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POST-NOVARTIS AGENDA TO CURB PATENTING OF KNOWN SUBSTANCES

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The judgment of the Supreme Court on Novartis case put an end to a 10-year-old litigation around the generic availability of anti-cancer medicine Imatinib Mesylate for the treatment of chronic myeloid leukemia (CML), a type of blood cancer. The immediate visible result of the judgment is the uninterrupted supply of the generic versions of Imatinib Mesylate. Currently, generic versions of the medicine are available within the range of Rs. 4000--8000, against the Novartis price of Rs.125,000, from nearly seven Indian companies. The most important implication of the judgment is that the Supreme Court has brought great degree of clarity with regard to the interpretation of the Section 3(d) of the Indian Patents Act.

The judgment has been welcomed and celebrated by government, civil society organisations across the world, intergovernmental organisations like the South Centre and the generic industry. Section 3(d) of the Patents Act is a piece of legislative innovation to effectively address the issue of the extension of patent monopoly by securing multiple patents on the known substance. There were even calls to replicate Section 3(d) in developing countries. This article attempts to analyse the strengths and weaknesses of Section 3(d) in the light of the Supreme Court judgment. It also suggests various measures in the Indian law and policy domains to effectively address the issue of extension of patent monopoly through the patenting of known substances in the post-Novartis context.

Strengths and Weaknesses of Section 3(d)

It is important to understand the emergence of Section 3(d) as a legal response to prevent patenting of new forms of already known molecules, also known as evergreening, to assess the implication of the Supreme Court judgment. At the time of

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introduction of product patent protection in 2005, there was ample evidence regarding the practice of pharmaceutical transnational corporations (TNCs) to seek multiple patents for the same molecule to extend the patent beyond the expiry of the original patent on the molecule. At the end of the transition period in 2005, there were around 10,000 product patent applications pending for the examination. These applications were received to fulfil the mailbox protection obligation under the Article 70 of the TRIPS Agreement. Most of the mailbox applications were claiming patents on known substances including the substance invented prior to 1995, the year TRIPS came into force. Thus the practice of seeking patent protection on the known molecule was one of the overwhelming concerns at the time of the introduction of product patent protection in India.

The policy objective, with regard to scope of patent protection on pharmaceuticals, was to limit the scope of patent protection to new chemical entities (NCEs) to facilitate the generic entry at the earliest by specifically addressing the following issues: Firstly, to provide patent protection only to those molecules invented on or after 1st January 1995 from the mailbox applications; and secondly, to prevent the patenting of known substances invented even on or after 1st January 1995.

Two flexibilities in the TRIPS Agreement provide the policy space for India to achieve the above-mentioned objectives. First, to define the patentability criteria viz. novelty, inventive step and industrial application, in a manner to set high threshold level so that trivial claims are not qualified for patent protection. Second, to make use of the Article 70 of the TRIPS Agreement which states: "There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain".

From a policy angle an ex ante exclusion of the patenting of known substance should be the first option, because it saves the financial and human resource for the examination of patents. Further, it limits the filing of patent applications seeking patent protection for the known substance. Hence, one of the important demands from the generic industry and various public interest groups including the National Working Group on Patent Laws (NWGPL), which played a prominent role in shaping India's post TRIPS patent law, was to limit the patent protection only to the NCEs. The left parties took up this demand during their negotiation with the government on patent law amendment. The government proposed Section 3(d) as a compromise along with the assurance of appointing a technical expert group (TEG) to examine "*Whether it would be TRIPS*

(Trade Related Intellectual Property Rights) compatible to limit the grant of patents for pharmaceutical substance to new chemical entity or new medical entity involving one or more inventive steps".[45] In a way, Section 3(d) was supposed to be a temporary arrangement if the TEG would have done its work sincerely and seriously.

India had the option of explicitly excluding patenting of any substance invented prior to 1st January 1995 from product patent protection. A study by the author shows that by analysing the patent expiry data provided in the United States Food and Drug Administration's *Orange Book* and further research to trace the patent history of NCEs reveal that out of 301 NMEs (New Molecular Entities) approved by the USFDA between 1995 and 2004, 291 were invented prior to 1995.[46] An explicit exclusion of inventions prior to 1995 would have put many NCEs approved by USFDA till 2004 out of the patent protection in India.

However, India opted for a more circuitous route of Section 3(d). While implementing the Exclusive Marketing Rights (EMRs) obligations, India used this flexibility to exclude the inventions prior to 1995. Section 24(B) of the EMR stated that in ordered to be eligible for EMR "where an invention has been made in India or in a country other than India before filing such a claim, filed an application for the same invention claiming identical article or substance in a convention country on or after 1st January 1995". Thus the EMR provision excluded any invention prior to 1995 and removed the possibility of claiming EMR on an invention prior to 1995. However, during the third amendment in 2005 the deadline of 2005 has been ignored conveniently and introduced Section 3(d), which does not exclude either inventions prior to 1995 or patenting of known substance *per se.*

Section 3(d) itself was taken out by the government from a letter of Justice V R Krishna Iyer, who obtained the language from Veda Raman, the former Controller General of

[45] The Technical Expert Group (TEG) on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion *vide* O. M. No. 12/14/2005-IPR-III dated April 5, 2005. Paragraph 2 of the order mentions the terms of reference: "2. The Group will have the following terms of reference: (a) whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and (b) whether it would be TRIPS compatible to exclude micro-organisms from patenting."

[46] Sudip Chaudhuri, Chan Park and Gopakumar K. M., *Five Years into the Product Patent Regime: India's Response,* Kajal Bharadwaj (ed.), United Nations Development Programme, December 2010, at p.118 para 3.

Patents. The language of Section 3(d) is borrowed from the EU Regulation dealing with the data exclusivity provision defining generic medicines, which can be approved without additional data requirement.[47] Hence, the legal innovation really lies in the importation of a definition of generic medicine from the EU Directive on Medicinal Product for Human Use, which essentially regulates the marketing approval of medicines, to prevent the patenting of known substance.

Section 3(d) of The Patents Act, 1970 states: *"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 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 efficac*y".

The main shortcoming of the Section 3(d) is that it does not shut the door for patenting of known substances and it allows the patenting of salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substances if they differ significantly in properties with regard to efficacy. Thus the legislation, instead of excluding the patenting of known substances, provided a small opening of patenting of known substances. This opening is complicated by the absence of any definition on the term 'efficacy'. Thus the Section 3(d) does not fully reflect the policy objective of denying patents to known substance even though the Madras High Court clarified the term 'efficacy' as 'therapeutic efficacy' in 2007. Further, the court stated: "*What the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body"*. However, there was no attempt by the Patent Office to incorporate the interpretation of the High Court into its examination manual and reject patent claims on patenting of known substance in the absence of enhancement of therapeutic efficacy. As a result, patents were granted on known

[47] Directive 2004/27/EC Of The European Parliament And Of The Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, *2004 O.J (L 136) 34-57.*

substance without any enhancement in the therapeutic efficacy. The Parliamentary Standing Committee on Commerce in its report in 2008 recommended that "The Government should clarify the usage of terms 'significantly' and 'efficacy', which form parts of Section 3(d), to clear the ambiguities involved in the interpretation of the said section". The patent office continues to grant patents on known substances even after the verdict of the Madras High Court.

The Patent Office granted patents to 3470 pharmaceutical products between 2007 and March 2010, and this huge number of patents prima facie makes the case against the effectiveness of Section 3(d) in checking patenting of known substance. A study by the National Intellectual Property Organisation (NIPO) identifies at least 86 patents granted on known substances or combinations of substances bypassing Section 3(d)[48]. Even though the Patent Office rejected many patents citing Section 3(d), it failed to act as an effective gatekeeping mechanism and translate the legislative intent into practice. The absence of clarity to decide whether the claim satisfies the Section 3(d) and the room for discretion on whether the application qualifies the test of efficacy under the Section 3(d) make the Patent Office, judiciary and government vulnerable to lobbying.

As part of the training of examiners, Indian Patent Office entered into a Memorandum of Understanding (MoU) with various developed country patent offices, including the US Patent and Trademark Office (USPTO) and the European Patent Office (EPO). These trainings lead to importation of the developed country practices and the functional harmonisation of patentability criteria. This has resulted in virtual marginalisation of legislative intent against patenting of known substances.[49]

Further, judiciary is also subjected to lobbying by the pro-patent groups of the

[48] James T.C., 'Patent Protection and Innovation: Section 3(d) of the Patents Act and Indian Pharmaceutical Industry', NIPO, 2010 available at www.nipoonline.org/section-report.doc.

[49] For instance, the Patent Office MoU with the US Patent Office (USPTO) states that: *The Parties shall work together in capacity building in Intellectual Property Rights including automation and modernization of Intellectual Property Offices, development of databases, and procedural rationalization and simplification of processing of Intellectual Property applications, inter alia, through the exchange of information on patent data, best practices in patent examination procedures, etc. The two Parties shall cooperate in the training of personnel and human resource development in the area of Intellectual Property Rights with a view to strengthening the working of the Intellectual Property (IP) systems in the two countries, including in patent examination training.* As part of the MoU, many patent examiners were trained under USPTO. Hence the manual brings a backdoor harmonisation of patent examination standards with the US and the EU patent examination practices.

developed countries. George Washington University's India Project is a case in point, which brought a large contingent consisting of IP attorneys and IP judges and lobbied with the judiciary in India. Moreover, even the Supreme Court judge who heard the Novartis case had to recues from the case due to his participation in an international conference organised by the IP Owners Association of USA.[50] The Supreme Court decision has reinforced the Chennai High Court opinion on the meaning of the word 'efficacy'. 'Efficacy' now clearly means 'therapeutic efficacy'. The Court clearly rules out any efficacy in terms of properties. The following section summarizes the reasoning of Supreme Court

Supreme Court's Reasoning

There were two questions came up before the Supreme Court. First, the legal validity of the decision of Intellectual Property Appellate Board (IPAB), which rejected Novartis's claim for the patent protection on the Beta Crystalline form of Imatinib Mesylate under Section 3 (d) of the Patents Act by IPAB. IPAB accepted Novartis claim on novelty and inventive step but rejected the patent under Section 3 (d). According to Section 3 (d) a patent on known substance cannot be granted unless there is a significant enhancement in the known efficacy. Further, as per the explanation of section 3 (d) *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*".

Second, Natco's and Cancer Patient Aid Association's (CPAA) legal challenges on the IPAB's decision to accept the argument of Novartis with regard to novelty and inventive step on the Beta Crystalline form of Imatinib Mesylate. IPAB modified the decision of the Patent Office order, which rejected Novartis Patent application on multiple grounds including absence of novelty, inventive step and non-satisfaction of

[50] Justice Markandey Katju and Justice Dalveer Bhandari, both have recused from the Novartis case. Justice Markandey Katju recused due to his previous publication of the article on the issue and Justice Dalvir Bhandari recused because of the participation in international conferences for judges organized by the US-based Intellectual Property Owners Association (IPOA), whose members include Novartis, among a host of pharmaceutical and IT giants. A group of activists demanded the Government of India to ask the recusal of the judge . See the full text of the activists' letter to the Government of India. See http://spicyip.com/2011/09/full-text-of-letter-asking-for-justice.html; See Manoj Mitta, 'Novartis case: How two SC judges had recused themselves from the case', *The Times of India*, 2nd April 2013 available at http://timesofindia.indiatimes.com/india/Novartis-case-How-two-SC-judges-had-recused-themselves-from-the-case/articleshow/19334224.cms [accessed on: 15 November 2014]

Section 3 (d) criteria. Novartis could not file the patent application, which discloses the Imatinib molecule in its patent application filed in developed countries in 1994 known as Zimmerman patent because there was no product patent protection in India. Realizing the market potential, filed the patent application in 1998 in India seeking priority from a patent application filed in 1997 in Switzerland. Natco and CPAA argued that the invention claimed in the 1998 application i.e. the Beta Crystalline form of Imatinib Mesylate is fully disclosed in the 1994 patent application. Further, making a beta crystalline form of salt from the Imatinib molecule is obvious to the person skilled in the art and therefore does not satisfy the inventive step requirement. Even though the Patent Office accepted these arguments IPAB rejected and held the invalidation of the patent only on one ground under Section 3 (d).

At the Supreme Court, Novartis came up with a brand new argument, which is not mentioned, in its patent application filed in 1998. Novartis argued that the invention mentioned in the 1994 patent application is only the Imatinib freebase. Two more inventive steps are required to reach to the Beta Crystalline form of Imatinib Mesylate. First invention is the development of salt from Imatinib freebases and the salt is known as Imatinib Mesylate. The second inventive step is the development of Beta Crystalline form of Imatinib Mesylate from the Imatinib Mesylate. According to Novartis the Zimmerman patent does not disclose these two inventive steps and therefore does not cover the Beta Crystalline form of Imatinib Mesylate claimed in its 1998 patent application.

On the issue of whether Imatinib Mesylate i.e the salt form is disclosed in the Zimmerman patent the court clearly brings out the evidence to show that Zimmerman patent covers not only the Imatinib freebase but also the salt form of Imatinib. Towards this purpose Court found the following points.

Court found the following statement in the Zimmerman's patent, which clearly covers both freebase and salt of Imatinib. *"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.****"*

Court further finds that the Novartis filed the patent application for Beta Crystalline

form of Imatinib Mesylate in the US on January 18, 2000. The US patent for Beta Crystalline form of Imatinib Mesylate was granted to Novartis only after five and a half years on May 17, 2005 following the order of the US Appellate Court dated November 23, 2003.The USPTO initially refused the patent application. Court found out that Novartis launched the medicine in the market much earlier on the basis of the Zimmermann patent and declared to the USFDA that the Zimmerman patent covers "the composition, formulation, and /or method of use of Imatinib Mesylate".

Further Courts also found that Novartis applied for extension of the patent term of the Zimmerman patent immediately after the obtainment of the market approval for Imatinib Mesylate. According to Court "*this application leaves no room for doubt that Imatinib Mesylate, marketed under the name Gleevec, was submitted for drug approval as covered by the Zimmermann patent*."

Court cites the fact that Novartis successfully prevented Natco from marketing its generic version of Imatinib Mesylate in UK on the basis of Zimmerman patents. Court quotes from the order of the US Board of Patent Appeals decision rejecting the USPTO order of refusing patent for Beta Crystalline form of Imatinib Mesylate. The Board of Appeals allows the patent claim on the Beta Crystalline form but states that "*In claim 23, Zimmermann recites imatinib, a specific compound within the scope of formula I, or a pharmaceutically acceptable salt thereof. In light of 35 U.S.C. § 282, therefore, we may presume that the specification of the Zimmermann patent teaches any person skilled in the art how to use imatinib, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease."*

Therefore the Court clearly states: "*That Imatinib Mesylate is fully part of the Zimmermann patent is also borne out from another circumstance. It may be noted that after the Zimmermann patent, the appellant applied for, and in several cases obtained, patent in the US not only for the beta and alpha crystalline forms of Imatinib Mesylate, but also for Imatinib in a number of different forms. The appellant, however, never asked for any patent for Imatinib Mesylate in non-crystalline form, for the simple reason that it had always maintained that Imatinib Mesylate is fully a part of the Zimmermann patent and does not call for any separate patent*".

Second, to support its argument regarding the non-coverage Beta Crystalline form of Imatinib Mesylate in the Zimmerman patent Novartis argued that there is a difference

between coverage and disclosure in a patent application. According to Novartis the coverage of a patent application is different from the scope of disclosure of the patent. In simple terms it means that the absence of novelty or inventive steps can be attributed to the steps involved in making Beta Crystalline form of Imatinib Mesylate only if there is a complete disclosure in the Zimmerman patent.

While rejecting that argument the Court said: "*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 seems to negate the fundamental rule underlying the grant of patents*".

Court further states: "*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 skillful 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"*.

The Court did not examine whether the so called inventive step of transforming Imatinib Mesylate into Beta Crystalline form of Imatinib Mesylate satisfy the inventive step criterion. According to Court there was no need to examine that because Beta Crystalline form of Imatinib Mesylate is a polymorph and directly attracts Section 3 (d) of the Patents Act, which checks the patenting of known substance.

Third, Novartis 's made two arguments before the Court against the application of Section 3 (d) to evaluate its patent application on Beta Crystalline form of Imatinib Mesylate. First, Novartis argued that Section 3 (d) is a provision of abundant caution and does not apply to invention, which satisfies novelty, inventive step and industrial application i.e. basic patentability criteria. Second, Novartis argued that since there was no known efficacy of Imatinib freebase and Imatinib Mesylate it is not possible to show that Beta Crystalline form of Imatinib has any enhanced efficacy.

Nevertheless, Court rejected both the arguments. Court clearly stated that the legislative intention shows very clearly that in course of the *Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially. to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension* of the patent term on spurious grounds

On the second issue the Court decided "*On facts also we are unable to accept that Imatinib Mesylate or even Imatinib was not a known substance with known efficacy. It is seen above that Imatinib Mesylate was a known substance from the Zimmermann patent. In the NDA submitted by the appellant before the US FDA, it was clearly stated that the drug had undergone extensive preclinical, technical and clinical research".* Therefore the Court rejected the claim that efficacy of Imatinib Mesylate or even Imatinib is unknown.

Therefore on the question of Section 3 (d) test the Court held that *"it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act. 191. We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d)".*

Court also noted that fact that on the package the description of the drug includes "each film coated tablet contains: 100mg Imatinib (as Mesylate) and teher was no reference of Beta Crystalline form Imatinib Mesylate.

On the argument that there are two steps involved to develop a Beta Crystaline form of Imatinib Mysylate form the Imatinib freebase court remarked that "*… this position is not reflected in the subject application, in which all the references are only to Imatinib in free base form (or to the alpha crystalline form of Imatinib Mesylate in respect of flow properties, thermodynamic stability and lower hygroscopicity)".*

On the patent application on Beta Crystalline form of Imatnib Mesylate Court observed that "*It may also be stated here that while going through the Zimmermann patent one cannot but feel that it relates to some very serious, important and valuable researches. The subject patent application, on the other hand, appears to be a loosely assembled, cut-and paste job, drawing heavily upon the Zimmermann patent*".

Implications on the Patenting of Known Substance

The most important outcome of the Court decision is its implication on the future of patenting of known substances. It is a well-known fact that pharmaceutical MNCs obtain multiple patents on the same molecule. An investigation of the European Competition found that multiple patenting of known substances can delay the generic entry and prevents competition in the pharmaceutical market. The Court clearly recognizes the policy concern with regard to patenting of known substances as reflected in the Section 3 (d) of the Patents Act.

Towards this purpose Court traces the legislative history of Indian Patents Act including the parliamentary debate during the 2005 amendment which introduced Section 3 (d) . Court notes : *"in course of the debate in Parliament, an amendment (by way of addition) in clause (d) of section 3 was proposed by the Government in order to allay the fears of the members from the Opposition concerning the introduction of product patents for pharmaceuticals and agricultural chemicals, and it was on the Government's assurance that the proposed amendment in section 3(d) (besides some other changes in the Act) would take care of the apprehensions about the abuse of product patent in medicines and agricultural chemical substances that the Bill was passed by Parliament".*

Further Court in clear terms states: "*the importance of the amendment made in section 3(d), that is, the addition of the opening words in the substantive provision and the insertion of explanation to the substantive provision, cannot be under-estimated. It is seen above that, in course of the Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially".*

The Section 3 (d) of the patent Act States: "*"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 the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

One of the important critique with regard to Section 3 (d) is the lack of explanation with regard to the word "efficacy". According to critiques in the absence of definition of the term "efficacy" may lead to multiple interpretation. The term efficacy can mean technological efficacy, therapeutic efficacy, economic efficacy or efficacy in the physical property of the substance.

The Court agreed with the Madras High Court's interpretation of the term and held that : "*… the explanation requires the derivative to "differ significantly in properties* ***with regard to 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 case of medicine, as seen above, is its therapeutic efficacy*". Thus the Court clearly narrows down the meaning of the term efficacy to therapeutic efficacy.

Further the court clearly states that any improvement in the physical property does not pass the Scrutiny of Section 3 (d). The Court stated: " *While dealing with the explanation it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, e. g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of "invention". Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy"*[51].

The significance of the Supreme Court judgment lies in the fact it brings great degree of clarity with regard to the term 'efficacy'. The Court interpreted the term to include only 'therapeutic efficacy' in line with the interpretation of the Madras High Court. It rejected any efficacy claim with regard to the physical property, without any

[51] Novartis *v.* Union of India & Others, Civil Appeal Nos. 2706-2716 OF 2013, at p.91 para 180-181.

corresponding enhancement in therapeutic efficacy.

The Court thus has narrowed down the interpretational scope for the term 'efficacy' and limited it to 'therapeutic efficacy'. However, it does not answer or explain what types of elements, which can fall under therapeutic efficacy. For instance, it does not deal with the question whether the reduction in toxicity or enhanced bioavailability can be considered for therapeutic efficacy. Hence, the patent applicant may argue that these elements constitute an enhanced therapeutic efficacy. Another round of litigation may clarify the constituent elements of the therapeutic criteria.

Further, the Section 3(d) makes it possible for the pharmaceutical TNCs seeking patents on fixed dose combination (FDC) of medicines. In certain cases, FDC medicines can fulfil the criteria of therapeutic efficacy under Section 3(d). This does not necessarily mean that such claims would obtain patent because the patent office can still reject such claims on the ground of lack of novelty or inventive step[52].

Most importantly, the Court has not examined what are the requirements to prove enhancement in the therapeutic efficacy. Even though questions like whether increased bioavailability or fewer side effects can be considered as an enhancement of therapeutic efficacy were raised, the Court did not answer it. Regarding bioavailability the Supreme Court stated as follows:

> *"Thus, even if Mr. Grover's submission is not taken into consideration on the question of bioavailability, the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. 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". (Emphasis supplied)*

[52] For issues relating to the grant of patents to FDCs, *See generally* 'Patents and licences on antiretrovirals: A snapshot', *UNITAID Report*, World Health Organization, 2014; Tapan Ray, 'India, China Revoke Four Pharma Patents in A Fortnight: A Double Whammy for MNCs?', *12th August 2013* available at http://www.tapanray.in/india-china-revoke-four-pharma-patents-in-a-fortnight-a-double-whammy-for-mncs/ [accessed on: 15 November 2014]; Warren Kaplan, 'Fixed-Dose Combination (FDC) Drugs Availability And Use As A Global Public Health Necessity : Intellectual Property And Other Legal Issues', 2003 available at http://whqlibdoc.who.int/publications/2003/a86263_part9.pdf [accessed on: 15 November 2014]; Sangeeta Shashikant, 'Opposition to drug patents in India highlights access fears', *Third World Resurgence*, Third World Network, May – June 2006.

Thus the Court has not passed judgement that increased bioavailability *per se* can be treated as enhancement of therapeutic efficacy. It says that enhanced bioavailability should be claimed separately and research data to prove the claim should be submitted. These questions may be litigated in future. Hence, the decision on Novartis is a landmark decision but not the final decision.

The main shortcoming of the Section 3 (d) is that it does not shut the door for patenting of known substances and it allows the patenting of known substances on a case to case basis if the patent applicant can prove that the claimed invention differ significantly in properties with regard to efficacy. In other words Section 3 (d) does not exclude the patenting of known substance *per se* and it only limits the patenting of known substance. This requires a case-to-case approach and requires examination of each patent application.

The Supreme Court does not rule out the patent protection of known substances while narrowing down the scope of efficacy criteria. In a way, it restored confidence by stating: "*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"*. The Court decision only narrowed down the scope of the word 'efficacy'. On ground, the patent examination should be conducted on a case-to-case basis, at least on claims on known substances with enhanced efficacy. This may still put the patent office and judiciary vulnerable for lobbying.

Hence, the replication of Section 3 (d) as such is not suitable for resource crunch developing country settings. Further, Section 3 (d) provides an element of discretion for the examiners and judges to interpret the term efficacy and it may make these institutions vulnerable for lobbying. Further, the scope of interpretation also may result in the undermining of policy objective to curb the patenting of known substance by a narrow interpretation by the patent office or the judiciary. Hence it is always better for developing countries to provide an *ex ante* exclusion of patenting of known substances without any substantive examination. Towards this end what is required is a modified Section 3 (d) which does not contain any scope for patenting of known substance in cases of enhancement of known efficacy. The next section suggests various policy steps to curb the patenting of known substance in the light of Novartis case.

Agenda to Curb Patenting of Known Substances

The above discussion clearly shows that the Supreme Court judgment does not rule out the patenting of known substance, but significantly narrowed down the scope of Section 3(d) to the enhancement of the known therapeutic efficacy. However, the decision does not clearly spell out the types of claims, which satisfy the therapeutic efficacy. Thus, there is still an element of uncertainty and it is expected that the Court may interpret the test of therapeutic efficacy narrowly or broadly in a subsequent case. There is a risk of neutralisation of policy objective through judicial interpretation. The practice of the Patent Office clearly shows that it failed to translate the policy objective in its day-to-day business. Moreover, the use of Section 3(d) is not very cost effective and efficient and it is often marred by lengthy litigations. Hence, a country like India should ponder on the ways and means to curb the patenting of known substance through legal provisions thereby explicitly excluding its patenting. The easiest way to do so is by deleting the three qualifications from Section 3(d): First, the word *mere;* second, *which does not result in the enhancement of the known efficacy of that substance*; and third, *unless they differ significantly in properties with regard to efficac*y".

If there is no clear political will to make such an amendment, the government should at least amend Section 3(d) to limit the 'efficacy' to 'therapeutic efficacy', as mentioned in the Supreme Court judgment with certain clear criteria to judge the therapeutic efficacy. This is essential to consolidate the policy objective against the patenting of known substance. We also need to minimise the risk of policy deviation through future judicial interpretation. The following suggestions, relevant to curb the patenting of known substance, are towards that direction.

1. Review the granted patents in the light of judgment

Since the introduction of the product patent protection in 2005, the Patent Office has granted around 6000 to 7000 product patents on pharmaceutical inventions. The Patent Office itself revealed that between 2007 and March 2010, it has granted 3470 product patents. As mentioned above, many of these patents have been granted in violation of Section 3(d). Therefore, it is important to review the decision of the Patent Office in the light of the Supreme Court judgment and revoke the wrongfully granted patents under Section 66 of the Patents Act. Section 66 states: *Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.*

Many of the patents may not be of any consequence for the generic entry. However, there are certain patents, which have the potential to prevent the generic entry. For instance, the patent on Trastuzumab, which is a drug used for the treatment of HER2 Positive breast cancer. This is one of the most important medicines proved effective in the treatment of breast cancer. It is marketed in India by Roche, which owns the patent through its subsidiary Genentech. Roche sells this medicine in India under two brand names at different prices. The first brand, i.e., global brand known as Herceptine, is sold at the maximum retail price (MRP) of Rs. 134,000. The second brand has the MRP of Rs. 75,000. According to news reports, the Ministry of Health is considering to issue a notification under the Section 92 of the Indian Patents Act to expedite the issuance of compulsory licence.

The original molecule, a pre-1995 one, is not under patent protection India. However, there is another patent with Patent No.205534, granted by the Kolkata Patent Office. This patent claims priority on 6 May 1998. The drug obtained the marketing approval on 25 September 1998.

This patent claim contains seven claims. The first claim states[53]: A composition comprising a mixture of anti-HER2 antibody and one or more acidic variants thereof, wherein the amount of the acidic variant(s) is less than 25%. One cannot find any claim on therapeutic efficacy even in the subsequent claims. However, a patent has been granted on this application and it is blocking the generic entry of Trastuzumab in India. This patent was not renewed by the applicant i.e. Roche in 2013 and therefore not valid anymore.

2. Disclosure of INN

Another important step to curb the patenting of known substances is through the mandatory disclosure of the International Non Proprietary Names (INN). The disclosure of INN clearly provides evidence whether the substance is known or not. This would further make the examination procedure easy to gauge the claims of enhanced therapeutic efficacy. Hence, there should be an obligation on the part of the applicant to disclose the INN, whenever the patent application is on a pharmaceutical substance. An

[53] *See* Patent office website for details on Patent No.205534 available at http://ipindiaonline.gov.in/patentsearch/GrantedSearch/ReportProjectPopUp.aspx?Appl_No=IN%2fPCT%2f2000%2f00391%2fKOL&Pbl_No=IN%2fPCT%2f2000%2f00391%2fKOL&Pat_No=205534 [accessed on: 15 November 2014].

intentional non-disclosure or wrong disclosure should lead to the revocation of patent. In the case of NCEs, there should be an obligation on the part of the applicant to disclose the INN immediately after the allocation of INN.

The Patent office in 2013 had at least two consultations to implement the disclosure of INN. The patent attorneys, who represent the pharmaceutical TNCs and as well as pharmaceutical TNCs opposed the move. The author learned that the matter is now pending before the Department of Industrial Policy and Promotion (DIPP). Meanwhile the Revised Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals states that the patent examiner ask the applicant to inform the INN of the said pharmaceutical substance. It further states " if the applicant does not inform the INN even of the request, the examiner should try to find out the INN and use the same in search strategy".[54] Thus the Draft Guideline considers INN as a search strategy but does not shift the burden of INN disclosure to the applicant. As a result the request of the examiner can be ignored by the applicant.

3. Amendment to the Manual of Patent Office Practice and Procedure

The patent office should incorporate the Supreme Court judgment in the examination manual and apply the therapeutic efficacy as the sole criteria to apply Section 3(d). The current manual even bypasses the legislative intent behind Section 3(d). It states "Isomers having the same empirical formula but having structural differences may be considered novel and may not normally offend 'obviousness' as they are structurally different". This statement instructs the examiner to ignore the legislative requirement on efficacy and accepts claim on an isomer having structural difference and therefore eligible for patent protection. Hence, it is important to amend the manual to incorporate the Supreme Court decision and the criteria to gauge the therapeutic efficacy.

The Patent Office currently undertaken an initiative to come out with a Draft Guidelines for the examination of patent applications in the field of pharmaceuticals. Based on consolations the Patent Office may either come out with the final version of the Guideline or produce a third draft of the Gridline. The revised Draft Guideline in a way failed to incorporate the Supreme Court judgment in its right spirit.

[54] *See* Draft Guideline for the Examination of the Patent Applications in the Field of Pharmaceuticals, at p. 9 available at http://www.ipindia.nic.in/iponew/draft_Pharma_Guidelines_12August2014.pdf [accessed on: 15 November 2014]

The revised Draft Guideline quotes the parts of the Supreme Court judgment i.e. "*the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance.* .In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy". However it failed to provide the necessary explanation/guidance to implement the Supreme Court decision in the Guideline. Thus according to Supreme Court salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance should be treated as known substance unless the applicant failed to prove an enhanced therapeutic efficacy than the known substance. This means that any patent application which claims patent on a isomers or salt form etc. would be rejected *per se* in the absence of evidence s to prove enhanced therapeutic efficacy. Thus the Patent Office can reject patent application claiming patent on any new forms in the absence of a claim and evidence with regard to therapeutic efficacy.

4. Limiting the number of divisional applications

Another important step is to check the practice of filing the divisional applications. A divisional patent application is allowed to help the applicant to claim the priority date of the original application and file subsequent improvements in the invention. However, often the pharmaceutical TNCs use divisional application to scare the generic manufactures to show the pending patent applications and thereby delay the introduction of generic version. There is no restriction on the number of divisional applications one can file. Often divisional application is filed even after the rejection of the original patent application. Gilled Life Sciences used the divisional applications on Tenofovir to issue voluntary license to Indian generic companies with restrictive conditions.[55]

The scope for misuse of the provision of divisional patent application emerges from the Section 16 of the Patents Act. Section 16 states a divisional application can be filed at any time before the grant of patent. Even though the IPAB attempted to bring some degree of discipline[56] still it provides enough space to misuse the provision to file the

[55] For further details, *See* License Agreement between Gilead Life Sciences and Medicines Patent Pool and the sub-liquescence agreements available at http://www.medicinespatentpool.org/current-licences/ [accessed on: 15 November 2014]

[56] *See* Essence Obhan and Sneha Agarwal, 'Searching for Clarity in India's Divisional Patent Applications', available at http://www.managingip.com/Article/3243288/Searching-for-clarity-in-Indias-divisional-applications.html [accessed on: 15 November 2014]

patent application because the divisional patent application would be still pending for examination even after the rejection of the original application.

5. Training of patent office and judiciary

It is important to train both the patent office and the judiciary regarding the Supreme Court's interpretation of Section 3(d) and on the measures to be taken on how a public health-oriented jurisprudence should be used to interpret the therapeutic efficacy criteria. Further, the training should ensure that both the judiciary and the patent office should reflect the legislative intent while interpreting Section 3(d), i.e., while deciding on the patentability of known substance. Towards this purpose, the government should review its MoU with the developed country patent office and remove clauses on capacity building. Further, there should be clear norms and standards for the interaction of judicial officers with their foreign counterparts, as well as their participation in the conferences and other meetings organised by academic institutions, NGOs, industry lobbies and law firms.

6. Policy coherence

Lastly, the Government of India should ensure policy coherence across the sectors. While the government welcomes the Novartis judgment and support the non-patenting of known substance, such a policy should be implemented across the board. However, this approach is currently missing. The concrete case is the exemption rules under the Drug Price Control Order (DPCO), which provides exemption to price control on the basis of patents for five years. DPCO fixes the prices for medicines in the National List of Essential Medicines (NLEM), which currently contains 348 medicines without any product patent protection[57]. According to DPCO "*a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country.*[58]" It is very clear that such patents can be obtained only on known substances.

Similarly, India should not negotiate IP as part of its Free Trade Agreement (FTA)

[57] *See* National List of Essential Medicines of India 2011, available at http://www.cdsco.nic.in/writereaddata/National%20List%20of%20Essential%20Medicine-%20final%20copy.pdf [accessed on: 15 November 2014].

[58] *See* Drugs (Prices Control) Order, 2013 at para.32.

engagements. The developed countries often push for strong IP protection and enforcement standards through FTA. India is currently negotiating with the EU, Canada, Australia and New Zealand. The EU is demanding extension of border measures to exports and covering even goods suspected of infringing patents. Similarly, Pfizer has demanded to the US government at the hearing of the House Sub-Committee on *Trade "The U.S. government should pursue a robust trade agenda that includes strong intellectual property protections that build on the Korea-U.S. Free Trade Agreement and U.S. law, including robust provisions in the Trans-Pacific Partnership Agreement (TPP). 10 Strong IP provisions in U.S. trade agreements will demonstrate to countries like India that the U.S. is firmly committed to protecting intellectual property".* Hence, India bears the danger of its policy objective of curbing patenting of known substance by agreeing for negotiating IP as part of FTA.

7. Review of Bilateral Investment Treaties

Lastly, there is one more reason to review India's Bilateral Investment Treaties (BITs) to effectively curb the patents on known substance. The current definition of investment includes IPRs including patents, and therefore the proposed review of BITs should also aim at removing IP from the definition of investments. This is relevant, especially in the light of the revocation of Eli Lilly's patents by the Canadian Court. The Canadian court revoked the patents citing failure to deliver the benefits Eli Lilly claimed while obtaining the patents. The current BIT provisions threaten the post-grant revocation of patents by the patent office, the Intellectual Property Appellate Board (IPAB) and the courts.

Conclusion

The above discussion clearly shows that while the Supreme Court narrowed the possibilities of obtaining the patents on known substances, it does not rule out the possibilities. There is still an element of uncertainty with regard to the interpretation of 'therapeutic efficacy'. In the absence of a shared understanding on the content of the term 'therapeutic efficacy', there is the threat of diluting the policy concern on patenting of known substances through judicial interpretation or the practices of the patent offices. Therefore, further strengthening of law to reflect the policy concern is important to have a long-standing solution. The article also suggests certain measures to effectively implement the Supreme Court judgment and limit the patent protection to known substances on the sole criteria of enhanced therapeutic efficacy.

Briefs

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Mahesh Menon, WBNUJS

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Suhruth Kumar, GLC Thrissur