THE NOVARTIS DECISION OF THE INDIAN SUPREME COURT: A PILL BY ANY OTHER NAME WOULD TREAT AS NEAT

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I. Introduction

On April 1, 2013, in a much-awaited 112-page decision, the Hon'ble Supreme Court of India rejected global pharmaceutical major Novartis AG's patent application on the Beta Crystalline form of Imatinib Mesylate (hereinafter referred to as "BCIM"), which ostensibly claimed Novartis's blockbuster anti-cancer drug "Gleevec/Glivec". The decision of the Supreme Court was anxiously awaited for several reasons, but most importantly because the observations and ruling of the Court would affect the course of pharmaceutical innovation in India, pharma patent-filing strategies, and the manner of disposal and outcome of pending pharmaceutical product patent applications and appeals by the Indian Patent Office (IPO) and the Intellectual Property Appellate Board (IPAB) respectively.

Although Section 3(d) of the Patents Act, 1970 (hereinafter referred to as "the Act") has been applied by the Indian Patent Office on multiple occasions since its introduction through the Patents (Amendment) Act, 2005, the Novartis case is the first case where the Supreme Court had the occasion to test the patent-eligibility of a pharmaceutical product on the anvils of the provision. As part of this analysis, the case also offered the Court a wonderful opportunity to clarify and lay down the law on several fundamental aspects of the Act such as the interpretation of "invention" and "inventive step", and their interplay with subject-matter proscriptions under Section 3 of the Act, which have concrete implications for practitioners and patent examiners.

The broad mandate before the Court was to strike a balance between incentivising innovation and discouraging attempts to "evergreen" pharmaceutical product patents, which is the manifest legislative intent behind the inclusion of Section 3(d). However, in the eyes of the international patent community, the Novartis case was a test of:

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(a) The Indian Patent regime's approach to the rights of innovator pharma companies in general, and incremental pharmaceutical innovation in particular; and

(b) The Indian Judiciary's ability to comprehend and apply the nuances of patent jurisprudence, without falling back on the "public interest" argument to whittle down or do away with a rigorous fact-based techno-legal analysis.

This paper analyses the decision in detail to assess its success or otherwise in addressing each of these aspects of the pharma patent discourse, besides the issue of TRIPS compliance which the Supreme Court did not have to deal with since Novartis chose not to raise it.

II. Facts leading to the Supreme Court decision

At a time when India did not grant pharmaceutical product patents, on July 17, 1998, Novartis AG filed its "mailbox" Indian patent application (1602/MAS/1998) on BCIM titled "*Crystal Modification of a N-Phenyl-2-Pyrimidineamine derivative, processes for its manufacture and its use*" seeking Exclusive Marketing Rights (EMR). The Indian application claimed priority from a Swiss application dated July 18, 1997. A US application US09/463,097, which too claimed priority from the Swiss parent application, was filed on July 16, 1998 and granted as US6894051.

Novartis was granted EMR in India on November 10, 2003, and subsequent to the introduction of pharma product patents in India through the Patents (Amendment) Act, 2005, its application was taken up for examination for grant of a product patent. However, pursuant to five pre-grant oppositions filed by Cancer Patients Aid Association, NATCO Pharma Limited, Cipla Limited, Ranbaxy Laboratories Limited, and Hetero Drugs Limited, Novartis's application on BCIM was rejected by the Chennai branch of the Indian Patent Office January 25, 2006.

The primary grounds for rejection of the application by the Patent Office were lack of novelty and failure to tide over the prohibition of Section 3(d). With specific reference to the objection under Section 3(d), following were the observations of the Patent Office:

> *"9. The Opponent (Cipla) said that the application claims only a polymorphic form of the known substance, imatinibmesylate. There is*

no enhancement of known efficacy as required under Section 3(d) of the Patents Act. Moreover the present specification states that all the inhibitory and pharmacological effects are also found with the free base, or other salts thereof.

10. Countering the arguments of the Opponent, the Applicant (Novartis) said that the crystal form of imatinibmesylate is an invention and not a more discovery. They further said that, a discovery graduating into a patentable invention solely on the basis of efficiency defies logic and, therefore, Section 3(d) may be unable to stand legal scrutiny. The Applicant submitted that this aspect of Section 3(d) is against the tenets of our patents act and well established principles of jurisprudence and therefore, the said Section cannot be used against the subject application.

11. I do not agree with the contention of the Applicant that this application claims a new substance. It is only a new form of a known substance. As regards efficacy, the specification itself states that where ever crystals are used the imatinib free base or other salts can be used. Even the affidavit submitted by the Applicant states that "the proviso to the Section 3(d) is unique to India and there is no analogous provision in the law of any other country of the world".

As per the affidavit the technical expert has conducted studies to compare the relative bioavailability of the free base with that of crystal form of imatinibmesylate and has said that the difference in bioavailability is only 30 per cent and also the difference in bioavailability may be due to the difference in their solubility in water. The present patent specification does not bring out any improvement in the efficacy of the crystal form over the known substances rather it states the base can be used equally in the treatment of diseases or in the preparation of pharmacological agents wherever the crystal is used.

Even the affidavit submitted on behalf of the Applicant does not prove any significant enhancement of known efficacy. It is found that this patent application claims only a new form of a known substance without having any significant improvement in efficacy. Hence, I conclude that the subject matter of this application is not patentable

under Section 3(d) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005."

Several critical aspects of Novartis's approach are borne out from the above extracted observations of the Patent Office. First, instead of treating imatinibmesylate as the "known substance" for the purposes of proving novelty and efficacy of its beta crystalline form, Novartis insisted on treating the imatinib free base as the known substance. This, despite the fact that pharmaceutically acceptable salts of free bases (including mesylate salts) and their enhanced solubility properties were well-known in the prior art. Second, clearly the emphasis of Novartis's application was never on enhanced therapeutic efficacy. Instead, improved thermodynamic stability and subsequently, increased bioavailability were projected as the unique selling propositions of the application. This is clear from the absence of data in Novartis's affidavit to prove enhanced efficacy.

Further, despite the express observations of the Patent Office on the need to establish enhanced efficacy, there was no attempt on the part of Novartis to submit efficacy data by amending the application (assuming such amendment is permissible under the Act), even when the issue of efficacy was raised by the IPAB and the Supreme Court. As shall be seen from the ensuing portions of the paper, all along Novartis endeavored to either question the legitimacy of Section 3(d) or expand the scope of the definition of enhanced efficacy to include increased bioavailability within its ambit. The only logical conclusion that can be arrived at is that Novartis did not have any enhanced efficacy to show for BCIM.

Against the rejection of the Patent Office, Novartis filed seven writ petitions in all before the Madras High Court. Out of these, two petitions challenged the constitutionality and TRIPS-compliance of Section 3(d). Both these petitions were dismissed by the Madras High Court in 2007. These dismissals were not appealed against by Novartis.

The other five writ petitions challenged the pre-grant decision of the Patent Office. Pursuant to Section 117G of the Act, these five petitions were converted to appeals and transferred in 2007 to the then newly-constituted IPAB. By an order dated June 26, 2009, the IPAB upheld the rejection of Novartis's application by the Patent Office essentially relying

on Section 3(d). In contrast to the Patent Office, the IPAB held that BCIM was novel and inventive, but rejected it citing Section 3(d)[1]. The IPAB agreed with the Madras High Court's interpretation of "efficacy" as the ability of a drug to heal or treat a condition. The IPAB held that not every advantageous property fell within the definition of "efficacy" unless it led to enhanced efficacy. Specifically, the IPAB observed that it was not scientifically possible for Novartis to argue that bio-availability was either synonymous with or automatically led to enhanced efficacy. Instead, according to the IPAB, Novartis had to positively establish using experimental data that in the context of the application, increased bioavailability indeed led to enhanced efficacy, which it failed to.

It is against this decision of the IPAB that Novartis preferred Special Leave Petitions (SLPs) in which the Supreme Court finally pronounced its verdict on April 1, 2013.

III. Analysis of the Supreme Court's Decision

3.1 Interpretation of "Inventive Step"

As stated earlier, the Novartis case presented the Supreme Court with an opportunity to lay down the law on several fundamental aspects of the Act. For instance, misconceptions abound on the interpretation of "inventive step" under Section 2(1)(ja) of the Act. Inventive step under the Act is defined as follows:

> *"Inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art"*

The abridged and incorrect interpretation of the definition that is subscribed to by one school of thought is that inventive step is synonymous with "a non-obvious technical advance". This, however, has no basis in the legislative intent reflected in the phraseology of the definition. If inventive step were to mean a "non-obvious technical advance", it renders nugatory the presence of "*or having economic significance or*

1 The IPAB also erroneously relied upon the ground of public order under Section 3(b) to reject the application since the price of Glivec was, in its opinion, exorbitant.

both". The simpler way of understanding the definition is to expand it as follows:

> 1. Inventive step means a ***feature*** of an invention that involves technical advance as compared to the existing knowledge and ***that*** (the reference here is to "feature", not to "technical advance") makes the invention non-obvious to a person skilled in the art
>
> 2. Inventive step means a ***feature*** of an invention having economic significance and ***that*** (the reference here is again to "feature", not "technical advance") makes the invention non-obvious to a person skilled in the art
>
> 3. Inventive step means a ***feature*** of an invention having technical advance and economic significance and ***that*** (the reference here too is to "feature", not "technical advance") makes the invention non-obvious to a person skilled in the art.

In other words, inventive step refers to that feature of the invention which satisfies the following twin criteria:

> 1. The feature involve a technical advance ***or*** must have economic significance ***or*** both; and
>
> 2. The feature must be non-obvious to a person skilled in the art.

Therefore, inventive step does not refer to a "non-obvious technical advance", but in fact refers to a "non-obvious feature" which involves either a technical advance or has economic significance or both. Clearly, the definition distinguishes "technical advance" from the requirement of non-obviousness. In other words, a technical advance by itself is not non-obvious, since if that were to be the case a "non-obvious technical advance" would be a pleonasm.

One of the principles of statutory interpretation is that no word or term or phrase used in a provision must be rendered redundant. Applying this principle to the definition of inventive step, it bears out that a technical advance simply refers to a feature which is technical in nature, but whose

qualitative contribution is to be further assessed by the requirement of "*that makes the invention not obvious to a person skilled in the art*".

The other important corollary is that the presence of technical advance is not the only acceptable criterion to examine if an invention has an inventive step. Economic significance of a feature which is non-obvious too could help the product or the process satisfy the "inventive step" requirement. Importantly, the criterion of economic significance is equally applicable to products and processes. This line of interpretation has been expressly endorsed by the Supreme Court in Para 90 of the decision, which is as follows:

> *"90. On a combined reading of causes (j), (ac) and (ja) of section 2(1), in order to qualify as "invention", a product must, therefore, satisfy the following tests:*
>
> *(i) It must be "new";*
>
> *(ii) It must be "capable of being made or used in an industry"*
>
> *(iii) It must come into being as a result of an invention which has a feature that:*
>
> *(a) entails technical advance over existing knowledge;*
>
> *Or*
>
> *(b)has an economic significance*
>
> *And*
>
> *(c) makes the invention not obvious to a person skilled in the art."*

Clearly, according to the Supreme Court, a feature which has an economic significance, which feature also makes the invention non-obvious, also qualifies as "inventive step" under the Act.

3.2 Relationship Between Section 2(1)(j) and Section 3: "Invention" and "Patentability"

Another critical aspect touched upon by the Supreme Court is the interplay between Sections 2(1)(j) and 3 of the Act. The former spells out the definition of invention, whereas the latter enumerates subject-matter which does not qualify as "invention" within the meaning of the Act. One

way of approaching these two provisions could be to treat Section 3 as the eligibility filter which separates eligible subject-matter from ineligible subject-matter. Unless a patent application satisfies the minimum threshold of eligibility by steering clear of proscribed subject-matter under Section 3, it would be meaningless to undertake a novelty and non-obviousness analysis. In other words, only an application claiming eligible subject-matter is entitled to be examined for novelty and non-obviousness.

However, this approach cannot be uniformly applied to all categories of subject-matter listed in Section 3. This is because the reasons for ineligibility and the conditions for ineligibility of subject-matter under Section 3 are not uniform, which the Supreme Court acknowledges in Paras 91 and 92 of the decision. For instance, Section 3(a) precludes anything which is frivolous or contrary to natural law. The exclusion of frivolous subject-matter is a matter of subjective policy, whereas the latter is fundamental to patent jurisprudence. Similarly, the exclusion of a discovery or scientific principle under Section 3(c) is based on fundamental patent jurisprudence, whereas preclusions of computer programmes*per se* or algorithms under Section 3(k), and new forms of known pharma substances which do not exhibit enhanced efficacy under Section 3(d), are policy calls of the Legislature which have been provided for in exercise of municipal/national flexibilities under TRIPS.

That said, the manner of analysis of an application which attracts Section 3(k) cannot be the same as an application which attracts Section 3(d). In rejecting an application on grounds of Section 3(k), the examiner need not undertake a novelty and non-obviousness analysis the moment he concludes that the claimed subject-matter is an algorithm or a mathematical or business method or a computer programme*per se.* This view finds endorsement in the decision of the IPAB in *Yahoo Inc. v. Assistant Controller of Patents &Anr.*, whose observations are as follows[2]:

> "*Finally we come to the ground of non-patentability under S.3(k). If the claimed subject matter is not an invention or if the invention is not patentable or of it excluded by S.3 of the Act, then none of the other objections need to be considered. Only if the claimed subject matter is a patentable invention we need to look at anticipation, obviousness etc"*

2 This decision was delivered by the IPAB on December 8, 2011.

Such an approach under Section 3(k) is possible since the determination of whether or not the claimed subject-matter is an algorithm or a mathematical or business method, does not involve or require a novelty and non-obviousness analysis. However, the very nature of exclusion under Section 3(d) does not enable or facilitate a similar approach. This is best explained using the phraseology of Section 3(d) itself. Extracted below is the provision along with its explanation:

> *(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 derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;*

A combined reading of the provision and its explanation inform us that enhancement in efficacy has been used as the parameter to lend novelty to the new form of a known substance. In other words, if the new form of a known substance exhibits enhanced efficacy, it shall be considered novel over the prior art and only then it shall be treated as eligible subject-matter. As opposed to the standard test applied for novelty which is independent of the qualitative leap from the prior art to a claimed invention, the criterion of enhanced efficacy is applied to pharmaceutical product patent applications to bestow novelty over new forms of known substances and to recognize them as patent-eligible subject-matter. Therefore, since a Section 3(d) analysis involves the application of an elevated novelty standard, it is not possible to rigidly compartmentalize the application of Sections 3(d) and 2(1)(j).

Further, contrary to popular assumption, Section 3(d) may not involve an elevated obviousness standard. This is so because Section 3(d) prescribes a desired result or trait (enhanced efficacy) to bestow novelty and subject-matter eligibility on a new form of a known substance, but the

enablement of such a new form could still be obvious in light of the prior art. In other words, merely because the new form of a known substance exhibits enhanced efficacy, it need not necessarily translate to a non-obvious invention. Whether or not the new form of a known substance with enhanced efficacy is non-obvious over the prior art, is a subjective call based on the teachings of the prior art.

From the above, what follows clearly is that in overcoming a Section 3(d) objection, the subject-matter of a pharma product patent application necessarily establishes its novelty (albeit based on a different criterion), thereby partially fulfilling the requirement of "invention" under Section 2(1)(j). Therefore, unlike the use of Section 3(k) to filter patent applications before a novelty and non-obviousness analysis is undertaken, the application of Section 3(d) necessarily involves examining the subject-matter for novelty based on enhanced efficacy. Be that as it may, the pharma product patent application must still be viewed first through the prism of Section 3(d) before the second and third limbs of the definition of "invention", namely inventive step and industrial applicability, are applied to it. This is because notwithstanding the difference in criteria employed under the various clauses of Section 3 for different categories of subject-matter, the fundamental object of using Section 3 to eliminate proscribed subject-matter remains unaltered.

A clear, unobfuscated understanding of this central object of Section 3 and the nuances of a Section 3(d) analysis is extremely critical in order for patent examiners and the IPAB to pass crisp decisions which do not venture into an inventive step analysis where one is not needed. Simply put, if an examiner or the IPAB is able to arrive at the conclusion that a pharma product patent application fails to satisfy the elevated novelty standard of Section 3(d) by failing to exhibit enhanced efficacy, no further analysis for inventive step under Section 2(1)(j) is necessary since the application may be rejected citing Section 3(d) alone.

In this context, although in Para 181 of the decision the Supreme Court categorically states that a new form which does not display enhanced efficacy is "*expressly excluded from the definition of "invention",* it inconsistently states in Para 192 (read with Para 104) that "*the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation*". The problem lies in the sequence or priority in which the Court applies Section 3(d) and Section 2(1)(j) and (ja).

Having stated in Para 181 that enhanced efficacy is a condition precedent to be considered as eligible subject-matter of a patent application, the Court ought not to have said in Para 192 that Section 3(d) must be satisfied ***in addition*** to Section 2(1)(j). Stated otherwise, Section 3(d) is not an additional test, it is the primary test which a pharma product patent application must pass.

It remains to be seen how the Patent Office and the IPAB interpret and apply the observations of the Supreme Court regarding Sections 3(d) and 2(1)(j)to pending pharma product patent applications. At this juncture, it must be critically borne in mind that the Supreme Court has interpreted only those portions of Section 3(d) which apply to pharma product patent applications, and not the whole of it. Therefore, the application of the provision to process patent applications is not yet settled.

3.3 Standard of Disclosure, Enablement and Anticipation

In this case, the Supreme Court had the occasion to deal with the law on disclosure and anticipation. This is because in order to apply Section 3(d) to Novartis's BCIM application, it was imperative to first prove that the beta crystalline form was a "new form of a known substance". Therefore, as part of this enquiry the Court had to identify the "known substance" whose "known efficacy" would serve as the benchmark to assess the 3(d)-compliance of the BCIM patent application.

Novartis took the position that the imatinib free base must be treated as the "known substance" to check for enhanced efficacy. According to Novartis, imatinibmesylate was not a known substance since there was no literature which enabled the manufacture of the mesylate salt. The Court, on the other hand, took the view that the mesylate salt had been disclosed in Novartis's earlier filed US patent US5521184 (the "Zimmerman patent"). In arriving at this conclusion, the Court dealt with the specification of the Zimmerman patent and Novartis's own application for term extension of the Zimmerman patent extensively. The following was stated in the latter:

> "(9) *Statement Showing How the Claims of the Patent for Which Extension is Sought Cover the Approved Product: The operative claims in question are Claims 1-5, 10-13, and 21-23. Each of claims*

> *1-5, 10-13 and 23 claim a compound or compounds which include the approved product,* ***imatinibmesylate****. Claim 21 claims a composition containing a compound or compounds which include the approved product,* ***imatinibmesylate****. Claim 22 claims a method of treating tumors in warm-blooded animals with a compound or compounds which include the approved product, imatinibmesylate*."

Further, in granting the US counterpart of the Indian application, namely US6894051, after the US examiner had rejected it on grounds that the Zimmerman patent also covered the beta crystalline form, the Board of Patent Appeals and Interferences held that the Zimmerman patent did not disclose the beta crystalline form, but that imatinibmesylate was disclosed in the Zimmerman patent. Below is the relevant extract of the decision:

> *"For the sake of completeness, we note what appears to be an inadvertent error in claim 14. In that claim, applicants do not recite the β-crystal form of the methanesulfonic acid addition salt of the illustrated compound. Manifestly, the methanesulfonic acid addition salt is intended. (Appeal Brief, Paper No. 16, page 5, second full paragraph)."*

It is indeed surprising that despite such clear observations, Novartis insisted that the imatinibmesylate was not disclosed in the Zimmerman Patent. If one were to apply the reverse infringement test to the Zimmerman patent, it becomes apparent that on the basis of the said patent Novartis could have prevented the manufacture of the mesylate salt by a third party. This is precisely what Novartis did in relation to NATCO's generic drug VEENAT in the United Kingdom, whose active ingredient was imatinibmesylate. Novartis issued a legal notice to NATCO alleging infringement of the European counterpart of the Zimmerman patent by VEENAT. In light of this, admittedly the mesylate salt was disclosed and claimed in the Zimmerman patent and its counterparts.

Apart from these documents, the Court also placed reliance upon journal publications of the year 1996 by Novartis's inventor Jurg Zimmerman wherein the mesylate salt had been disclosed. To this, Novartis argued that these documents merely "covered"/"claimed" the mesylate salt, but had not disclosed it since they did not enable the manufacture of imatinibmesylate. It was also submitted with respect to the

Zimmerman patent that a "*claim defines through language the various ways the invention could be used, i.e., possible but not actualized products*" and that the standard for disclosure was higher.

In the facts of the case, this was a specious argument since a reading of Column 3 of the specification of the Zimmerman Patent makes it difficult to argue that imatinibmesylate was not "disclosed" in the patent. Below are certain Paras from Column 3:

> "*Salt-forming groups in a compound of formula I are groups or radicals having basic or acidic properties. Compounds having at least one basic group or at least one basic radical, for example a free amino group, a pyrazinyl radical or a pyridyl radical, may form acid addition salts, for example with inorganic acids, such as hydrochloric acid, sulfuric acid or a phosphoric acid, or* ***with suitable organic carboxylic or sulfonic acids****, for example aliphatic mono- or di-carboxylic acids, such as trifluoroacetic acid, acetic acid, propionic acid, glycolic acid, succinic acid, maleic acid, fumaric acid, hydroxymaleic acid, malic acid, tartaric acid, citric acid or oxalic acid, or amino acids such as arginine or lysine, aromatic carboxylic acids, such as benzoic acid, 2-phenoxy-benzoic acid, 2-acetoxybenzoic acid, salicylic acid, 4-aminosalicylic acid, aromatic-aliphatic carboxylic acids, such as mandelic acid or cinnamic acid, heteroaromatic carboxylic acids, such as nicotinic acid or isonicotinic acid,* ***aliphatic sulfonic acids, such as methane-, ethane- or 2-hydroxyethane-sulfonic acid, or aromatic sulfonic acids,*** *for example benzene-, p-toluene- or naphthalene-2-sulfonic acid. When several basic groups are present mono- or poly-acid addition salts may be formed.*
>
> *For the purposes of isolation or purification, as well as in the case of compounds that are used further as intermediates, it is also possible to use pharmaceutically unacceptable salts. Only pharmaceutically acceptable, non-toxic salts are used for therapeutic purposes, however, and those salts are therefore preferred.*
>
> *Owing to the close relationship between the novel compounds in free form and in the form of their salts, including those salts that can be used as intermediates, for example in the purification of the novel compounds or for the identification thereof, hereinbefore and hereinafter*

> *any reference to the free compounds should be understood as including the corresponding salts, where appropriate and expedient."*

Clearly, the mesylate salt was disclosed *and claimed* in the Zimmerman patent since salt claims were appended to independent claims as "*or a pharmaceutically acceptable salt*". Besides, the argument advanced by Novartis failed to take into account the knowledge of a person skilled in the art to make a pharmaceutically acceptable salt of a new compound. After all, since it was Novartis's stance in the Zimmerman patent that a person skilled in the art could manufacture imatinibmesylate from the imatinib free base without undue experimentation, the argument that imatinibmesylate was not enabled and hence not disclosed, was not available to it.

Critically, it appears that according to Novartis it is possible to claim a "potential product" without enabling it, warranting the following reaction from the Supreme Court:

> "*139. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.*"

Assuming one was to hold Novartis to its own position, does this mean the Zimmerman patent claimed pharmaceutically acceptable salts without disclosing the method of making it? If these salts were only claimed but not enabled, would this not contravene the enablement requirement under Section 112 of the US Patents Act? Importantly, Section 7(3) of the Indian Patents Act requires a patent applicant to categorically undertake that he is in possession of the invention. Therefore, claiming "*possible but not actualized products*" is not possible under Indian law, which principle applies equally to analysis of the prior art for disclosure and anticipation. Consequently, the Supreme Court was justified in law and facts in treating imatinibmesylate, and not the imatinib free base, as the "known substance" with respect to which enhanced efficacy ought to have been established by the beta crystalline form of imatinibmesylate.

3.4 What is "Enhanced Efficacy"?

Novartis contended that in the facts of the case, there was no "known efficacy" of imatinibmesylate since it was merely a "possible" or "conceivable" product, and not an "actualized one". Consequently, according to Novartis, its efficacy was not known and therefore it could not serve as the benchmark to assess enhancement in efficacy. In response to this, the Court quoted the following portions of *Monsanto Company v. CoramandalIndag Products (P) Ltd* on the interpretation of "publicly known"[3]:

> *"…To satisfy the requirement of being publicly known as used in clauses (e) and (f) of Section 64(1), it is not necessary that it should be widely used to the knowledge of the consumer public. It is sufficient if it is known to the persons who are engaged in the pursuit of knowledge of the patented product or process either as men of science or men of commerce or consumers...."*

Applying this principle to the facts of the case, the Court held that since imatinibmesylate was disclosed and enabled in the Zimmerman patent, its efficacy too was known. This may not be an accurate observation since disclosure and enablement for anticipation do not translate to knowledge of the product's efficacy. However, in the facts of the case, Novartis's patent application on BCIM contained statements to the effect that "*all the indicated inhibitory and pharmacological effects*" of BCIM were found in the free base and its salts. Therefore, clearly the inhibitory effects/"efficacy" of imatinibmesylate were known, and BCIM did not differ in efficacy from imatinibmesylate or the imatinib free base. Further, this statement in the BCIM patent specification was consistent with Novartis's original emphasis on increased thermodynamic stability and other physical properties since enhanced inhibitory effect/efficacy was never the focus of the patent application.

On the meaning of "efficacy", the Court had no difficulty in arriving at the conclusion that efficacy was restricted to therapeutic efficacy, as reflected by the choice of words in the explanation to Section 3(d). Only those properties that directly relate to therapeutic efficacy are relevant for the purposes of Section 3(d). Consequently, the Supreme Court did not take the blanket position that "enhanced bioavailability" cannot be used to

3 1986 SCR (1) 120.

satisfy the requirement of "enhanced efficacy" under Section 3(d). Instead the Court ruled that "***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".*** In the facts of the case, since there was no material placed to establish that increased bio-availability of BCIM led to enhanced efficacy, it was held that BCIM failed the test of Section 3(d). Had Novartis presented data to prove that increased bioavailability led to enhanced efficacy, nothing stops one from plausibly and reasonably assuming that the Court would have ruled in its favour.

3.5 Position on Incremental Innovations and working of patented inventions

An unbiased and objective reading of the decision tells us that the Supreme Court's approach was entirely fact-based, with there being very little room for blanket observations/generalizations as demonstrated by the restrained observations on what constitutes efficacy. The Apex Court has done justice to the object of inclusion of Section 3(d) and has effectively sent out a very balanced and positive message in the process that India *does* encourage *genuine* enterprise and innovation by categorically drawing an unequivocal distinction between "ever-greening" and "incremental innovation". This is evident from the following observation of the Court:

> *"191. We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment."*

If there was any doubt about the status of incremental innovation under the Act, this paragraph removes all such doubts and myths with abundant clarity. Therefore, there is no real basis for fear-mongering that the decision has shut the doorcompletelyon incremental pharma innovation. If anything, this decision has only clarified the position of the

law by etching the contours of "efficacy" as envisaged in the Act, thereby reducing uncertainty to a fair extent which is significant from a commercial standpoint. Lack of clarity in law leads to capricious application and to the extent the Novartis decision "enhances known clarity" of the law, it is a positive development for all prospective patent applicants and patentees.

The other extremely significant observation of the Court is its re-statement of the goals of Indian patent law and jurisprudence, which is captured in Para 156 of the decision as follows:

> "*156. However, before leaving Hogan and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skilful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.*"

For a fledgling patent regime which is still exploring itself, setting out these first principles is important. This observation is particularly significant for it could be used by the Patent Office to interpret Section 83 of the Act in the context of working of patented inventions and grant of compulsory licenses, and by Courts in grant of interim injunctions.

3.6 Is Section 3(d) TRIPS-compliant?

As stated earlier, Novartis filed writ petitions before the Madras High Court challenging the TRIPS-compliance and constitutionality of Section 3(d), which were dismissed by the High Court essentially on grounds that it did not have the requisite jurisdiction to look into TRIPS-compliance. If however Novartis or any country which is party to TRIPS were to challenge the legitimacy of Section 3(d) before the WTO Dispute Settlement Panel, India is not without legally sound arguments to support the inclusion of Section 3(d). In fact, support for Section 3(d) may be

drawn from Article 27 of TRIPS which India is alleged to have violated by introducing Section 3(d). Extracted below is Article 27 of TRIPS:

> *Article 27: Patentable Subject Matter*
>
> *1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*
>
> *2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*
>
> *3. Members may also exclude from patentability:*
>
> *(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
>
> *(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

Article 27.1 clearly begins with a contingent clause which makes the obligations imposed under Para 1 of Article 27 subject to the flexibilities available under Paras 2 and 3. Para 2 of Article 27 clearly vests member countries with flexibilities to exclude from patentability those inventions whose commercial exploitation could adversely affect public order, including public health. In other words, thanks to Article 27.2, member

countries have the right to exclude from the purview of Para 1 those inventions which negatively impact public health. Consequently, the obligation to treat inventions in different fields of technology without discrimination is subject to the exercise of flexibilities under Paras 2 and 3 to exclude certain inventions as being ineligible for grant of patents.

Further, Article 27.2 does not prescribe or limit the minutiae or specifics of the criteria which may be used to exclude such inventions from patentability, thereby giving member countries the freedom to select criterion they deem fit to preserve public health. Consequently, India is well within its rights to use an elevated novelty standard under Section 3(d) to exclude subject-matter which have a bearing on public health/public order. It is also possible to treat Section 3(d) as an extension of or yet another category of Section 3(b) which addresses the issue of public order and morality.

Although a separate instrument is not necessary to prove this point any further, the Declaration on the TRIPS Agreement and Public Health dated November 20, 2001, popularly known as the Doha Declaration, categorically recognizes this right in Para 4 as follows:

> *"4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.*
>
> *In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*

Therefore, the allegation that Section 3(d) is violative of India's TRIPS obligations is baseless. In fact, anyone who argues to the contrary clearly does so to undermine the sanctity of the Doha Declaration, and the flexibilities of member countries.

IV. Conclusion

The Novartis decision clearly proves that if ably assisted, Indian Courts can handle patent litigation and address critical issues objectively with restraint. That said, the hype and interest surrounding the Novartis decision seems to have created this misplaced notion that weeding out frivolous patent applications is the panacea to all our healthcare challenges. With pharma patent litigation increasingly taking centre stage, the one thing that we need to be wary of is the temptation to expect the patent system to solve all our healthcare challenges, including that of affordable access to medicines. This temptation to put all our eggs in the patent basket becomes a compulsive habit particularly in the absence of a clear-cut healthcare strategy, since the health establishment of the country would want to be seen as doing something, and patent busting is probably the most public way to be seen as doing something given the unpopular perception of patents and innovator drug companies.

Patents are without a doubt relevant to the debate, and patents which add no value must definitely be discouraged. But the question is, apart from pitting innovator drug companies against generics and deriving a vicarious pleasure out of this slugfest, have we truly explored all plausible and available options under and outside the Patents Act, 1970? For instance, if the Government is truly keen on nipping frivolous patent applications or patents in the bud, it could and ought to have actively employed the pre-grant and post-grant opposition mechanisms and revocation petitions. After all, the definition of "person" under the Act includes the government, and the Ministry of Health could arguably qualify as a "person interested". Therefore, nothing prevents the Government from filing oppositions to and seeking revocations of frivolous patent applications and patents.

Also, what has prevented the Government from stocking adequate quantities of patented drugs in hospitals and dispensaries owned by the Government, thereby giving effect to Section 47(4) of the Act? Section 47 lists the conditions subject to which a patent is granted under the Act. One of these conditions under Section 47(4) is that in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for distribution in any dispensary or hospital or other medical institution maintained by or on behalf of the Government. The

provision further empowers the Central Government to notify and permit importation of patented medicines by hospitals and institutions which render public service. If the Government is truly intent on increasing affordable access to drugs, these are concrete steps which it can take forthwith without having to legislate any further.

Apart from patent-related issues, one of the issues central to the healthcare discourse is elevating the quality of research undertaken by Indian pharma companies and providing impetus to the growth of home-grown entities in related areas such as clinical trials. Instead of investing efforts in this direction, the Government has in fact contributed to the potential decline of Indian clinical trial industry by implementing feckless provisions such as the new Rule 122DAB of the Drugs and Cosmetics Rules, 1945, which states, *inter alia,* that *failure of an investigational product to provide the intended therapeutic effect shall be considered as having caused a clinical trial-related injury or death*. If the very purpose of a clinical trial is to evaluate the drug, what sense does it make to hold the sponsor of a trial or the Clinical Trial Organization (CTO) responsible for failure of the drug to provide the intended therapeutic effect? This is again demonstrative of the Government's need to appear to have taken stringent action after being hauled over hot coals by the Supreme Court in October 2012 in a PIL filed by an NGO, SwasthyaAdhikarManch, for clinical trial-related deaths. But in the process, thoughtless provisions such as the Rule 122DABcould have the effect of deterring companies from undertaking clinical trials in India, thereby adversely affecting the fortunes of CTOs/CROs in India, which already face stiff competition from China.

Unfortunately, instead of holistically addressing issues like these, the healthcare discourse seems to revolve entirely around the system of patents. It would help to formulate our healthcare goals in specific terms, and explore options under multiple legislations instead of pinning all our hopes on the patent system. This calls for a comprehensive and strategic approach to healthcare, which though is the need of the hour, hardly seems to engage the attention of the powers that be.