JUDICIAL ACTIVISM AND PATENT LAW IN INDIA

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Abstract

In India, the law which governs patent right is "Indian Patent Act 1970". Patent law in India starts from 1911 after the Indian Patents and Designs Act, 1911, came into force. The present Patents Act, 1970 came into force in the year 1972, amending and consolidating the existing law relating to Patents in India. The Patents Act, 1970 was again amended by the Patents (Amendment) Act, 2005, wherein product patent was extended to all fields of technology including food, drugs, chemicals and micro-organisms. After the amendment, the provisions relating to Exclusive Marketing Rights (EMRs) have been repealed, and a provision for enabling grant of compulsory license has been introduced. The provisions relating to pre-grant and post-grant opposition have been also introduced. This Paper aims at the study of the role of the judiciary in patent protection in India. It begins with a theoretical exploration of the role of the judicial organ in democratic society. It explains how the judiciary is not merely the arbiter of disputes but is also instrumental in delivering justice through determining and clarifying the status of law. The article then demonstrates the active nature of the Indian Judiciary in patent protection through an examination of case law on the nature of patents and the legal consequences of infringement. The article moves to a brief survey of the landscape of patent law in India in the post-WTO era and concludes with the observation that the judiciary today faces new challenges in the wake of new international obligations, which only enhance its responsibility towards the law and justice.

Key Words – Court, dispute, patent, right.

Introduction

The third amendment to Patents Act 1970, in 2005, was a major breakthrough for Indian IP practice in patents. The beginning of the product patent regime in food, chemicals and drugs gave an impetus to patent litigation that started with some well-known patent disputes between innovator companies and Indian generic drug industry. This litigation space has now considerably moved ahead and lately a wave of instances has significantly indicated settling of laws in some pertinent areas of patent law. The current crop of judicial decisions, as discussed in this note, has initiated the need to have a critical mass of judicial precedents

The TRIPs agreement, together with the 1968 Stockholm Conference that adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organization (WIPO), is undoubtedly the most significant milestone in the development of intellectual property in the twentieth century. Its scope is in fact much broader than that of any previous international agreement, covering not only all areas already protected under extant agreements, but also giving new life to treaties that failed and protecting for the first time rights that did not benefit from any multilateral protection. In addition, the TRIPs agreement enshrined detailed rules on one of the most difficult and, for rights holders, painful aspects of intellectual property rights' enforcement. [1] The Uruguay Round of multilateral trade negotiations resulted in the adoption of the Agreement Establishing the World Trade Organization (WTO Agreement) on April 15, 1994 in Marrakech. The TRIPs agreement was contained in the Annex to the WTO agreement, which entered into force on January 1, 1995. Built upon the foundations laid by the Paris Convention and the Berne Convention, the TRIPs agreement is an unprecedented international agreement in terms of its coverage, scope, specificities and enforceability. As regards geographic coverage, the TRIPs agreement is binding on all WTO members. Compliance with its provisions is a precondition of joining the WTO, which deals with the rules of trade between members at a global level. Although intellectual property rights (IPRs) and their effects on trade have been advocated for a long time, the TRIPs agreement is the first international instrument to focus on trade-related aspects of IPRs. In view of the different levels of ‘preparedness’ among members to implement the TRIPs agreement under national laws, the TRIPs agreement sets out certain periods of time after the entry into force of the WTO Agreement before members are obliged

[1] Daniel Gravis, The Trips Agreement: Drafting History and Analysis, 2nd ed., (London: Sweet & Maxwell, 2003), p.3.

to implement the TRIPs agreement.[2] Different periods were prescribed for developed countries (January 1, 1996), developing countries (five years from the date on which the TRIPs agreement becomes mandatory for developed countries) and least-developed countries (ten years from the date on which the TRIPs agreement becomes mandatory for developed countries). The targeted date for least-developed countries, which was January 1, 2006, has proved to be too ambitious, and was extended further to July 1, 2013.[3] In the area of patents, the TRIPs agreement established the standards concerning the availability, scope and use of patent rights. They include: (i) basic standards for patentability and a limited list of exceptions to patentable subject matter;[4] (ii) in terms of the availability of patents and the enjoyment of rights, no discrimination as to the field of technology, the place of invention and whether products are imported or locally produced;[5] (iii) rights conferred by a patent and exceptions to the rights;[6] (iv) conditions concerning the disclosure of the invention in a patent application;[7] (v) compulsory licenses;[8] (vi) availability of judicial review process for any decision to revoke or forfeit a patent;[9] (vii) the term of protection[10] and (viii) the burden of proof in deciding whether a product was obtained by a patented process.[11] Setting international standards on a number of issues is an extraordinary result achieved by the TRIPs agreement. However, the controversy as such has not disappeared with the adoption of the TRIPs agreement. Re-examination of provisions with respect to patents is under way. Among all the provisions of the WTO agreement, the one relating to Trade Related Intellectual Property Rights (TRIPs) has possibly been the most widely debated in the country. There are very good reasons why this has been so. First, because provisions in TRIPs relate to the country's Patent Laws and have a very serious bearing on major areas of the country's well being – health, agriculture, research, etc. Second, because India has been particularly fortunate among all developing countries in having a very liberal Patents regime since 1970 that promoted the country's interests. Third, because in the initial stages of the "Uruguay Round" of negotiations under the aegis of the then General Agreement on Tariffs and Trade (GATT), which finally led to the formation of the World Trade Organisation (WTO). India

[2] TRIPs Agreement, Articles 65 and 66
[3] Toshiko Takenaka (edr), "Patent Law and Theory", (U.K: Edward Elgar Publishing, 2008), p.170.
[4] Article 27, TRIPs Agreement.
[5] Article 27, TRIPs Agreement.
[6] Articles 28 and 30, TRIPs Agreement.
[7] Article 29, TRIPs Agreement.
[8] Article 31, TRIPs Agreement.
[9] Article 32, TRIPs Agreement.
[10] Article 33, TRIPs Agreement.
[11] Article 34, TRIPs Agreement.

had been extremely vocal in opposing the inclusion of Patent laws in the negotiations. While the Uruguay Round was initiated in 1986, it was only in 1989 that India did a sudden volte face and succumbed to pressure from the US and European countries by agreeing to include TRIPs in the negotiating agenda. Many, today, feel that if India had not succumbed in that crucial phase of the negotiations, the TRIPs agreement itself may never have seen the light of day.[12]

Product Patents for Pharmaceutical Inventions

Under TRIPs agreement, WTO members have to enforce product patents for agrochemicals and pharmaceutical compounds. About 50 developing countries, including India had not complied with this requirement during the Uruguay round of GATT negotiations. The much awaited and debated patents amendment was finally passed in parliament in March 2005. This third amendment to the Indian Patents Act 1970 brought India in the line with the TRIPs agreement. Omission of product patents for agrochemicals and pharmaceuticals was our strength until now. This had contributed to widespread growth of generic pharmaceutical industries, also making available medicines to the public at very low cost. The Indian domestic pharmaceutical industry grew strong, highly competitive and a big supplier of medicines and drugs within the affordable prices to common man because of a regulatory system focusing only on process patents along with a rigid price control. India developed into a world class generics industry. In fact in 2002, India was the world's largest producer of generic drugs in terms of volume.[13] Introduction of product patent along with the new regulations has caused significant changes in the Indian IPR industry. Product patent regime will be particularly favourable to the players already developed and well equipped in terms of scientific and technical resources. So, naturally, the main concern was about the fate of our pharmaceutical industry and consequent cost escalation of medicines when we allowed product patent form 1st January 2005. Hopefully Indian pharmaceutical industry will not be much impacted by the new Product Patent regime. More specifically, it has been suggested that all countries should adopt product patents instead of process patents. Supporters of product patent argue that this regime actually provides more comprehensive protection to the inventor since the product itself is protected. Supporters of process patent argue that this regime promotes competition and may also inspire innovation of new technologies that are

[12] Amit Sen Gupta, "Final Amendment to India's Patent Act", People's Democracy, Vol. XXVIII, No.40, October 03, 2004.

[13] http://www.ideas.rpec.org/p/nbr/nberwo/10159.html. Accessed on 8-6-2015.

more efficient. Many countries, following process patent systems, have been forced to change their laws and start pursuing product patent regimes.[14] India moved from a process patent system to a product patent system in 2005. The patent law is one of the seven intellectual property laws protected under this agreement. Section 5 of the TRIPs agreement deals with Patents. Article 27 says that "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". The most prominent and controversial change has been the deletion of section 5 of the Patents Act, 1970, thereby paving the way for product patents in the area of pharmaceutical and other chemical inventions. Section 5 of the Patents Act, 1970 (as it stood after the 2002 amendments) had provided that, in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained. This deliberate strategy of denying product patent protection to pharmaceutical inventions is traceable to the Ayyangar Committee Report,[15] a report that formed the very basis of the Patents Act, 1970. The Committee found that foreigners held between eighty and ninety percent of Indian patents and that more than ninety percent of these patents were not even worked in India. The Committee concluded that the system was being exploited by multinationals to achieve monopolistic control over the market, especially in relation to vital industries such as food, chemicals and pharmaceuticals. Medicines were arguably unaffordable to the general public and the drug price index was rising rapidly. The Committee therefore recommended that certain inventions such as pharmaceutical inventions, food and other chemical inventions be granted only process patent protection.

India's well-developed generic industry today is testimony to the farsightedness of this report.[16] For the first time since 1972, India's patents regime once again recognizes the potential patentability of pharmaceutical products. Section 4 of the Patents (Amendment) Act, 2005, is the cornerstone provision for bringing India's patents law into compliance with TRIPs. Product Patent is the granting of patent to the 'final' product irrespective of the process used for obtaining the product. Once you obtain a patent on the product, then one is

[14] 5 Product v Process Patent under Indian Patent Law, http://ssrn.com/abstact=1758064. Accessed on 27-3-2015.
[15] Justice N. Rajagopala Ayyangar, Report on the Revision of the Patent Laws', September 1959.
[16] Shamnad Basheer, "India's Tryst with TRIPS: The Patents (Amendment) Act, 2005", The Indian Journal of Law and Technology, Vol. 1, 2005, p.18.

precluded from manufacturing that product, even though with a different process.[17] The immediate impact of this fundamental expansion of patentability in India was a huge influx of product patent applications. Approximately 9,000 mailbox applications were filed with the Indian Patent Office during the TRIPs transition period of January 1, 1995 to December 31, 2004 claiming substances capable of use as food, medicine or drug. During the first eighteen months of the new patents regime, i.e., during January 1, 2005 to June 30, 2006, summaries of approximately 6,700 of those mailbox applications have been published. The Indian Patent Office began taking up the mailbox applications for examination in January 2005. In addition, regular (non-mailbox) applications claiming pharmaceutical substances were also filed on or after January 1, 2005. The first pharmaceutical product patent to issue under India's new patents regime was granted in March 2006 to Hoffman-La Roche for its Hepatitis C therapy sold under the brand name Pegasys.[18] The product patent regime replaced one of the important policy tools used for the development of the Indian pharmaceutical industry. In the absence of product patent protection prior to 2005, the Indian pharmaceutical industry was able to introduce new medicines in the Indian market and abroad within a short period of time at a fraction of the originator's price. Further, competition was generated among Indian pharmaceutical manufacturers because, with no product patents, many companies introduced the same products in the market. This competition, coupled with price control on essential medicines up to the mid-1990s resulted in the availability of medicines at low prices. The reintroduction of product patentability takes away the freedom of Indian pharmaceutical companies to introduce generic versions of New Chemical Entities (NCEs) in the normal course because NCEs often come with product patent protection. Under the product patent regime, a generic version of a patented NCE can be introduced in the market only by having recourse to flexibilities in the patent law, viz., patent opposition, compulsory licensing or parallel importation. Seven years after the introduction of product patent protection, there is ample evidence of growing control of MNCs in the Indian pharmaceutical market. Figures released by the Indian Patent Office reveal that out of 3,488 product patents issued from 2005 to March 2010, 3,079 were granted to MNCs. A study (2011) examining the post-TRIPs behaviour of MNCs in India states, 'Strong IPRs [intellectual property rights] have not

[17] Mini Gautam & Anshuman Chandan, "Product Patent and Exclusive Marketing Rights – Loopholes in the TRIPS Agreement and its Repercussions on India", www.legalservicesindia.com/article.html. Accessed on 3-7-2014.

[18] Ibid

favoured India with the claimed benefits of increased access to good quality FDI, technology transfer, overseas product R&D and stimulation of domestic investment in R&D for product innovation for local needs.' On the technology transfer front, the study says, 'During the pre-TRIPs era foreign pharmaceutical firms often exhibited in India an almost near complete aversion to technology transfer in bulk drug production. Evidence collated on the recent patterns of technology transfer from foreign firms to domestic companies shows that the results are not very encouraging for pharmaceuticals.' Regarding investment in R&D for drug development, the study finds that Hoechst and Astra, which carry out limited drug discovery operations in India, still remain, 'while others have closed down the units that had the mandate to develop products for the benefit of local markets'.[19] The introduction of pharmaceutical product patent was supposed to have negative impacts on the Indian pharmaceutical industry. It would hamper the growth of the Indian pharmaceutical industry. The industry can no longer manufacture by reverse engineering and export drugs that product patents are effective. However, contrary to the expectations, the Indian pharmaceutical industry has been growing post-TRIPs period. The productivity of the Indian pharmaceutical industry has been improving even in post-TRIPs period. It can be said that the introduction of pharmaceutical product patent brings new business opportunity to the Indian pharmaceutical industry and promotes growth of the industry.[20]

Judicial Approach

Imatinib

Imatinib product patent does not exist in India and Novartis had filed beta crystalline form patent application (1602/MAS/1998) in 1998. This application was published after 2005 and which was opposed by many Indian companies & NGOs. This application was rejected in pre grant opposition and in appeal IPAB also rejected. While this application was rejected under section 3(d), Novartis challenged the section 3(d) in HC and this HC judgement is precedential for the term efficacy in section 3(d). Novartis had appealed in Supreme Court.

[19] Dinesh Abrol, "Knowledge Diffusion under the Emerging Post-TRIPS Indian Pharmaceutical Scenario", http://www2.druid.dk/conferences/viewpaper.php?id=2460&cf=16. Accessed on 1-5-2016.
[20] Atsuko Kamiike & Takahiro Sato, "The TRIPS Agreement and Pharmaceutical Industry: The Indian Experience", src-home.slav.hokudai.ac.jp/rp/publications/noll/11-07Kamiike&Sato.pdf. Accessed on 1-5-2015.

Erlotinib

Erlotinib product patent (537/DEL/1996) was challenged at pre grant level by Natco, it was not successful. Opposition filed by Natco was rejected and patent was granted as 196774 with specific claims of Erlotinib Hcl and its process of preparing. Cipla announced and launched Erlotinib even when patent was granted in India. Roche/OSI sued Cipla and requested injunction for marketing generic version. Delhi High court rejected Roche's injunction request. Polymorphic patent applications filed (IN/PCT/2002/507/DEL & IN/PCT/2002/497/DEL) by Roche were also opposed by Cipla. Polymorphic claims were rejected and only process claims were granted. This product patent infringement suit is pending with Delhi high court. As a new development, Divisional application of Erlotinib product patent published last year march as 2018/CHE/2006. This application is opposed by Glenmark and Matrix at pre grant level. Many patent revocation applications are pending at IPAB .

Sorafenib

Sorafenib product patent is granted in India 215758 (IN/PCT/2001/799/MUM) and divisional is 1633/MUMNP/2007. This patent is opposed by Cipla at post grant level. Cipla launched generic sorafenib and patent infringement case is filed by Bayer at Delhi High court pending outcome. Bayer tried to prevent generic launch by arguing for Patent-product approval linkage, that was rejected by Delhi high court and by SC in appeal. Pending Cases are Bayer Vs Cipla[21]. Natco has been sued by Bayer on 06/05/2011 (CS(OS) 1090/2011). Bayer's writ petition challenging controller decision on Natco's CL is disposed of by Bombay high court and asked Bayer to file in Delhi High Court [22]

Valganciclovir

Valganciclovir product patent (959/MAS/1995) was opposed at pre grant level by NGOs and opposition rejected and patent granted as 207232. In this case, NGO were considered as person interested to participate in post grant opposition. This patent was opposed at post grant level by Cipla, Matrix, Ranbaxy & NGOs. Product claim was revoked in post granted opposition and patent maintained with process claim.

[21] CS(OS) 523/2010

[22] *Bayer Vs Emcure Pharmaceuticals CS(OS)* 2641/2011.

Entecavir

Entecavir is protected by pharmaceutical formulation related patent 213457 (IN/PCT/2002/891/MUM). BMS filed patent infringement and permanent injunction at Delhi high court against Ranbaxy. Injunction was not granted.[23]

Dasatinib

Dasatinib is protected by 203937 (IN/PCT/2001/1138/MUM) and assigned to Bristol Myer Siqubb. BMS sued Natco (CS(OS) 2279/2009) and Hetero Drugs (CS(OS) 2680/2008).

Amoxicillin Formulation patent

Astellas sued Micro labs for patent infringement of 234753 (1398/MAS/1997) on May 2011 [(C.S. (O.S.) No. 1166 of 2011)] in Delhi high court.

Novartis Case

When pharmaceutical company Novartis challenged the rejection of its patent application for the leukemia drug Gleevec in *Novartis AG v. Union of India*, [24] it became the first major legal challenge to India's newly amended patent law. In 2005, India purportedly made the final changes required to bring its intellectual property laws in compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPs), the World Trade Organization's (WTO) minimum standards for intellectual property protection, but its patent law is still fraught with a number of controversial provisions. The ability of pharmaceutical companies such as Novartis to secure patent protection in India not only is important in creating incentives for pharmaceutical research, but also greatly affects the Indian generic drug industry, and therefore the price of medicine available to patients. India is the world's second most populous country and the second fastest growing major economy, but has 70% of its population living on less than $2 per day, making Novartis AG of paramount importance. Gleevec is used for the treatment of chronic myeloid leukemia (CML), a disease that afflicts nearly 5,000 new patients in the United States each year. Studies have shown that Gleevec,

[23] *Bristol-myers squibb v ramesh adige cs(os)* 534/2010.

[24] *Novartis AG v. Union of India*, (2007) 4 MADRAS L.J. 1153, http://www.scribd.com/doc/456550/HighCourt-order-Novartis-Union-of-India. Accessed on 13-5-2010.

which targets specific cancer proteins, is almost ten times more effective than traditional interferon therapy. In 1993, Novartis filed patents worldwide for the active molecule imatinib. Novartis did not patent imatinib in India because the 1970 Act did not allow patenting of pharmaceutical products at that time. After India's entry into the WTO in 1995, Novartis filed a "mailbox" patent application in the Madras Patent Office for imatinib mesylate, a beta crystalline form of the free base imatinib. In 2002, Novartis started its Gleevec donation program in India to provide Gleevec to patients who were unable to afford the medicine, but halted that program after Indian drug manufacturers began to produce a generic version of Gleevec. In 2003, the Patent Office granted Novartis Exclusive Marketing Rights (EMR) in India, which allowed Novartis to enjoin generic Gleevec manufacturers and raise the price of Gleevec almost ten-fold. When the Gleevec mailbox application came up for examination in 2006, some commentators suspected that the application was fast-tracked due to controversies over the donation program and the divisive rise in price. In January 2006, the Madras Patent Office refused to grant Novartis a patent for imatinib mesylate. The first major ground for rejection was that because imatinib mesylate was a salt form of the free base imatinib, and Novartis claimed all pharmaceutical salt forms of imatinib in its 1993 patents, the Indian application therefore lacked novelty and inventiveness. The second major ground for rejection was based on Section 3(d) of the 2005 Amendment, which required that new forms of a known substance could only be patented as a product if they demonstrated "enhanced efficacy." Although Novartis disclosed information that imatinib mesylate had a 30% increase in bioavailability (the percentage of the drug absorbed into the bloodstream) as compared with imatinib, the Patent Office found this insufficient to meet the "enhanced efficacy" requirement of Section 3(d). 54 In May 2006, Novartis petitioned the Madras High Court, opposed by the Indian Government, the Patent Office, several Indian generic drug manufacturers and an Indian public interest group. Novartis claimed that the Patent Controller erred in rejecting the Gleevec patent application, that Section 3(d) was not compliant with TRIPs, and that Section 3(d) was vague, ambiguous and in violation of Article 14 of the Constitution of India because it was discriminatory against Novartis. The case was bifurcated between the Madras High Court and the Intellectual Property Appellate Board (IPAB). The challenges on TRIPs compliance and constitutionality of Section 3(d) were heard by the Madras High Court, which issued a judgment against Novartis on August 8, 2007. IPAB rejected the claim, but gave certain findings favourable to the company. The Madras High Court entertained three issues: First, whether courts in India have jurisdiction to review if Section 3(d) of the 2005 Amendment is compliant with Article 27 of TRIPs, and

alternatively, whether courts in India can grant declaratory relief that Section 3(d) is not compliant with TRIPs. Second, if courts do have jurisdiction, whether Section 3(d) complies with Article 27 of TRIPs. Third, whether Section 3(d) violates Article 14 of the Constitution of India because it is vague, arbitrary and confers uncontrolled discretion to the Patent Controller.[25]

The court held that Section 3(d) did not violate Article 14 of the Constitution of India and was not vague or arbitrary, and did not confer uncontrolled discretion to the Patent Controller. The court rejected Novartis's arguments that Section 3(d), which denies patents to new uses of known substances unless the patentee can show "enhancement of the known efficacy" or "differing significantly in properties with regard to efficacy," was ambiguous and unclear. While these two phrases are not explicitly defined, the court held that it was a common practice for the legislature to use general language and leave the courts to interpret the language based on the context and facts of each case. Moreover, the court held that Novartis was a sophisticated party who had the technological expertise to comprehend the enhanced efficacy requirement. The court also rejected Novartis's argument that Section 3(d) was arbitrarily enacted. Novartis argued that the actual amended Section 3(d) was not the same as the one originally proposed to the Parliament, which made no mention of an efficacy requirement, and was substituted in the current form of Section 3(d) without explanation. The court held that Section 3(d) was not arbitrarily enacted, referring to the parliamentary debates leading to the 2005 Amendment. The debates revealed that there was widespread fear that the earlier proposed amendments would deny Indian citizens of access to affordable medicines and open up the possibility of ever-greening. Thus, the court found that the legislature did not arbitrarily enact Section 3(d) in its final form. Finally, the court held that Section 3(d) did not confer unlimited discretionary power to the Patent Controller and was not discriminatory. The court emphasized that discretionary power did not necessarily mean that it would be discriminatory. The Patent Controller's discretionary power under Section 3(d) in deciding whether a known substance has enhanced efficacy did not automatically lead to an arbitrary exercise of discretionary power or discrimination against Novartis. Furthermore, the court opined that the judiciary should be more deferential to the legislature in the field of economic regulation. Because the Patent Act was designed to encourage the economic interests of India, the courts should be especially cautious before overruling the legislature.[26] The

[25] Ibid

[26] M.D. Nair, "TRIPS and Access to Affordable Drugs", Journal of Intellectual Property Rights, Vol. 17, July 2012, p.312.

Hon'ble High Court of Madras, on the issue of compliance of section 3(d) of the Indian Patents Act 2005, with Article 27 of the TRIPs agreement, decided mainly on the jurisdictional issue and said that it lacked jurisdiction to entertain the issue. Court relied on using a 'contractual' approach and concluded on the basis of general principle, which states that 'non-compliance with an international obligation does not provide private parties with the right to challenge a domestic statue unless the international instrument expressly grants such right'. The TRIPs agreement in this regard grants right only to member states. The Court further mentioned that the WTO's Dispute Settlement Understanding provides the exclusive remedy and a comprehensive dispute mechanism for violation of TRIPs agreement. The High Court looked into various previous decisions in case of conflict between the international law and municipal law and decided that municipal law prevails in such conflict. Moreover, in India, international treaties are not directly enforceable. Thus, the decision leaves crucial question before the Court unanswered. It is a well-founded decision both on the understanding of settling the claims under the TRIPs agreement and also in the light of the precedents relating to the place of international law in the Indian legal regime. It also rejected the second contention of Novartis regarding the unguided power granted to the Patent Controller by the impugned provision. While deciding on the issue, the Court upheld that Section 3(d) is neither vague nor arbitrary and therefore is not violate Article 14 of the Indian Constitution. The Court also studied the requirements of the impugned provisions placed on the Patent Controller. The whole argument of Novartis to hold Section 3 (d) vague and arbitrary rested on the fact that, since the term 'efficacy' was undefined, the term 'enhanced efficacy' was ambiguous. The Court is right in its decision because undefined terms cannot essentially be deciphered as lack of guidance to the patent controller. In fact, the explanation in Section 3(d) provides as to what constitutes 'enhanced efficacy'. The Court also pointed out that intention of the provision is clear and simple- for a patent to be granted it must be shown that the substance discovered has a 'better therapeutic effect'. Therefore, the Court concluded that the patent controller could competently determine the issue and the enhancement of a drug could also be most definitely determined.

On August 2009, Novartis approached the Supreme Court of India. In a major blow to the Swiss pharma giant Novartis, the Supreme Court on Monday, April 1st, 2013, rejected its plea for a patent on cancer drug Glivec. The verdict is expected to pave the way for Indian firms to provide affordable drugs to lakhs of cancer patients. Ending a seven –year legal battle by Novartis to have exclusive right for manufacturing Glivec, and to restrain Indian

firms from making generic medicine.[27]The apex court held that there was no new invention and no new substance used in the drug prescribed for treating blood, skin and other cancers.[28] The judgment allows suppliers to continue making generic copies of Swiss firm Novartis' Glivec, which has been shown to fight chronic blood cancer effectively. While the Novartis drug costs Rs 1,20,000 or US $ 2,400 per month per patient, while generic versions are available at a cost of Rs 8,000 (US $ 160) to Rs 12,000 (US $ 240) per month, with doctors often advising patients to take it lifelong, the ruling would be a relief to some 300,000 patients in India currently taking the drug. A bench of Supreme Court Justices Aftab Alam and Ranjana Desai said: "We firmly reject the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann (original) patent". The Bench said that the patent application contains a "clear and unambiguous averment" that all the therapeutic qualities of the modified form, for which the patent was applied, "are possessed' by the original version. The court held that patents can be granted only for medicines that are truly new and innovative. For new forms and new uses of existing medicines, patent applicants should prove improved efficacy. The court said that the Patents (Amendment) Act, 2005 established that 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" is not an invention – for the purpose of patenting.[29]

Conclusion

Observers say that the Court's judgment sets a precedent against the practice of "ever greening" – a strategy through which drug manufacturers introduce modifications of drugs to extend the five-year patents on them. They say that other "ever greening" patent applications could be rejected citing this judgment, helping to keep many lifesaving drugs out of the patent regime and pushing down costs. Pfizer and Roche are fighting for similar patents on their Cancer and Hepatitis C drugs. Ruling is bad news for them. It is a big boost to Indian generic drug suppliers and a big positive for generic manufacturers, patients and consumers and certainly a negative for multi-national pharmaceutical companies as ruling sets a precedent against the practice of drug companies extending patents by introducing small modifications of old drugs. India exports $10 billion worth generic drugs. The objective of

[27] Archana A. Jatkar, "The Indian Patent (Amendment) Act, 2005 and the Novartis Case", Trade Law Brief, No. 3, 2008, p.2-3.
[28] The Times of India, Tuesday, April 2, 2013, p.1.
[29] The Hindu, Tuesday, April 02, 2013, p.1.

India's Section 3(d) is not a radical departure from international practices to regulate the patenting of derivatives and new uses. Nevertheless, Novartis claimed that Section 3(d) was not compliant with TRIPs Article 27. Assuming that the patent laws of other countries are TRIPs-compliant and absent WTO ruling on the contrary, Novartis has likely overstated the noncompliance of Section 3(d). Thus our judicial system has been instrumental in protecting the rights of patentee's. Under the TRIPS compliant patent laws the active role of judiciary shall be pivotal to interpret in depth the provisions for the grant of patent.

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