

Restrictive Interpretation of Section 3(d), The Patents Act, 1970: Key Challenges and the Road Ahead

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Abstract

The Indian patent regime underwent a significant overhaul in the year 2005 with the amendment of Section 3(d) of the Indian Patent Act of 1970, pursuant to India's outstanding obligation under the Trade Related Aspects of Intellectual Property (TRIPS). The amended provision seeks to prevent 'evergreening' of patents that results from inhibiting minor variations in the name of inventions while at the same time allowing genuine breakthrough innovations to come to the fore. Thus, Section 3(d) of the Act therefore represents an attempt to strike the necessary balance between competing interests of patent holders, technological innovation and public health through access to medicines. Since its enactment, it has thus far been a controversial provision and became a subject of interpretation in the celebrated Novartis AG v. Union of India ruling. This paper critically examines the implications of Section 3(d) in the light of the Novartis judgement. Part A deals with the judicial interpretation of the Novartis decision with respect to "enhanced efficacy" and the like. Part B evaluates whether the precedent set by Novartis serves as roadblock for innovations by incremental steps or does it need to be revisited for a broader interpretation to serve the interests of patent holders and the general public alike. Part C offers solutions to equipoise contrasting individual and public interests for a more robust patent protection system.

Introduction

With the coming into force of the TRIPS Agreement in 1995, member nations were obligated to introduce obligatory mechanisms stipulated therein into their domestic legislations. That allowed a flexibility to developing countries where they were given a transitional period up to

the year 2005 to comply with pharmaceutical product patent production system.

Thus, India brought a major amendment in the same year to the Patents Act (The Patents Act, 1970, § 3(d), as amended by The Patents (Amendment) Act, 2005 (India)) to comply with the same as mandated by Article 27 TRIPS (TRIPS Agreement, 1994, art. 27). There was a lot of hue and cry engulfing the amendment as product patent protection was argued by critics as a bait usable by large pharmaceutical giants to recoup investments for a statutory period of 20 years, thereby creating obstacles for generic medicines to enter the market and address the issues of access to medicines.

However, a counter argument to this position could be that Section 3(d) ["3(d)"], was enacted not to grant patents to frivolous inventions, rather it was inducted as an additional barrier to patentability to prevent what is known as patent 'evergreening', i.e., a practice adopted by pharmaceutical companies to extend the life of their patented drug by introducing minor variations to it, without necessarily enhancing its therapeutic efficacy. It places a check in the form of a requirement of "enhancement of known efficacy" which needs to be met by the invention in order to save it from the clutches of 3(d). The provision reads as follows:

"3. What are not inventions- The following are not inventions within the meaning of this Act-

(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.

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Explanation- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. (*The Patents Act, 1970, § 3(d)*)"

The judgement from the *Novartis case* has been incorporated into the guidelines for examination of applications in the field of pharmaceuticals issued by the controller in October 2014. (Office of the Controller General of Patents, Designs and Trademarks, 2014, pp. 2, 28--33) The provision is 'cut above the rest' as it makes the Indian patent law stand on a different footing as compared to other IP advanced regimes like the U.S. or E.U. It was enacted with an intention to segregate Bonafide inventions from mere improvements by "mandating enhanced efficacy" to help build a robust patent protection system.

Making of minor variations to an already existent patented drug stalls the entry of generic drugs into the market. The outcome is a patent monopoly which keeps on elongating and blocking the access of generic drugs to the market which is referred to as "evergreening" (Banerjee & Roy, 2009, p. 611). Consequently, pharmaceutical giants maintain their investment and redemption cycle and the actual benefits of generic drugs do not reach the ones who lack manufacturing capacity or bargaining power vis a vis these giants, for accessing subject matter of the patent (Banerjee & Roy, 2009, p. 611). However, there a few ambiguities in this section which have been interpreted by a landmark judgement of the division bench of the Supreme Court of India in the "Novartis case".

Judicial Interpretation of 3(d) in light of the Novartis ruling

The introduction of this section was hailed as a victory for pharmaceutical companies who were longing for product patents but at the same time, it was vehemently criticised for its apparent conflict with public health. It wasn't long until the deadlock began to unfold and became manifest by the

rejection of the patent application of pharmaceutical giant, Novartis' anti leukemic drug, Glivec, by the Chennai Patent office (Novartis AG v. Natco Pharma, Indian Patent Office). Consequently, Novartis went into appeal to Madras High Court against the patent office decision and even took a bold step by challenging the constitutional validity and TRIPS compatibility of Section 3(d), which was upheld by the High court (Novartis AG v. Union of India, 2007). Meanwhile, the five writ petitions filed challenging the order of the assistant controller were transferred to the newly constituted intellectual property appellate board (hereinafter IPAB). The IPAB reaffirmed the findings of the assistant controller on the point of patentability of the subject product, which it held to be hit by Section 3(d) (Novartis AG v. Union of India, 2013). Against this order, the appellant, Novartis preferred a Special Leave Petition to the Supreme Court of India under Article 136 of the constitution. (Novartis AG v. Union of India, 2013, p. 7)

For the sake of brevity, the facts which resulted into the controversy at hand in the present case, are iterated as follows- A derivative of N-phenyl-2-pyrimidine-amine in free base called Imatinib, which was a part of the "Zimmermann patent" was improved upon to devise the subject product, Imatinib Mesylate in beta crystalline form (Novartis AG v. Union of India, 2013, p. 4). This form of the drug referred to as "Gleevec" (the name for Imatinib Mesylate) was granted US FDA approval in 2001 (Novartis AG v. Union of India, 2013, p. 43), and the beta crystalline form of the same, was granted a patent in the U.S. in 2005 (Novartis AG v. Union of India, 2013, p. 43). According to the judgement of the US Board of Patent appeals, though the beta crystalline form was not covered by the Zimmermann patent, yet the Zimmermann patent offered teaching for the making of Imatinib Mesylate from Imatinib (Novartis AG v. Union of India, 2013, p. 45). The Supreme Court of India, in the present case also affirmed likewise, that Imatinib Mesylate was a known substance from the Zimmermann patent itself (Novartis AG v. Union of India, 2013, p. 47). However, the beta crystalline form of the same was noted to be a 'new form of a known substance' and

therefore, had to be tested on the anvil of Section 3(d) and the explanation appended to it. (Novartis AG v. Union of India, 2013, p. 55)

Does the beta crystalline form have 'enhanced efficacy' over the known substance immediately preceding it?

The beta crystalline form has i) more beneficial flow properties ii) better thermodynamic stability and iii) lower hygroscopicity, as compared to its predecessor, Imatinib Mesylate but whether these pharmacological effects have a bearing upon the efficacy of the drug, is yet to be seen (Novartis AG v. Union of India, 2013, p. 58).

Efficacy, as per the New Oxford Dictionary of English, Ed.1998 means "the ability to produce a desired or intended result". The test of efficacy has to be conducted with respect to the function, utility or purpose for which the product claims protection, which in case of a medicine that necessarily has curative purposes, would be "therapeutic efficacy". According to the court, this standard has to be observed strictly and narrowly. The words of Sec. 3(d) have mandated the condition of "*enhancement of the known efficacy*" and the explanation appended to it needs the derivative to "*differ significantly in properties with regard to efficacy*" (The Patents Act, 1970, § 3(d)). The court therefore held that all superior properties would not automatically translate to therapeutic efficacy:

"What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in the case of medicine, as seen above, is its therapeutic efficacy." (Novartis AG v. Union of India, 2013, p. 59)

The test of bioavailability

Delving further into the problem, it was highlighted in the midst of multifarious arguments made before the court that in the field of pharmaceuticals, there were broadly two kinds of properties which could explain drug action- "pharmacokinetic", i.e., the effect the body had on the drug and the other one, "pharmacodynamics", i.e., the effect the drug had on the body.

It was argued by the counsel for the respondents that **efficacy** was a pharmacodynamic property,

which was distinct from other properties like- **bioavailability**, **affinity** and **potency**. The "affinity" of a drug is a pharmacodynamic property, which means the capacity of a drug to attach or bind to a target or receptor or the like biological target. "Potency", another property linked to a drug is the amount of drug required to make the treatment possible as compared to a standard reference (Novartis AG v. Union of India, 2013, p. 60).

"Bioavailability", a term central to the judgement, is a pharmacokinetic property which is used to indicate the extent to which the drug is able to reach its intended site of action. **Bioavailability** is measured in terms of the percentage of the drug passing through the bodily system and reaching the target area. However, the question which arose here was whether increase in bioavailability translated to an inference of enhanced **therapeutic efficacy**? The court answered this partly in affirmative and partly in negative by holding that mere increase in bioavailability is not a necessary corollary to enhanced therapeutic efficacy. The court observed-

"Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data." (Novartis AG v. Union of India, 2013, p. 61)

Lack of any material on record to demonstrate the above, led to a failure to prove the enhanced therapeutic efficacy of the beta crystalline form of Imatinib Mesylate (Novartis AG v. Union of India, 2013, p. 61).

Problems posed by the narrow interpretation of > 3(d)

Restrictive meaning to the term 'efficacy'

Patchy TRIPS Compliance

The Supreme Court's interpretation of the term "efficacy" was restricted to "therapeutic efficacy" which was also the approach taken by the Madras High Court. Such a restrictive definition, that too by placing reliance on a dictionary, would not be comprehensive enough to serve the purpose of such a significant provision. This has the capacity to shake the patent regime and pharmaceutical

industry of India, which is emerging as a global leader in pharmaceuticals and can pave the way for breakthrough inventions, if backed by enough incentive.

The court has plainly regarded other advantageous properties as to not contribute to an increase in therapeutic efficacy, without much deliberation about the reasons behind such interpretation.

The **first issue** with such an exposition is that the language of the section makes it far from being TRIPS-compliant. Why is it so?

Because, the inclusion of 3(d) is a barrier to patentability and this is a provision unique to the Indian regime. Other jurisdictions as U.S. rely on expressly stated qualifiers under TRIPS, of being a new, non obvious and useful invention. If U.S. be considered as a touchstone of TRIPS compliance, then there is no reason why India's compliance with TRIPS should not be questioned (Du, 2014, p. 245). This is backed by WTO jurisprudence, past TRIPS adjudications and more significantly, the way Article 27 of TRIPS (TRIPS Agreement, 1994, art. 27) has been drafted (Du, 2014, p. 246). The obscurity of this provision cannot be debated but for the record, it stipulates only three requirements-"novelty", "inventive step" and "capable of industrial application", to be met by a patentable invention. If a member places other fences to patentability in its domestic legislation, it would be a violation of the spirit of the agreement, which is aimed at better intellectual property protection mechanisms (Du, 2014, p. 246).

Equating efficacy with therapeutic efficacy only

The Supreme court's approval of the circumscribed construction of "therapeutic efficacy" as has been construed by the Madras High Court and IPAB alike leads to the conclusion that secondary improvements over existing forms, however superior they may be in other terms, would fail to pass the test of 3(d), if they aren't contributing to the healing effect resulting from the drug.

This is in no way rewarding for inventions which could genuinely be considered notable advancements over their pre-existing forms and would also provide generic manufacturers freebies

over genuinity and extravagant finances sustained by pharmaceutical corporations in the research and development of an invention (Du, 2014, p. 252). Some **secondary advancements** may have offer real bonuses over their predecessors, though they may not be essentially contributing to therapeutic efficacy in the literal sense, for example they may be having lower toxicity, better dissolving capacity or may be the only form for commercial viability, as was the case in Novartis (Du, 2014, p. 252).

Moreover, restriction of efficacy to therapeutic efficacy **suppresses innovations** which could be prove to game changers. It would not be sound logic to ignore non-therapeutic qualities in assessing non-obviousness. Judge Lourie in his dissenting opinion (Pfizer, Inc. v. Apotex, Inc., 2007) criticized the panel decision on patentability of a compound, wherein the panel heavily relied upon therapeutic value of the claimed compound, rather than considering other non-therapeutic properties, for instance increased stability, etc. He considered it illogical to base the conclusions regarding patentability only on therapeutic properties (Pfizer, Inc. v. Apotex, Inc., 2007), which was also what the Supreme Court did in Novartis. Though the court asserted that the test of therapeutic efficacy must be applied strictly and narrowly (Novartis AG v. Union of India, 2013, p. 59), but it has not stated with precision and clarity as to what the test should be. What the court did in the case was establishing a relation between some properties of a compound and their possible contribution to therapeutic efficacy, which again remains an open ended question.

Prof. Basheer cites an example of a drug named "CIPRO" from one of the country's forerunner pharmaceuticals, Ranbaxy, wherein the said drug exhibited efficacy as regards a non therapeutic use (Basheer & Reddy, 2008, p. 261). The said drug has a mechanism because of which it needs to be consumed once a day only, this being a very convenient property of the drug (Basheer & Reddy, 2008, p. 261).

Also, the **context** in which efficacy has to be understood is not certain. For example, if it were to be seen from the point of view of drug regulation, it would be too much to ask for from the patentee, as patent applications are filed much earlier than

actual clinical trials can be conducted. Therefore, to supply such data at the inception would be an unjustified burden for the patentee to discharge. (Basheer & Reddy, 2008, p. 256) Furthermore, the requirement of clinical trials would also throw open to challenge the novelty of the patent being claimed (Basheer & Reddy, 2008, p. 256), thereby opening a Pandora's box. These ambiguities could have been kept at bay, had the court supplied a lesser vague interpretation of or a definite test for efficacy.

Discouraging innovation by incremental steps

The court called it a "grave mistake" to read the ruling as to mean that it bars patent protection for all incremental innovations of chemical and pharmaceutical substances. However, in effect most claimed inventions fail to pass the test of 3(d), which proves otherwise.

There are broadly **two kinds** of inventions- **Radical** and **incremental**, wherein the radical type connotes a completely new class of drugs having a new action mechanism, while incremental refers to drugs which are new, but in the existing class with differences in therapeutic or non-therapeutic properties but similarities in action mechanism. (Banerjee & Roy, 2009, p. 614)

The importance of incremental innovations cannot be downplayed in patent systems, as they lead to development of "blockbuster drugs" at times. Even parliamentary debates centred around the amendment of 2005 suggested that allowing incremental innovations in India would not only help multinationals, but also Indian companies. The cost of bringing out a new molecule at the relevant time was quoted to be around Rs. 6000 crore (Swain, 2005). How many companies, especially in the Indian context could possibly afford to develop from scratch, a radical innovation given the exponentially high costs of drug development and the cumbersome procedure which follows the financial expenditure (Swain, 2005)? The answer lies in patentability of incremental innovations. Though they are not barred from being patented in India by virtue of the legislation or the judicial pronouncement in Novartis, yet effectively most applications with

incremental innovations are hit by the language of and rendered unpatentable.

It is interesting to note that most advances in medical field take place by incremental innovations building on previous inventions (Eger et al., 2010, pp. 128--158), however, the conditions stipulated by 3(d) extinguish the chances of the same, the most pertinent example being the beta crystalline form of Imatinib Mesylate. The patent sought to protect the pharmaceutically viable form of the drug, which the free base form wasn't able to achieve. This kind of incremental innovation needs to be protected (Du, 2014, p. 239), as it could have been a critical improvement which otherwise may not have been possible by an independent development.

Ambiguity on 'bioavailability' as a signifier of therapeutic efficacy

As already explained in 1.2, therapeutic efficacy was given a narrow interpretation and the court failed into take into account the properties which could escalate the same to pass the test of 3(d). Though bioavailability (Liu, 2015, p. 220) is not a direct measure of therapeutic efficacy, yet it could be taken into account as, if more of a drug reaches the target area, it could result in a faster cure. Thus, increased bioavailability does not necessarily translate to therapeutic efficacy but it could very well be a contributing factor, which the court also considered.

But, something which the court missed out on was the fact that what the beta crystalline form of imatinib mesylate sought to achieve, could not be done by the free base form of imatinib, as it could not be administered in the said form at all (Liu, 2015, p. 225). This implies that if the drug could not reach the target area, there was no question of efficacy at all but if it could, then that would catalyse the efficacy of the drug in producing the intended effects, exactly what the beta crystalline form was aimed at. Characteristics such as bioavailability do have an impact upon the efficacy of a drug, as for the drug to take effect, it must be able to be administered to the patient (Holman, 2017, p. 769). It simply negated the contention of Novartis by holding that research data should have been presented to demonstrate a relation between

the bioavailability and enhanced efficacy of the claimed compound (Liu, 2015, p. 225), which again, as has been iterated earlier, is an unreasonable expectation in the initial stages of drug development (Du, 2014, p. 251).

Going by the definition of 'efficacy' as considered in the Novartis case, anything which could produce desired effects would fall squarely covered by it, then why not bioavailability (Basheer & Reddy, 2008, p. 244)? The implication is clear as it draws its justification from the stance taken by the court in defining 'efficacy'.

Apart from this, many applications have been rejected by the patent office despite the presence of superior properties as compared to their previous counterparts. A recent example could be wherein the Chennai patent office rejected an application claiming "a crystalline form of Cyclosporin A, methods of preparation and methods for use thereof" (Allergan Inc., Indian Patent Office) due to its failure to meet the standard under 3(d). Ready milling properties, higher solubility leading to improved stability of the compound were some of the properties on the basis of which the applicant tried to defend the application, but to no avail. In another application as well, the patent office did not consider the claim on the basis of better stability of a polymorph over its existing form; despite a more conveniently possible storage offered by the compound (Syngenta Limited, Delhi Patent Office), it could not meet the requirement of 'enhanced efficacy' Section 3(d) as set by the Novartis case. Thus, inventions with effective physical properties that otherwise do not bear a relation to therapeutic efficacy, have a hard time at the patent office.

Flawed reasoning on evergreening

Section 3(d) was enacted to prevent what is known as evergreening of patents. As Dorothy Du puts it,

"Evergreening is a term used primarily by detractors of the alleged practice, to describe the acquisition of secondary patents on reformulations or minor modifications of pharmaceutical products in order to unfairly extend the monopoly over the drug beyond the life of the initial patent." (Du, 2014, p. 228)

The term can have multifarious meanings like **extended market monopoly** beyond the life of the original patent or simply multiple patenting enveloping different dimensions of a drug, or obtaining a secondary patent while the first one is in existence (Tarsa, 2016, p. 50). The Court considered that 3(d) was aimed at the prevention of evergreening but failed to appreciate that Imatinib, in its free base form did not have an evergreening effect, as it wasn't capable of being administered as such to the patient (Tarsa, 2016, p. 51).

A solid dosage form of it, even if administered would settle in the stomach like a brick and pass out with no therapeutic effect (Novartis AG v. Union of India, 2013, p. 58). Getting a patent during the pre-existence of the first one, is an impossibility in India, as an invention has to satisfy the criteria of novelty (The Patents Act, 1970, § 2(1)(j)) and inventive step (The Patents Act, 1970, § 2(1)(ja)) as well, apart from the 3(d) criterion. The problem with the court's stance in Novartis was keeping imatinib free base and not Imatinib Mesylate as a frame of reference with respect to 'known compound' and drawing a parallel between the beta form and the free base form. What would 3(d) prevent from evergreening if the 'known compound' does not have the capacity to be administered in the first place (Liu, 2015, p. 225)? This renders the underlying rationale of prevention of evergreening by means of 3(d), otiose to a certain extent.

3(d) aims to draw a justifiable distinction between incremental innovations and evergreening (Basheer & Reddy, 2008, p. 239). How? Improvements of drugs if significantly efficacious, as compared to the previous forms would triumph the 3(d) test and if not, they would fall short of grant. It acts as a check on evergreening at the same time keeping the scope of incremental innovation open. Whether they are granted patents or not is a different issue altogether, but the statute or the judgement of the Court has nowhere barred patentability of incremental innovations, if one may say so.

Repercussions of the state of affairs on the Indian Pharmaceutical sector

The decision of the Novartis case has had far reaching effects on the **pharmaceutical sector**.

Particularly, before the introduction of the product patent regime, there was a strong market for generic medicines in India but with the introduction of the 2005 amendment, pharmaceutical product patents started gaining ground. Though 3(d) was a welcome change to the pharmaceutical industry as its prime objective was to cull out genuine inventions, but facts and figures don't have great news to offer.

According to a recent data by Department of Science and Technology (DST), reported by the Economic Times, 76% of patent filing in India in the last 13 years was done by foreign companies and the rest by Indian companies. (Kumar, 2020) The backdrop of section 3(d) suggests that it was brought in to bolster the patent regime in India, particularly with reference to Indian companies, which was also an argument made in favour of 3(d) at parliamentary debates (Swain, 2005). India has been a global leader in generics pre and post the enactment of the Patent Act but it is yet to develop and market new drugs.

According to NASSCOMM's report, the Internet of Things (IoT) patent filing has seen a consistent increase, but the share of MNCs heavily overshadows all other contributors to innovation (Jain, 2020). The lack of awareness on filing, a backseat taken by the patent office are all reasons for this stunted growth of Indian pharmaceutical companies in terms of patent filing (Jain, 2020).

The stringent requirements of Section 3(d) may pose challenges to incremental pharmaceutical innovations, particularly when Indian Pharma companies primarily develop improvements to existing compounds rather than entirely new chemical entities. Although such innovations may meet standard patentability criteria, they may nevertheless fail "enhanced efficacy" threshold under 3(d), as illustrated under point no. 3 (Allergan Inc., Indian Patent Office; Syngenta Limited, Delhi Patent Office). While S. 3(d) plays a material role in facilitating access to affordable medicines by preventing unjustifiable patent extensions, an outrageously may reduce incentives for beneficial incremental innovations. While generic manufacturers encourage easy access to drugs, but their ability to enter the market only after the patent expires may diminish returns

available to innovators, which in turn can adversely affect incentives for pharmaceutical research. This might end up hurting the patent regime by restricting beneficial inventions which could otherwise have met the yardstick of patentability as happens in the U.S.

Given the standard set by the Novartis ruling, it wouldn't be long before the foreign pharmaceuticals which have low or nil incentive in manufacturing medicines for neglected diseases, limit research and development of drugs specific to the global south (Tarsa, 2016, p. 52; Liu, 2015, p. 226). The change in patent regime post 2005 signifies how companies undertake R&D, if incentive is offered and protection is assured. However, it would be a 'back to square one' situation if despite this assurance, the 3(d) barrier cannot be crossed.

Conclusions and Solutions

Prof Basheer calls Section 3(d) a "**crudely worded provision**", and it holds true because the purpose and policy behind the section aims at a higher threshold for pioneering inventions but the manner in which the provision has been drafted is bereft of lucidity. The true import of the section also has not been accounted for by the Supreme Court in Novartis. Dimensions of 3(d) are wide ranging and envelops within itself a range of possibilities that if it is construed liberally, it would make available to the people real inventions that have the potential to radically revolutionise the patent system. Therefore, there is a definite chance of reconsidering the purview of the section to reap maximum advantage.

First of all, the term '**efficacy**' **needs to be redefined** by the court to broaden its ambit to include other physical properties such as "higher stability", "heightened level of safety", "convenient storage capacity", "potency", "affinity" and the like, which may or may not directly contribute to its therapeutic efficacy, but render it administrable enough so as to make it a better and effective formulation over its previous forms. Even the properties which are purely contributing to the hassle-free administration of the drug could be considered efficacious for the purposes of the section. Not to mention, notable

innovation as compared to its precursors should still be a mandate to qualify the **3(d)** test. Too liberal an interpretation could also lead to an imbalance between individual interests in the form of patent rights and public interest in the form of access to generic drugs.

Secondly, the requirement of **demonstration of bioavailability to prove therapeutic efficacy should be relaxed** to some extent, the reason being that absence of bioavailability does not entail the question of therapeutic efficacy at all. If at all there is an evidence of enhanced bioavailability, only then does the question of a rise in therapeutic efficacy emerge. Bioavailability is the quantum of a drug which binds to the receptors so, as a necessary corollary, significant increase in bioavailability could be construed as a contributor to enhancement of therapeutic efficacy.

Thirdly, **the court drew an incorrect finding in the Novartis ruling by comparing the beta crystalline form of Imatinib to its free base form**, latter of which was not a 'known substance' in the context of Section 3(d). It was actually Imatinib Mesylate which need to be placed against the beta form for the consideration of known substance. Thus, this is an error **which needs to be rectified** when constructing 'known substance' to determine efficacy.

Fourthly, until the judiciary decides to reconsider its interpretation, the parliament could consider **amending 3(d) to define terms like 'efficacy'** which have created ambiguities

in the wake of the Novartis judgement. This present language of 3(d) is purely a matter of legislative policy but in absence of a clear direct or indirect test to determine therapeutic efficacy, the ruling may be exposed to challenge. This would remain the case unless another precedent defines what actually the term could encompass or the legislature itself takes up the tedious task of amending the provision for a better understanding to avoid the existing ambiguities.

All in all, this provision could prove to be a cornerstone of patent jurisprudence in India, provided it is given a more liberal interpretation than exists presently. A necessary distinction has to be drawn between evergreening and genuine

incremental innovations to strike a balance between the rights of a patentee and impact of grant of patent on public health, all of which can be done by widening the scope of 3(d) aptly as suggested, with due regard to the interpretation of the courts and the wisdom of the legislature.

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