian way of life towards industrialization. Thus, while TRIPS ensures that innovators have commercial impetus, nowhere in the agreements does it advocate the granting of unfettered right of evergreening to pharmaceutical companies.[15]

Under the emerging rubric of Section 3(d), pharmaceuticals can no longer shape the market exclusivity in their favor, nor, can they subsume broader public interest within the predatory property rights framework. This is consistent with the various flexibilities offered to the member States by the Articles 7, 8, and 27 of the TRIPS agreement.[16] Thus, India is within its rights under the TRIPS agreement to adjust its patentability criteria and set higher standards for patent protection. And it is therefore TRIPS compliant.

The Novartis Case: An Analysis

On 1 April 2013 the Indian Supreme Court delivered the landmark judgment of Novartis AG v Union of India[17] in an appeal that had been brought to it by Novartis, a Swiss-based pharmaceutical company with a business presence in India, against rejection by the Indian Patent Office of a product patent application for a specific compound, the beta crystalline form of Imatinib Mesylate. Novartis lost the case because the Supreme Court ruled that the beta crystalline form of Imatinib Mesylate failed both the tests of invention and patentability.

[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S. 299.
[14] Molly M. Chen, Reconsidering the U.S. Patent System Lessons from Generics, 45 VAND. TRANSNAT'L L. 1249, 1257 (2012).
[15] *Id*.
[16] *Supra* note 11.
[17] Novartis AG v India (Supreme Court of India) Civil Appeal No 2706-2716 of 1 April 2013.

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Factual Matrix And Context Of The Case

The crux of the matter was whether or not the appellant was entitled to a patent for the beta crystalline form of the compound Imatinib Mesylate, which is a therapeutic drug for chronic myeloid leukaemia and certain kinds of tumours and is marketed under the name "Glivec".

The basis for Novartis' patent application for the beta crystalline form of Imatinib in India was an alleged inventive step that materialised when a two-stage invention process involving the introduction of a specified amount of beta crystals into the base form of Imatinib was embarked upon.[18] Very specifically, the claims in the patent application alleged the following about the Beta crystalline form of Imatinib:

(a) it had more beneficial flow properties;

(b) it had better thermodynamic stability; and

(c) it had lower hydroscopicity than the alpha crystalline form of Imatinib.

It was alleged that these properties made the beta crystalline form of Imatinib "new" and superior due to its ability to store better, be processed more easily, and its having "*better processability of the methanesulfonic acid addition of a compound formula I*" coupled with the advantage of storing and processing.[19]

Two important developments occurred before the patent application was considered by the Chennai Patents Office. Firstly, the Patents Act was amended and section 3(d)40 was introduced. Secondly, before the patent application was considered, it had attracted five pre-grant oppositions.41 The most vocal oppositions came from rival pharmaceutical companies and patient groups, basing their opposition mainly on the fact that the alleged invention had been anticipated, was obvious, and ran afoul of section 3(d) of the Patents Act.

The matter relating to the patentability of the beta crystalline form of Imatinib was heard by the Assistant Controller of Patents and Designs and the application was rejected.42 The Assistant Controller of Patents and Designs rejected the application on the basis that the invention had

[18] *Id.*
[19] *Id.*

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been anticipated by reason of prior publication,43 its lack of novelty and its not meeting the acid test of section 3(d).[20]

Novartis appealed the decision of the Assistant Controller of Patents and Designs to the High Court in Madras, in addition to asking for an order that section 3(d) was unconstitutional and also fell afoul of the TRIPS Agreement. At that time the Intellectual Property Appellate Body (hereinafter **"IPAB"**) had not yet been formed. After the IPAB had been formed the matter was remitted to it by the Madras High Court. Despite ruling in favour of Novartis by reversing the findings of the Assistant Controller on novelty and non-obviousness, the IPAB ruled that the patent could not be granted in the light of the provisions of section 3(d) of the Act, which, according to the IPAB, introduces a higher standard of inventiveness and provides that what is patentable in other countries will not necessarily be patentable in India.46 The IPAB went a step further and observed that the specific section was particularly targeted at drugs/pharmaceutical substances.[21]

Further, the IPAB referred to the pricing policy of Novartis, which had exclusive marketing rights over Glivec, which sold at 120 000 Indian Rupees per month48 per required dose, and concluded that the patentability of the subject product would fall foul of section 3(b) of the Act, which prohibits the granting of patents on certain inventions the exploitation of which could cause public disorder, among other social ills.[22]

Novartis then appealed the decision of the IPAB to the Supreme Court of India, which was initially reluctant to hear the appeal but was swayed by the public interest in the matter50 and the delays that had accompanied the finalisation of the matter. Judgment was delivered on 1 April 2013.

The Supreme Court's Verdict

The key question to answer in the opinion of the Court was "does the product which Novartis claims as a patent qualify as a new product?" 52 As a corollary to the question, it was crucial to enquire into whether the product in question had a characteristic feature that involves a

[20] *Id,* para 15.
[21] *Id*, para 17.
[22] *Id.*

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technical advance over existing knowledge that makes the invention not obvious to a person skilled in the art.[23]

After affirming that the meaning of an invention is delimited by clauses (j) and (ja) of section 2(1) of the Patents Act, the Court went further and asked the rhetorical question of whether or not a product qualifying as an invention under the relevant clauses of section 2(1) could have its patentability status questioned under section 3(d).

Clauses (j) and (ja) had deleted section 5 of the previous Patents Act, which prohibited product patents in India, and at the same time, amendments were effected to section 3, introducing section 3(d). The Court expressed the opinion that in order to understand the purport and objects of the amendments it was important to identify the mischief parliament wanted to check. The object which section 3(d) sought to achieve was to prevent evergreening, provide easy access to life-saving drugs to citizens, and realise the constitutional obligation to provide good health care to citizens.

After a detailed exposition of India's legislative history relating to intellectual property generally and patents in particular, the Supreme Court concluded that the law had been passed in order to protect India's policy space to afford good health to its citizens while complying with the basic prescripts of the TRIPS Agreement. The Court believed that the patent protection of pharmaceutical and agricultural chemical products might have the effect of putting life-saving medicines beyond the reach of a very large section of the population,60 and that the amendments were therefore justified.[24]

Further, it was submitted on behalf of Novartis that section 3(d) was not an exception to patentability. Hence, once a substance satisfies the requirements in section 2(1)(j) and (ja), it satisfies the requirements of patentability. Consequently, section 3(d) did not apply to the Novartis case. With specific reference to public health and the use of TRIPS flexibilities, Novartis argued that the best route was to make use of compulsory licences,[25] revocation proceedings and multiple stages of patent opposition procedures rather than to make use of section 3(d).[26]

[23] *Id*, para 3.
[24] *Id,* para 42.
[25] *Id,* para 102.
[26] *Id,* para 103.

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The Supreme Court dismissed the above submissions on a number of grounds:

Firstly, the Court held that section 3(d) is not a provision *ex majorie cautela* (out of abundant caution), as was submitted on behalf of Novartis, when taking into account the totality of the historical development that led to the enactment of the provision.

Secondly, the Court cautioned that the relevant provision was enacted to deal with chemical patents and pharmaceuticals by setting additional qualifications for the patentability of such products.

Thirdly, and very importantly, the Court clarified the position by stating that the door was wide open for true inventions but closed by Section 3(d) for repetitive patenting or the extension of patent terms on spurious grounds. In coming to the conclusion that section 3(d) applied to the case, the Court emphasised that different standards are set for things of different classes to qualify as inventions; and for medical drugs and other chemical substances, the invention threshold is set higher.[27]

Now, with specific reference to the beta crystalline form of Imatinib, it was submitted on behalf of Novartis that section 3(d) applies if a substance is a new form of a known product having known efficacy, and that "known" in the specific context meant proven and well established while "known efficacy" meant "*efficacy established empirically and proven beyond doubt*".

Citing with approval the case of Monsanto Company v Caramandel Indag Products (P) Ltd,[28] the Supreme Court disagreed and rejected the submission on the basis that it was wrong in both fact and law. The court sealed the dismissal of the submission with the powerful observation that the beta crystalline form of Imatinib Mesylate is a new form of a known substance, namely, Imatinib Mesylate, with well-known efficacy.90 Therefore, the fact that the beta form of Imatinib was a product that claimed to enhance the form of its old counterpart triggered the application of section 3(d).[29]

Very specifically, the Court observed that in its application for a patent, Novartis averred that all the therapeutic qualities of the beta crystalline form of Imatinib Mesylate were also possessed by Imatinib in a free base form.

[27] *Id,* para 104.
[28] Monsanto Company v Caramandel Indag Products (P) Ltd (1986) 1 SCC 642.
[29] *Supra* note 15.

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This, therefore, raised the question of whether an enhanced efficacy over a known substance as demanded by section 3(d) existed. The Court held that the correct "efficacy" to consider in section 3(d) is "therapeutic efficacy" in the specific context of medicines. The Court further noted that the test for enhanced therapeutic efficacy must be applied strictly.[30]

The Court, therefore, held that the chemical properties of beta crystalline Imatinib Mesylate may be beneficial but do not add anything to therapeutic efficacy. On the contention submitted on behalf of Novartis that the beta crystalline form of Imatinib had increased bioavailability, the Court held that an increased bioavailability, in the absence of compelling proof, may not necessarily lead to an enhancement of therapeutic efficacy, hence Novartis' bid for a patent for the beta crystalline form of Imatinib Mesylate had to fail.[31]

To conclude, the Court ruled that the impugned form of Imatinib failed the test of invention as provided for in section 2(1) clauses (j) and (ja) and section 3(d), that it did not have enhanced therapeutic efficacy, and that Novartis' appeal had inevitably to fail.

Post-Novartis Regime: Overview Of Recent Judgements On Section 3(D)

The Supreme Court's decision was warmly welcomed by access to medicines activists and patient organisations in India and beyond. It thus established a significant precedent and various High Court judgements have cited the Novartis case with approval.

Interestingly, all of the cases after the Novartis judgment have given a strict interpretation to Section 3(d) and various drug product patents have been denied by the patent office and by the Intellectual Property Appellate Board. These include enantiomer for Tofacitinib (Sep 2015); Enzalutamide, a derivative (Nov 2016); Epothilone B a polymorph (Dec 2018); Tiotropium bromide, a polymorph (July 2015) at the patent office; and Valganciclovir, a prodrug (July 2015) and Lapatinib ditosylate salt (August 2013) by the IPAB. Recently, multiple oppositions against Bedaquiline fumarate salt, had been filed in 2020.

Some of the significant judgements have been discussed below.

[30] *Id,* para 179.
[31] *Id*, para 182.

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Takeda Gmbh V. Controller Of Patents And Designs

In this case, the Controller refused Indian patent application entitled "Isotopically Substituted Pantoprazole" owned by Takeda GmBH (Takeda) for falling under the purview of Section 3(d) of the Act.[32]

Takeda's application discloses and claims isotopically substituted (deuterated) pantoprazole and enantiomers thereof that can be used to inhibit acid secretion in subjects suffering from a gastrointestinal disorder. According to the specification, the claimed deuterated compounds exhibit a decreased metabolization rate compared to the corresponding non-deuterated compounds and thus have an improved half-life. The specification also contained data demonstrating that 5 deuterated compounds exhibited higher metabolic stability and intrinsic clearance values compared to their equivalent non-deuterated (pantoprazole) compounds. Takeda argued that this data demonstrated that the claimed compounds exhibited higher efficacy than pantoprazole.

The closest prior art was European Patent Application 0 005 129 (D1) which disclosed non-deuterated pantoprazole derivatives for the same use and U.S. Patent 6,818,200 (D2) which taught that deuterated compounds have enhanced efficiency and thus are less susceptible to the typical metabolic pathways, thereby resulting in an increase in half-life. In view of this prior art, the Examiner rejected the claims as being obvious and for failing to qualify as an invention under Section 3(d).

The Controller noted that when examining whether or not a claimed invention violates Section 3(d), the following analysis must be performed:[33]

1. Compare the claimed invention with the closest compound known in the prior art (in this case the closest prior art compound was pantoprazole); and

2. Determine whether Applicant has provided sufficient evidence (such as through arguments and experimental evidence) to demonstrate that the claimed compounds demonstrate significantly improved therapeutic efficacy when compared to the closest prior art compound.

[32] Takeda GmBH v. Controller of Patents and Designs, 293/MUMNP/2008 (2013).
[33] *Id.*

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The Controller found that the only experimental evidence provided related to metabolic stability and intrinsic clearance values. According to the Controller, this data demonstrated how the system acted on the claimed compounds. However, evidence of therapeutic efficacy requires demonstrating how the drug acts upon the system. Because such evidence was missing, the Controller affirmed the Examiner's rejection under Section 3(d).

Cipla Ltd. Vs F.Hoffmann-La Roche Ltd. & Anr.

Another major decision which outlines Section 3(d) is the Roche case.[34] The dispute commenced over anti-cancer drug between Roche and Cipla. Roche sold Erlotinib drug with brand name 'Tarceva' which was introduced by Roche in the Indian market in 2006. Cipla planned to launch the generic version of this drug in 2007.

In 2015, the division bench of Delhi High Court finally stated that there was no infringement as the patent which was in question was a mixture of Polymorphs A and B, whereas the drug Tarceva drug consisted of only Polymorph B. The point here to be noted was that Roche had applied for patent of Polymorph B but was denied by the Indian Patent office as it did not satisfy the criteria of Section 3(d) and the test of patentability was not satisfied. Moreover, the court considered the intent of the legislature in enacting Section 3(d) and anti-evergreening laws and held public interest above everything.

The Court analysed Sections 2(1)(j), 2(1)(ja), 2(1)(l), 2(1)(ta) and Section 3(d) and held:

> *"Section 3 of the Act lays down a threshold for patent eligibility and is not an exception to Section 2(1)(j) as urged by learned Senior counsel for Cipla. Section 2(1)(j) provides a theoretical definition of an invention while Section 3 illustratively outlines what are not inventions. In other words, for subject matter that falls outside the scope of Section 3, a qualitative analysis needs to be employed to ascertain whether it satisfies the conditions of Section 2(1)(j), while for subject matter that falls within the scope of Section 3, an analysis under Section 2(1)(j) need not be employed as it will be rejected at the threshold."*[35]

[34] Cipla Ltd. vs F.Hoffmann-La Roche Ltd. & Anr., RFA(OS) 92/2012 DelHC (2015).
[35] *Id,* para 61.

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It must be noted that the Supreme Court in Novartis case[36] did not decide whether Section 3(d) was a patent eligibility or patentability standard since this question did not impact its determination on validity in the facts of that case. Here, Delhi High Court negatived the proposition that Section 3(d) is a patentability standard.

The Court further clarified that the deeming fiction in Section 3(d) implies that when a patent application for a substance is rejected by Section 3(d) because it is a derivative of known substance, that substance would automatically be deemed to be covered and disclosed by the prior art on the basis of which the application was rejected, i.e., the known substance if under patent.

Thus, what Section 3(d) does impact, apart from the prosecution of a patent application, is the construction of claims of the patent of the known substance whose 'salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance' is sought to be patented independently, but fails because of Section 3(d).

Abraxis Biosciences Drug Abraxane Case

Another patent that has been refused by the patent office is for the anti-cancer drug Abraxane sold by the US firm Abraxis BioSciences which was claimed to be a combination of new form of a known substance Paclitaxel and anti-SPARC antibody.[37]

The patent application on the Abraxane formulation was refused by the Controller of Patents on the basis of lack of inventive step and Section 3(d) violation as the new form of a known substance is patentable only when it exhibits enhanced efficacy. It paved way for generic companies to launch affordable versions in the domestic market.

Boehringer Ingelheim Drug Spiriva Case

Boehringer Ingelheim filed a patent application (558/DELNP/2003) for crystalline tiotropium bromide monohydrate in Patent Office, Delhi on 16th April, 2003. Indian Patent office issued an order in March 2015 to revoke Boehringer's patent covering crystalline tiotropium bromide monohydrate.[38]

[36] *Supra* note 15.
[37] Mukherjee R, US Co. Abraxis denied patent on cancer drug, http://timesofindia.indiatimes.com/business/india-business/US-co-Abraxis-denied-patent-on-cancer-drug/articleshow/47521553.cms.
[38] *See* Controller's decisions - Indian Patent Office, IN 254831

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In its decision, the Patent office ordered,

> *"The physical stability of the compound during formulation cannot be considered as a sole factor for improvement of therapeutic efficacy of the drug under as required under section 3 (d) of the Indian Patent Act, adding the compound is "a product of mere trial and error" and does not "involve any inventive skill"*[39]

Further, in consonance with the Novartis case, it was affirmed that Section 3(d) was incorporated in the amended Patent Act with the objective of blocking the pharmaceutical companies' attempt to claim the patent rights for incremental innovation involving new forms of a known molecule with no significantly enhanced efficacy.

Hoff-Man La- Roche Drug Valganciclovir case

Here, the patent related to Valganciclovir[40] drug used against active cytomegalovirus retinis infection affecting the eye of the patients living with HIV, was rejected. The drug showed improved bioavailability when administered orally but the Controller of Patents ruled that improved bioavailability cannot be correlated with the efficacy and hence was rejected on Section 3(d) grounds.

AstraZeneca AB & Anr. v. Emcure Pharmaceuticals Limited

On 15 January 2020, the Delhi High Court adjudicated upon interim injunction applications in two suits filed by AstraZeneca against Emcure Pharmaceuticals Limited and MSN Laboratories Limited respectively.[41] AstraZeneca had asserted three types of patents in the law suits: a species patent (IN'209907), a crystalline patent (IN'247984) and a formulation patent (IN'272674).

Rejecting each of the defendants' contention, the Hon'ble Court held that the species patent IN'907 was not anticipated by the genus patent IN'229; that the pleadings on record showed that the species patent IN'907 had enhanced efficacy over IN'229 and that while the invention claimed in IN'907 (i.e., the compound Ticagrelor) was covered within the Markush Structure of the genus patent and IN'229 did not specifically disclose Ticagrelor.

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http://ipindiaservices.gov.in/patentdecisionsearch/patentsearch.aspx.

[39] *Id.*

[40] Clasis Law, Indian patent office revokes Hoffman-La Roche's 'Valganciclovir' patent, https://www.inhousecommunity.com/article/indian-patent-office-revokes-hoffman-la-roches-valganciclovir-patent/.

[41] AstraZeneca AB & Anr. v. Emcure Pharmaceuticals Limited, 2020 SCC Online Del 101.

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With regards to Section 3(d), the Hon'ble Court held that in view of the plaintiffs' specific pleadings stating the compound Ticagrelor claimed by IN'907 was of high potency, high metabolic stability and demonstrated bioavailability, it could not be said that IN'907 did not result in an invention with enhanced efficacy.

FMC Corporation & Anr v. Natco Pharma Limited

In the recent 2021 case, the plaintiff in this case held two patents covering the product and process to make Chlorantraniliprole ("CTPR"), an insecticide.[42] The patents were species patents that were claimed in markush claims of an expired patent that covered several species along with the patents in question. When the plaintiff filed this suit for patent infringement of its CTPR patents, the defendant countered that the patents are invalid because they were covered in a prior patent. In response, the plaintiff argued that though the species were covered, they did not form part of the patent disclosure.

The plaintiff also argued that the decision of the Supreme Court in the Novartis would not advance the case of the Defendants, in the first place, because the case deals with the patentability of the invention specifically in the light of Section 3(d) of the Act. However, the issue in the present case is on the vulnerability of the granted patent, and the onus is on Defendants to show that the patent is vulnerable to challenge.

Rejecting this argument, the Hon'ble Court held that despite a proceeding that was instituted by the defendants for declaration of non-infringement prior to the institution of the suit for patent infringement, the suit for patent infringement would continue.

In this context, the Delhi High Court discussed Novartis elaborately and held the position of law laid down by it as *"something which is specifically claimed or covered by the specific claim cannot be disowned by asserting that it was not disclosed*." The Court stated that the Supreme Court's judgment in Novartis does not state that disclosure is equal to claim coverage, but simply points out that there cannot be a large gap between the two. The Court also observed that disclosure of a compound in a markush claim does not necessarily make the species patent susceptible to anticipation, prior claiming, obviousness or Section 3(d) challenge.

[42] FMC Corporation & Anr v. Natco Pharma Limited, I.A. 5801/2021 in CS(COMM) 69/2021

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Understanding The Threshold: Is There A Need For A Broader Scope?

A peripheral analysis of the Novartis case and the subsequent judgements, as discussed in the previous sections, makes it clear that the Indian courts have given higher importance to social justice instead of the intellectual property rights of the pharmaceutical companies.

As depicted in the previous section, the fear and confusion have only been exacerbated by subsequent decisions by Indian courts rejecting patents for a series of pharmaceutical substances. Most of these decisions centred on section 3(d) of the Indian Patent Act.

In addition to this, while Section 3(d) aims to prevent trivial patents, incremental inventions can often include a considerable innovation.[43] In particular, in the pharmaceutical industry, patents rarely involve new chemical entities but rather incremental improvements over prior inventions. If the nonobviousness standard is set so high that it effectively bars patentability of most incremental pharmaceutical innovations, that rule may contravene TRIPS and be detrimental to the Indian pharmaceutical industry by failing to provide proper incentives for research and development for the long term.[44]

The Need For Redefining The Scope

The interpretation of section 3(d) by the patent office, IPAB, and Indian courts has primarily focused on direct evidence for the enhancement of known efficacy of the drugs - indirect evidence in terms of improved bioavailability has not been taken into consideration. These patent applications did not have direct evidence in support of enhanced known efficacy, and therefore, the patent offices and courts have not ventured to examine the other terms of section 3(d).[45]

[43] Shamnad Basheer, Spicy IP, Deconstructing the Mashelkar Committee Report Controversy: Part I, http://spicyipindia.blogspot.com/2007 /02/deconstructing-mashelk.
[44] *See* Naresh Asuri, Proper Interpretation of Section 3(d) of the Indian Patent Act Could Save Incremental Innovations of Existing Pharmaceutical Substances, IPWatchdog, https://www.ipwatchdog.com/2019/06/22/proper-interpretation-section-3d-indian-patent-act-save-incremental-innovations-existing-pharmaceutical-substances/id=110581/.
[45] *Id.*

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Now, the "explanation" appended to section 3(d) was essentially taken from the definition of "generic substances" given in the Directive 2001/83/EC of the European Parliament[46]. Therefore, a proper interpretation of section 3(d) requires an understanding of the scope and intent of the European Directive. The lack of understanding around the scope and intent of the Directive is responsible for the existing debate and controversy concerning section 3(d).

Part II, Annex 1 to Directive 2001/83/EC states that generic substances must also contain the same therapeutic moiety as the innovative substance.[47] If that is not the case, the substance shall be considered a new active substance.

The scope of the Directive is to regard derivatives as generic substances and thus, derivatives differing in therapeutic moiety, possessing unknown efficacy, or either significant differences in enhanced or reduced known efficacy, are not considered generic substances under the Directive.

Further, European Union's Medicine Agency[48] lists what might constitute significant differences in safety and/or efficacy to justify a product as a new active substance. They include significant changes to the dosing frequency; meaningful changes to the overall efficacy; meaningful and clinically relevant changes that allow the product to be used in a wider patient population; or previously excluded sub-groups. Such circumstances could include shortened time for pain relief, decreased mortality etc.

Thus, the controversy and confusion can be removed by interpreting section 3(d) in light of the European Directive and its allied guidance documents. Such an interpretation would greatly enhance the scope of new physical forms and new derivatives of existing pharmaceutical substances outside the purview of section 3(d), would help remove the ambiguity, and would lead to proper interpretation of section 3(d).

[46] Directive 2001/83/EC, European Parliament.
[47] *Id.*
[48] European Medicines Agency, Reflection paper on considerations given to designation of a single stereo isomeric form, EMA/651649/2010 Committee for Medicinal Products for Human Use, https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-considerations-given-designation-single-stereo-isomeric-form-enantiomer-complex_en.pdf.

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Balancing Innovation And Country's Needs: Need To Lower The Efficiency Requirement

From the outcomes of the legal battles between the generics industry and Pfizer, Bayer, Hoffman-La Roche, and Boehringer Ingelheim, it is clear that the Courts are inclined towards protecting domestic generics industry. Pharmaceutical MNCs have yet to win a decisive battle in patenting their drug innovations. The Indian legal system has given no indication that it will provide MNCs with any sort of relief. Although the Indian government's intent to secure low-cost life-saving drugs to its population is laudable, scholars believe that this is an extremely limited view.[49]

According to Forbes, "*it really does cost billions of dollars to invent new medicines for heart disease, cancer, or diabetes. The reality is that the pharmaceutical business is in the grip of rising failure rates and rising costs.*"[50] As a result, without some sort of patent protection, pharmaceutical companies are rarely willing to develop drugs.[51]

These high costs, in conjunction with the recent string of legal disincentives, could very well and stifle innovation and drive pharmaceutical MNCs permanently away from the Indian market. Factoring in rigorous competition from generics manufacturers, pharmaceutical companies are unable to recover R&D costs.[52]

Thus, to achieve India's goal of providing low-cost, accessible drugs to its people while also maintaining some semblance of certainty for MNCs and protection to new drugs they seek to patent, India should expand the categories covered under the "efficacy" requirement of Section 3(d) of the Patents Act rather than limit it to products that have a "*therapeutic effect in healing a disease.*" Other provisions in the Patents Act, such as the "inventive step" provision in Section 2(1)(j) and compulsory licensing in Section 92A, already provide sufficient protection to the Patents Act to keep frivolous patents from issuing.

[49] Andrew Q. Leba, Lowering the Efficacy Threshold for Section 3(D) of the Indian Patents (Amendment) Act of 2005: A Case for a Broader Scope, 28 EMORY INT'l L. REV. 649 (2014).
[50] Matthew Harper, The Truly Staggering Cost Of Inventing New Drugs, Forbes (2012) https://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/?sh=ee762e94a948
[51] *Id.*
[52] Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability. 87 TEx. L.R. 503, 508 (2009).

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Conclusion

"Wherever the art of Medicine is loved, there is also a love of Humanity."

- Hippocrates 400 BC

The Supreme Court in its Novartis judgement made clear that India is a developing country and the availability of medicines at a cheaper rate is necessary for the lives of 1 billion people. However, the Court's decision to adopt a narrow interpretation of Section 3(d) is problematic. Although a narrow interpretation of Section 3(d) would provide drug manufacturers with notice that any drug must specifically have an increased healing effect on the body, such an interpretation does not serve the policies of India's patent system, nor does it promote innovation.

This restrictive interpretation excludes too many possible improvements on a drug. For example, increased bioavailability, enhanced lipid solubility, increased heat stability of the chemical drug inside the body, increased shelf life of the drug, improved drug delivery systems, drugs targeting protein kinases as therapeutic targets, and reduction of microbial growth would all likely fall outside the court's narrow interpretation of "therapeutic efficacy."

These classes of drug improvements may lead to increased efficiency by allowing patients to take smaller doses of drugs, take fewer combinations of drugs, and prolong the maximal potency of the drugs. Such improvements also increase the chances that the drug will fulfil its desired purpose. But because these improvements do not result in an increased "healing effect" on the body, they do not meet Section 3(d)'s "efficacy" threshold.

A broader interpretation of Section 3(d) will bring a stronger balance to the Patents Act and protect the kinds of drugs that will lead to future pharmaceutical breakthroughs. Companies such as Novartis must collaborate and cooperate with developing countries like India to promote access to their life-saving drugs. But, a patent system like India's, with weak protections and provisions that stifle innovation, is not the answer. Although foreign pharmaceutical companies seem to be the likely beneficiaries of a less restrictive Section 3(d) in the short-term, in the long-term, that interpretation will encourage an already-vibrant Indian generics industry to innovate and become leaders in scientific advancement.