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An Analysis on the Hypothetical Interpretations of Section 3(D) of the Indian Patent Act and its Impact

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ABSTRACT

Section 3(d) of the Patent Act recognizes innovations that stands the 3-pronged test of Patents: "inventive step", "non- obviousness", and "industrial application" thereby preventing a phenomenon called "evergreening of patents" which applies to secondary patents. Moreover, the Hon'ble Supreme Court in the Novartis case (2013) rooted for a narrow and strict interpretation of this provision. However, the question in discussion primarily focuses on the legal and economic consequences of applying different rules of interpretation to this provision with hypothetical illustrations.

Firstly, the literal interpretation appears to overlook factors such as utility, public importance and intention of the legislation. Secondly, a liberal approach does not effectively prevent evergreening of patents and also has major economic consequences. Lastly, the mischief rule overcomes the fallacies in other approach but does not detach the ambiguity. In addition to this, this paper focuses on the nuances of the effect of such constitutionally valid provision on day-to-day Patent application. The provision, though prima facie appears to be non- arbitrary, statistics prove that objections under Section 3(d) have been overutilized to deny primary patents.

Finally, it is asserted that there is a need to amend the provision to specifically address the threshold for 'new forms of discovery' and 'new forms of invention' to suit all rules of interpretation. Further, "efficacy" shall not only mean "therapeutic efficacy", but shall be justiciable as to expansively read it to include factors such as bio availability, potentable, shelf life, quick healing or any other corresponding factors which will keep the test of patentability intact.

Keywords*: Constitutionality, Efficacy, Evergreening of Patents, Invention, Rule of Interpretation.*

I. INTRODUCTION

Patents are one of the strongest forms of intellectual Property, giving rise to monopoly in trade

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and business in the interest of general public. The British India enacted a Patent Act in 1956 which gave 14 years of exclusive privilege to inventors. Later, designs were included in 1911 and post-independence with the recommendation of Rajagopala Ayyangar Committee[3], the Indian Patent Act, 1970 was passed. This law allowed for reverse engineering or copy-cat Licensing i.e., manufacturing of same product with different process. In 1995, when India became signatory to Trade related aspects on Intellectual Property Rights, hereinafter referred to as "TRIPS" and WTO granted 10 years to comply with the TRIPS. The (R.A.) Mashlelkar Committee [4] submitted a report to expand the scope of patentability, by allowing of patenting new substances brought about by incremental innovation. Therefore, 2002 and 2005 Amendment Acts were enacted which extended the time period to 20 years and recognized both 'product innovation' & "process innovation" and also placed emphasis on 'inventive step'; 'Novel'; 'Non-obviousness'; 'industrial application' and 'enhanced efficacy' as a test for Patentability.

(A) Problem Statement

It is contended that due to ambiguity with respect to the interpretation of Section 3(d) inserted by way of 2005 Amendment to the Indian Patent Act, 1970, the law is unable efficiently prevent evergreening of patents.

II. ANALYSIS

(A) Section 3(d) of Indian Patent Act: The Structure and Context

Section 3 is the key section on "patent eligibility" and lists out what are not "inventions" under the Indian Patents Act. Section 3(d) lists out one such non eligible patentable subject matter:

"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

[3] Rajagopala Ayyangar Committee, "*Report on the revision of patent law*", 1959, India. See, https://ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-_Justice_N_R_Ayyangar_committee_report.pdf. (Last accessed on 23/2/2024).

[4] (R.A.) Mashlelkar Committee, "Report of the Technical Expert Group on Patent Law Issues", 2006, India. See, https://ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf.(Last accessed on 23/2/2024).

significantly in properties with regard to efficacy".[5]

In essence, Section 3(d) aims to prevent a phenomenon commonly referred to as "evergreening" by providing that only those pharmaceutical derivatives that demonstrate significantly enhanced "efficacy"[6] are patentable. [7]Previously, Shamnad Basheer (Research Associate, Oxford IP Research Centre)[8] brings out the following questions that remain unanswered previous to his work.

i) The meaning of "efficacy" in context of "therapeutic efficacy" was in question along with the factors being "bioavailability", "heat stability" or "manufacturing efficacy"[9]

ii) Whether 30% increase in efficacy would mean enhancement?

iii) What would qualify as the "known substance" against which the comparison under section 3(d) ought to be made? In the case at hand, would the "known" substance be the imatinib free base (in relation to which it is far easier to show increased efficacy) or the later salt, imatinib mesylate? Or the alpha crystalline form of imatinib mesylate?[10]

However, the primary focus of this paper is on an unsolved question with respect to the consequences of applying different rules interpretation to disguise which would fit the true sense of law. In order to analyze this provision, it is necessary to break it down into the following:

a. Patentability, Eligibility and Invention.

The test for Patentability under Section 3(d) excludes discoveries and Natural Substances. "Patent eligibility" refers to the subject matter which is inherently protected for patents, which falls within the scope of patent law. In most jurisdictions, patent eligibility manifests itself in the term "invention," i.e. even it is a creative art, though new, non-obvious and useful, it is still not patentable, as it is not an "invention." The term "patentability," on the other hand, refers to those set of principles that inform the requirements that must be satisfied for a patent eligible

[5] The Indian Patent Act, 1970, § 3(d).
[6] Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d), 21 J. Intell. Prop. L. 223, pg 242(2013-2014).
[7] Jodie Liu, Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act, 56 Harv. Int'l L.J. 207 (2015). See, https://heinonline.org/HOL/LandingPage?handle=hein.journals/hilj56&div=7&id=&page=. (Lat accessed on 7th April, 2024)
[8] Shamnad Basheer and Prashant Reddy, The 'Efficacy' of Indian Patent Law: Ironing out the Creases in Section 3(d) Scripted, Vol. 5, No. 2, August 2008.
[9] Torrent Pharmaceuticals Limited v Astra Aktiebolag, Indian Patent Office, Decision on application no: 1354/DEL/98 dated May 21st. 1998.
[10] Controller General of Patents, Designs & Trade Marks, India, Draft Manual of the Indian Patent Office, 3 rd ed, 2008.

subject matter (i.e., an invention) to be granted a valid patent. Principally they are the requirements of novelty, inventive step (non-obviousness), utility (industrial applicability) and sufficient description.[11]

The term "patent eligibility" or "inherent patentability" denotes limitations in terms of the kind of "subject matter" that would qualify for patent protection – this question is different from and often precedes the question of whether the said subject matter meets the "patentability" criteria. Section 3(d), by denying patentability to new forms without increased efficacy, effectively acts as a **preliminary filter** at the onset of patent examination. Unlike non-obviousness, which is assessed later, Section 3(d) can raise similar issues early on, blurring the lines between eligibility and patentability.

The Hon'ble SC in **Novartis AG v. Union of India**[12] held that for grant of patents under Section 43 of the Patent Act, 1970, the subject matter must satisfy the twin test: 1) Invention and 2) Patentability. The SC further held that the 2005 amendment aims to distinguish between these tests because not all innovations and discoveries are invention and not all inventions are patentable if it does not pass the threshold set under Section 3 of the Act. Moreover, every limitation under section 3 has different aims and different threshold to satisfy the aim. [13]

b. An Invention, not a Discovery

One invention gives way to another invention and the inventive activity is accelerated, which in turn gives rise to more products and process. Patents are exclusive privileges granted to own, use or sell either the method or the product[14]. Therefore, it is pertinent to note that such monopoly rights cannot be given merely for a discovery, there must be something new, novel and useful. Section 3(d) prohibits the "mere discovery of new forms." One could read the law as it is to mean "*new form of known substance is merely a discovery and not invention*" as held in the case of Novartis[15]. Since this provision demands technical reading according to the context, a judge may not likely endorse such a proposition at all circumstances.

Illustration: A, a scientist finds "ABC" stone on a trek whose chemical formula is later tested. This is treated as a mere discovery and hence not patentable. The stone when crushed to powder cures a particular disease. Since these stones are not available in abundance, the scientist develops a laboratory form of the stone "XYZ" which is 30% efficient that "ABC". When the

[11] M.B.Rao, Manjula Guru, Patent law in India, Kluwer Law International, 2010.
[12] Novartis AG v. Union of India, (2013) 6 SCC 1.
[13] id.
[14] Patent Law in India, See *supra* note 9.
[15] Novartis, See *supra* note 10.

patentability of such a product is in question, the patent is likely to be rejected on the grounds of "new form of known substance". But, in reality it is new and nonobvious because, there is no laboratory created "ABC", it is useful as a medicine to public and has pharmaceutical industrial application. The question of evergreening is to address secondary patents and should not be used as a ground for rejecting primary patents. Denial of patents in such case, apart from law, the economic dead weight loss in this process will also be overlooked. Moreover, in view of the fact that a judge could interpret the section literally and deny the existence of 30% efficacy as done by the precedent, Novartis[16], section 3(d) ought to be amended to separately address issues regarding "discovery" and "invention".

Section 3(d) of the Indian Patents Act bars the patenting of a "mere use of a known method" unless such known method results in a new product or employs at least one new reactant. In other words, in order to overcome the imposition of the said section, the method should not be a mere use of a known method or should involve a new reactant or should result in a new product. Alternatively, if the claimed method has a significant improvement over the existing prior arts, then the claimed method can escape from the imposition of Section 3(d) of the Indian Patents Act, 1970.

(B) Relevance of the Issue in hand: The test for "enhanced efficacy"

As noted, the said section is divided in to four categories i.e., "mere discovery of a new form of a known substance," "mere discovery of any new property for a known substance, "mere discovery of new use of a known substance," and "mere use of a known process, machine, or apparatus." [17]Any invention lying in the ambit of any of the above categories is considered non-patentable.

From a literal interpretation of the Section 3(d) of the Patents Act, for inventions relating to a product, it is understood that new form of a known substance, the new property of a known substance, and new use of a known substance are not patentable unless an enhancement of efficacy is shown.[18] The said section further provides an explanation regarding the different forms of a known substance such as isomers, salts, ethers, etc. It also states under the explanation that such forms of known substance are patentable if they *"differ significantly in properties with regard to efficacy."* However, the terms such as "efficacy", "properties" and "derivatives" are not defined clearly anywhere in the statute. The question, therefore, lies before the Applicant that which property(ies) should differ between a substance and a new form

[16] Novartis, See *supra* note 10.
[17] The Indian Patent Act, 1970, § 3(d).
[18] The 'Efficacy' of Indian Patent Law: Ironing out the Creases in Section 3(d), See *Supra* note 6.

of that substance and how efficacy has to be demonstrated.[19]

The current position of law in India is laid down by the Hon'ble Supreme Court in ***Novartis AG v. Union of India and Ors. [(2013) 6 SCC 1]***. [20] It was clarified that enhanced efficacy in the context of "therapeutic efficacy" depends on the purpose, utility or function of the new product or form. The Court defines efficacy and lays down the rule for interpretation – "*Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there is sufficient internal evidence that leads to the same view. It may be noted that the text added to Section 3(d) by the 2005 Amendment lays down the condition of "enhancement of the known efficacy ". Further, the Explanation requires the derivative to "differ significantly in properties with regard to efficacy"*. However, it does not lay down any parameters or threshold to categorize or even differentiate between what constitutes "efficacy" and what is the "level of efficacy" recognized. Further, it held that merely establishing factors like "bioavailability" is not a sufficient parameter under Section 3(d), however, the same shall be backed by research data. [21]Therefore, not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy can be taken into account.[22] The Court in the Novartis case, further stated that whether or not an increase in bioavailability leads to an enhancement of efficacy in any given case must be specifically claimed and established by research data[23]. Therefore, it was concluded that for any invention relating to, for instance, such as salts or different polymorphic form of a drug, enhancement of "**therapeutic efficacy**" should be validated by the experimental data. However, even if the product was proved to be 30% more bioavailable using data, the Court was not satisfied to grant patent and considered it to be "merely a new form of known substance" and did not regard the actual/ potential efficacy the product had.

Recently, The High Court of Delhi in ***Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design[24]***, held that the solid form of an existing drug via direct compression is not patentable, relying upon Novak Principles. The Appellants asserted that they were seeking for

[19] Novartis AG v. Union of India and Ors. [(2013) 6 SCC 1].
[20] Shivaramjani Thambisetty, Novartis v Union of India and the person skilled in the art: a missed opportunity, Queen Mary Journal of Intellectual Property, 2014, Vol.4, Issue 1.
See, https://www.elgaronline.com/view/journals/qmjip/4-1/qmjip.2014.01.04.xml. (Last accessed 7th April, 2024).
[21] Archit Dhir, Novartis: A Critique, 3 GNLU L. Rev. 131 (2010-2012). See, https://heinonline.org/HOL/LandingPage?handle=hein.journals/gnlur3&div=12&id=&page=. (Last accessed on 7th April 2024).
[22] Jodie liu, See *supra* note 5.
[23] Patent Law in India, see *supra* note 7.
[24] Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents & Design, 2022 SCC OnLine Del 4785.

a "process" patent and not "product patent". Their medicine was merely a compression of the powdered form the drug. However, the process of manufacturing powdered substance is different from that of a "tablet form", hence, they deserve patent. The Respondents averred that this was merely a new form of known substance with no enhanced efficacy and shall be rejected under Section 3(d). The Delhi HC also took the same stance.

Therefore, in the light of above-mentioned the ***Novartis case*** [25]and the recent ***Chugai Seiyaku case*** [26]**,** it is concluded that the term "enhanced efficacy" in the context of pharmaceutical patent applications is applicable to "therapeutic efficacy" only. A Supreme Court decision that was decided in 2013 still has relevance in the current day patentability standards as seen in Chugai case. Any data that does not show the superior efficiency of new pharmaceutical drug or a new process of preparing the said drug over existing ones, in treating a patient, would not be considered as relevant data to overcome the hurdle of Section 3(d) of the Patents Act, thereby interpreting the provision in its strict sense

(C) Clash of Interpretations

The Section 3(d) of the Patent Act after 2005 amendment stands as under:

What are not inventions: — The following are not inventions within the meaning of this Act— "*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*[27]*".*

The 2005 amendment made the following changes to Section 3(d):

(*i*) adds the words "*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*" at the beginning of the provision;

(*ii*) deletes the word "mere" before "new use"; and

[25] Novartis, See *supra* note 17.
[26] Chugai, See *supra* note 22.
[27] The Indian Patent Act, 1970, § 3(d).

(*iii*) adds an explanation at the end of the clause.

The above-mentioned provision is capable of different interpretations having their own consequences and hence it is unclear and ambiguous as to which rule of interpretation is best suited to keep the legislative intent intact.

III. THE LITERAL RULE OF INTERPRETATION

A very well settled position of law India is that if the language of the statute is very plain and clear, there is no scope for considering factors such as "equity", "public interest" and "intent of the legislation". [28]Such language of the law shall be read and understood in a strict and absolute manner. Only when the language of the legislature is unclear, ambiguous, involves conflict or the plain reading leads to absurdity, in such cases the Judiciary shall deviate from the literal rule of interpretation. [29]However, in such cases, if there is conflict between "law" and "equity", the law, however hard it is, shall prevail. [30]This approach finds its root in a Latin maxim *dura lex sed lex* which means "the law is hard but it is the law". [31]

The question of rule of interpretation, more often than not, creates a conflict between the interests of Legislature and Judiciary. [32]The scope of judicial scrutiny has increased so much so that any citizen, under Art 32 can file a petition to scrutinize constitutional, legislative and executive powers of the Government. Even though, the Judiciary is an independent organ, it cannot interpret laws in an inadvertently ambiguous manner. [33]The power conferred is only with respect to ability to read down/ interpret statutes to fill up the absurdity in law.[34] Moreover, irrespective of the consequences, the courts are bound to give effect to plain reading of the law.[35] Narrow interpretation to Section 3(d) is often viewed as a threat to domestic as well as foreign drug development and eventually will stand as a threat to the economy. [36]

(A) Consequence of Interpreting Section 3(d) in literal sense.

Illustration: "ABC" is an Artificial chemical substance, which is inspired and developed from a natural one named "XYZ", by a Pharma Company named "MNC", which tends to cure a

[28] Tata Cummins Ltd. v. State of Jharkhand, (2006) 6 SCC 336.
[29] Pritipal Singh V. Union of India (AIR 1982 SC 1413.
[30] Vijay Narayan Thatte v. State of Maharashtra, (2009) 9 SCC 92.
[31] id.
[32] Nelson Motis v. UOI, AIR 1992 SC1981.
[33] High Court of Madras v. M.C. Subramaniam, (2021) 3 SCC 560.
[34] State of Jharkhand v. Govind Singh, AIR 2005 SC 294; Also see, Nathi Devi v. Radha Devi Guptha, AIR 2005 SC 648.
[35] Tata Cummins, See *supra* note 26.
[36] Kevin Tarsa, Novartis AG v. Union of India: Why the Court's Narrow Interpretation of Enhanced Efficacy Threatens Domestic and Foreign Drug Development, 39 B. C. Int'l & Comp. L. Rev. 40 (2016). See, https://heinonline.org/HOL/LandingPage?handle=hein.journals/bcic39&div=24&id=&page=. (last accesed on April 7th, 2024).

disease. The components of "ABC" and "XYZ" are the same, however since "ABC" is man-made it is less efficacious but a great substitute for "XYZ" that is non-renewable. The only difference is that "ABC" is a lab made form of "XYZ". If "MNC" applies for patent, it is highly likely that "ABC" will form under the category of "new form of known substance".

Firstly, the legislature does not give a hint as whether "known substance" indicates a natural one or a previously patented one. Further, "mere discovery" is the term proceeding "new form of known substance". The well-established principle is that "discovery of a natural substance is not patentable". Secondly, even though the law seeks to address the issue of evergreening of patents, in the instant case, there is no bifurcation between new form of naturally known substance and man-made and hence the patent of "ABC" is likely to be rejected by taking the literal interpretation of the Section. The law, however hard it is, is the law.

Due to such literal interpretation, the Pharma Companies would lose their zeal to research and develop substitutes. Without patent rights, it is difficult to recover the fixed cost and ultimately, they turn out to be sunk cost. Further, there unprotected product is available in the public domain, which invites more competition that could possibly work on efficacy and get patented. The initial player loses his market.

IV. GOLDEN RULE OF INTERPRETATION

The principle of statutory interpretation assumed "literal rule" to be the "golden rule", however, today it is the purposive approach that is adopted to judge the true essence of law. [37]

Firstly, it is pertinent to try to interpret the language of the section in a more liberal way. It is also believed that a liberal approach to this section will not satisfy the object of the provision because this provision is ambiguous. [38]The Parliament got in the 2005 amendment to prevent the phenomenon called "evergreening of patents", that is seeking patents for more than 20 years by making modification to the original substance. The words "new form of known substance" is incorporated to place restrictions on those pharmaceutical companies who apply for patents after slightly modifying the existing drug. Further, the threshold of "efficacy" is placed to ensure there is legitimate difference between the existing drug and newly devised one to be eligible to grant patent. There are scholars who advocate to lower the threshold for efficacy and give it a broad scope.[39]

[37] Shailesh Dhairyawan v. Mohan Balkrishna Lulla, (2016) 3 SCC 619; Also see, Anurag Mittal v. Shaily Mishra Mittal, (2018) 9 SCC 691.
[38] Shyam Sunder v. Ram Kumar, (2001) 8 SCC 24.
[39] 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). See, https://heinonline.org/HOL/LandingPage?ha

Illustration: 'Molo-600' a tablet owned by "XYZ" and 600 mg is the dosage used as a pain killer. Subsequently, if "MNC", a Pharma company manufactures 'SUMO 800', a syrup which has the same composition as of "Molo-650" but the dosage is varied 800. Humans can administer this composition of drug maximum for 2000mg per day. Is "MNC" eligible for patenting "SUMO-800" and claim it is 33.33% efficient.

The court cannot adopt a liberal view of "efficacy" to merely look into the arithmetical increase in efficacy to 33%. In such situation, the patent granted to "XYZ" would be meaningless. MNC could probably argue that their product is in a syrup form and is 33% efficacious. However, the question is primarily whether it satisfies the test of patentability- new, non-obvious, novel, inventive step. Granting such patents is no less than that of encouraging evergreening because the same composition a slightly different form with increased dosage does not satisfy the primary test of patentability. The Section does not only regulate forms but also the substance and its quality. "XYZ" will not be able to enjoy the monopoly that it deserves because "MNC" or any other Pharma Company is able to manufacture a different form with modified dosage, without incurring the cost of research that "XYZ" incurred. Therefore, a liberal approach to this section will cease the guaranteed right of the patent holder. Further, this market becomes easy to penetrate and more competitors will enter that will lead to non-recovery of fixed cost by XYZ.

(A) Monopoly v. Competition

Possible economic consequence could be a dead weight loss situation. The concept of fixed cost, sunk cost, monopoly and competition requires a merger to analyze the crisis in hand[40]. The new patent holder, who incurred minimum fixed cost but not the fixed cost on research would penetrate into the market with lower prices. However, the initial patent holder would still maintain his prices higher than the market price to recover the fixed cost incurred over and above the minimum. Due to increased price competition, the initial Patent holder is forced to bring down the prices to minimum fixed cost as he would have developed economies of scale to an extent. The new player would not have economies of scale and hence, could be pushed out of the market or incur loss. The intention behind granting patent, is to enjoy monopoly status for all 20 years. When there is competition during the tenure of 20 years, the period used to bring down the prices to chase such competition is a period of loss. Therefore, neither did

ndle=hein.journals/emint28&div=18&id=&page=. (Last accessed on 7th April, 2024).

[40] William J. Baumol, Robert D. Willig, "Fixed Costs, Sunk Costs, Entry Barriers, and Sustainability of Monopoly", Vol 96, No.3[1981] The Quarterly Journal of Economics pp. 405. *JSTOR*, See, https://doi.org/10.2307/1882680 (Last Accessed 23 Feb. 2024).

the initial patent holding firm get profits nor did the new one, thereby leading to a lose-lose situation.

V. MISCHIEF RULE/ HEYDON'S RULE

The following question of law shall be answered by the Court while adopting mischief rule of interpretation.:

"(*i*) What is the purpose for which the provision is made?

(*ii*) What was the position before making the provision?

(*iii*) Whether any of the constructions proposed would lead to an absurd result or would render any part of the provision redundant?

(*iv*) Which of the interpretations will advance the object of the provision?"[41]

The Hon'ble Supreme Court in Novartis case [42]relied on the parliamentary debate to ascertain the true intent of the legislation. "*A perusal of the Parliamentary debate would further reveal that the whole debate centered on medicines and drugs. It would not be an exaggeration to say that eighty per cent of the debate was focused on medicines and drugs and the remaining twenty per cent on agricultural chemicals. In the entire debate, no substance of any other kind came under discussion*"[43] Further the judgement states that "*The aforementioned amendment in Section 3(d) is one of the most crucial amendments that saw the Bill through Parliament and, as noted, the amendment is primarily in respect of medicines and drugs and, to some extent, agricultural chemical substances*".[44] Therefore, the product that the legislature is primarily focusing is the ones mentioned above.

Section 3(d) prohibits secondary use of patents but cannot be inferred as a ground to reject primary patents. The problem arises when there is no clear distinction made between the interpretation of "known substance" to mean natural substance and "known substance" to mean already patented product. The explanation to the said provision would suffice to be a threshold for "discovery new form of natural substance". However, the threshold of efficacy is only required to place additional checks to "new form of existing patents".

When mischief rule is adopted, the purpose of the legislature is given more importance than the effect that follows. The following observations are made by B.N Sampat and others in 2018

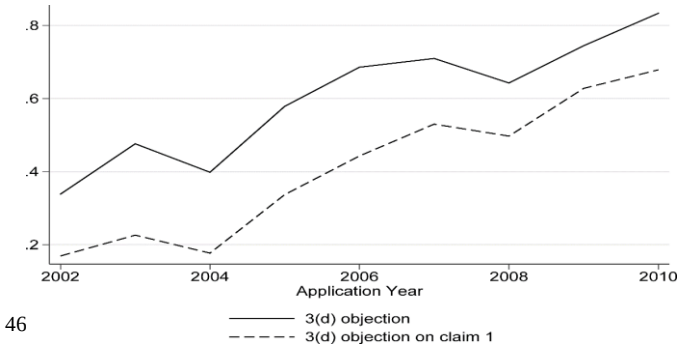
[41] Grid Corpn. of Orissa Ltd. v. Eastern Metals & Ferro Alloys, (2011) 11 SCC 334. Also see, Bengal Immunity Co. Ltd. v. State of Bihar [AIR 1955 SC 661]; Kanai Lal Sur v. Paramnidhi Sadhukhan [AIR 1957 SC 907]; Justice G.P. Singh's Principles of Statutory Interpretation, 15th Edn., Lexis Nexis,2022]
[42] Novartis, See *supra* note 17.
[43] See Novartis, *supra* note 17.
[44] id.

in their empirical study on secondary patents and the role of Section 3(d) as an objection over 2 decades. [45]The study says that previously, the provision was used to reject secondary patent claims, however, now the provision is being misused as an objection to primary patents, contrary to its intent, raising concerns on over-utilization.

The below figures are findings of the study:-

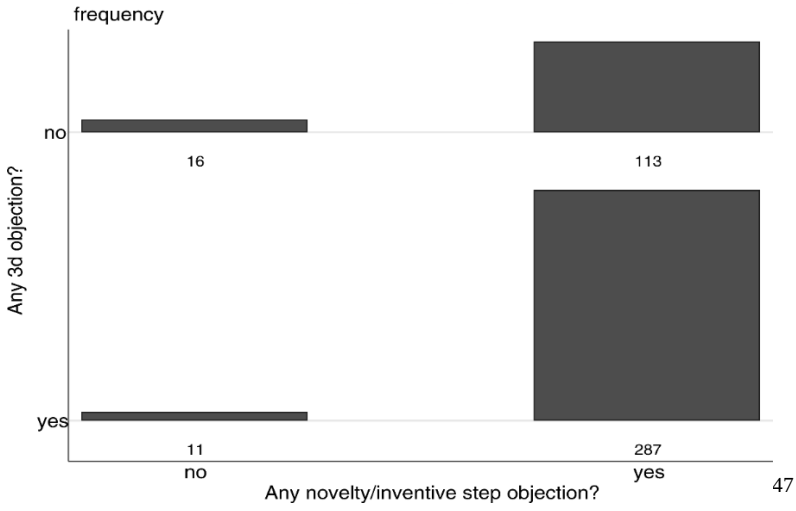
Figure 1 indicating the use of Section 3(d) as an objection to primary patent.

Figure 2 indicating the frequency of usage of Section 3(d) and other test for patentability as an objection.



[46]

Figure-1



[47]

Figure 2

It is also further believed that such increase in Section 3(d) objections to primary patents may be because of the discretionary power given to the Patent Office on this regard. The question of arbitrary delegation of legislation was previously questioned in the Novartis case, where the

[45] Sampat BN, Shadlen KC, Indian pharmaceutical patent prosecution: The changing role of Section 3(d), 2018. See: https://doi.org/10.1371/journal.pone.0194714 (last accessed on 23/2/2024).
[46] The changing role of Section 3(d), 2018. See *supra* note 43.
[47] id.

Hon'ble SC, relied on J.K.Cotton Spinning case [48]and held that the Legislature is quite competent to enact a deeming provision for the purpose of assuming the existence of a fact which does not really exist. This is to say that the legislature can give a skeletal structure and need to necessarily provide for detailed guidelines and definitions, in this case, as to what is efficacy. It evidently held that "*Rather, one has to look into factors such as the wordings of the statute, the amount of discretion conferred, the possibility of appeal to correct any wrong decision and the object of a statute to gauge the contours of a section*[49]."

Moreover, the word "efficacy" cannot have a strait jacket formula and therefore the law cannot possibly dictate as to what would amount to and not amount to "efficacy". Moreover, The Supreme Court has ruled in in re Delhi laws case held that while Parliament may delegate some functions to administrative bodies, it ought not to delegate an "essential legislative function."[50] In other words, it is permissible for the legislature to lay down broad policy and delegate powers of rule-making to the statutory authority to implement the policy. Delegated legislation is particularly common in areas of specialized knowledge, where the legislature lacks the knowledge and expertise to frame detailed rules.[51] Shamnad Bashheer [52]also discusses this aspect in his paper under the headings "Constitutional, yet crude".

The legal consequence of interpreting "efficacy" to only mean "therapeutic efficacy" excludes factors such as heat stability, enhanced bioavailability, humidity resistance, new drug delivery mechanisms. Such factors indeed satisfy the requirement of "an inventive step" and increased utility of the product.

Illustration: "ABC" is a "known substance" which can only be stored under 20 degrees Celsius and "OMG" is the new form of ABC substance with increased bioavailability and storage in places up to 45 degrees Celsius. In the instance case, there is efforts of research and development involved to increase the bio-availability and heat stability of a product. OMG is indeed useful in those places where the atmosphere does not always support 20 degrees Celsius. This new utility has more industrial application than that of the previous invention, therefore shall be patented. However, if public importance and utility is disregarded to mischievously interpret only the intent of the legislation picked from the word of law, such decisions might be questionable on justiciable grounds.

[48] M/s.J.K.Cotton Spinning and Weaving Mills Ltd. v Union of India, AIR 1988 SC 191.
[49] J.K cottons, See *supra* note 46.
[50] In Re Delhi Laws case AIR 1951 SC 332.
[51] Jyoti Pershad v. Administrator for Union Territory of Delhi, 1961 SCC OnLine SC 127.
[52] Shamnad Basheer, See *supra* note 6.

VI. RECOMMENDATIONS AND CONCLUSION

Section 3(d) is definitely a game changing provision of the 21st Century. Though it complies with TRIPS, and notwithstanding the constitutionality of section 3(d) and its laudable intent of preventing "evergreening", it is a crudely worded provision. Therefore, this paper has analyzed the hypothetical situations emerging out of every possible interpretation and I, hereby put forth the following recommendations: -

1. Section 3(d) could be divided into 2 following parts:

- New form of known natural substance: This could prevent mere discoveries of available natural substance from being patented. The current explanation shall prevail.
- New form of patented substance: This would shift the focus to secondary patent applications and the threshold can be the same as test for patentability and enhancement of efficacy. The current explanation shall prevail.

The primary intent behind such bifurcation is that the discoveries of natural substance shall not be subject to "efficacy" as a threshold.

2. Definition of "efficacy" shall not be determined merely on arithmetic figures but on certain factors regarding public utility and importance. Such factors shall not be limited to therapeutic efficacy but also heat stability, enhanced bioavailability, humidity resistance, new drug delivery mechanisms or any other factor that served the intent of the law.

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