law. The framework is set in appropriately to handle any interference with economic growth. However, a true understanding and application of laws and reasons behind the precedents would help in ensuring the smooth function of both the domains and specific needs of the Indian market.

THE SUPREME COURT ON THERAPEUTICAL EFFICACY AND SECTION 3(d) OF THE INDIAN PATENTS ACT

- Harekrishna Ashar[269]

Abstract

The Supreme Court of India has rejected the plea of Novartis for the grant of a pharmaceutical patent for its anti-cancer drug, sold in the name of Glivec/ Gleevec[270]. The judgment has received mixed reactions; both contented and condemned. It is essential to make a rational and unbiased analysis of the same and evaluate its potential impact on global pharmaceutical giants, which the author seeks to do in this paper.

Part I of this paper elucidates the object of patent protection, whereas Part II highlights the background of the legislation in India with regards to patent protection. Part III provides for the essential conditions to be fulfilled for the grant of a patent; Part IV stipulates a brief timeline of the Novartis case and Part V highlights the submissions of Novartis before the Hon'ble Supreme Court of India. Part VI deals with the repercussions and reactions of the judgment to the Indian economy and Part VII concludes with the author's view on the impact of the judgment to the Indian pharmaceutical market.

[269] Student, B.A LL.B (Hons.), Government Law College, Mumbai
[270]Novartis AG *vs.* Union of India & Ors.; (2013) 6 SCC 1;

1. OBJECT OF GRANTING PATENT

A statute is best understood if we know the reason for it, the reason being the safest guide to its interpretation.[271] It is essential to note that the purpose of the Patents Act, 1970 (**Patents Act**) is to encourage inventions and to ensure that the inventions are working in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. It must be noted that Patents are not granted merely to enable patentees to enjoy a monopoly over the importation of the patented articles[272]. In light of the same, an obligation is created and imposed on a patentee to work the patent in India on a commercial scale and to the fullest extent; either by the patentee itself or through licensees authorised by it. Novartis' failure to obtain Patent protection in the present case, therefore necessitates in the granting of a compulsory license[273], which is one of the flexibilities in Patent protection, included in the Trade Related Aspects of Intellectual Property Rights (**TRIPS**) Agreement, and is in most cases desired to be avoided at all costs by pharmaceutical giants.[274] Needless to say, compulsory licensing is a boon to developing countries, limiting the prospects of an epidemic, generating easy accessibility and affordability of basic life-saving drugs[275].

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[271] Justice Chinnappa Reddy in Utkal Contractors and Joinery Pvt. Ltd. and Others *vs.* State of Orissa and Ors., (1987) 3 SCC 279

[272] P. Narayanan, *Intellectual Property Law*, Third Edition, p. 68 (Eastern Law House, 2013)

[273] Section 82 to 98 of the Patents Act deal with the circumstances and the grounds under which compulsory licenses of different kinds may be granted.

[274] Compulsory licensing, as defined by the World Trade Organisation, is a practice whereby a government allows someone else to produce the patented product or process without the consent of the patent owner. The author maintains the opinion that it is in the interests of all pharmaceutical conglomerates such as Novartis in the present case, that compulsory licensing is not carried out for its product that is sought to be patent protected.

[275] *See 'Compulsory licensing as a public policy tool in developing countries'* [http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf

2. BACKGROUND

In the present case, the Supreme Court of India has in its judgment gone beyond the specific technical and legal issues surrounding the dispute and has taken in to consideration a much larger political and economic perspective. What the judgment says and what it implies has tremendous significance for the patent regimes in developing countries beyond the secondary patenting issues relating to Section 3(d) of the Patents Act, 1970. The judgment reads as

"*In order to understand what the law really is, it is essential to know the "why" and "how" of the law. Why the law is what it is and how it came to its present form?*"[276]

In order to understand the Patents Act, 1970 as per legislature's point of view, it is pertinent to look through the glasses of the statute maker[277]. With the introduction and commencement of the Patents Act, 1970, India abolished product patent protection in drugs (and food). However, with the advent of the TRIPS Agreement of the World Trade Organization (**WTO**) in 1995[278], product patents have become mandatory, despite countries being free to frame their own Patent laws.

Under the Patents (Amendment) Act, 1999, applications for product patents for inventions relating to medicine and drug were permitted with certain conditions and exceptions[279]. Nevertheless, it

] page 10; http://blogs.lse.ac.uk/indiaatlse/2013/03/25/compulsory-licenses-for-pharmaceuticals/

[276] Novartis AG *vs.* Union of India & Ors.;(2013) 6 SCC 1; Para 29, p. 16

[277] Justice Reddy in Reserve Bank of India v. Peerless General Finance and Investment Co. Ltd. And Ors., 1987 (1) SCC 424

[278] India, being a founding member of the GATT, and thus a member of the WTO since its inception, is bound by the TRIPS Agreement, like all other members.

[279] Exclusive marketing rights are not granted to an article or substance based on the system of Indian Medicine as defined in Section 2 (1) of the Indian Medicine Central Council Act, 1970; and where such article

was only in 2005 that in compliance with the TRIPS Agreement[280], India started granting pharmaceutical patent protection, albeit with a prerequisite in Section 3(d) of the Patents Act, 1970.[281] Further, applicants for such patents are allowed to make separate applications for grant of exclusive marketing rights to sell or distribute the article subject to certain conditions, the principal being the patentability of the article under the provisions of Sections 3 and 4 of the Patents Act, 1970.[282]

3. CONDITIONS TO BE FULFILLED FOR GRANT OF PATENT

The Supreme Court of India has in the present case, carved out a fine line for the grant of new patents, being that unless a *therapeutic benefit* is gained from the drug sought to be patented, a patent must not be granted, thereby keeping with the object of the introduction of Section 3 (d) to the Patents Act.[283]

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is already in the public domain. Further, excepting all chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances referred to in sub-clauses (i) to (iv) of section 2 (1) (l) of the Parent Act.

[280] It must be noted that India had already availed the 10 year transition period provided under the TRIPS Agreement and had no legal basis to delay implementation beyond the same.

[281] Section 3 (d) of the Patents (Amendment) Act, 2005 provides 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 patentable.

[282]Patents (Amendment) Act, 2005

[283]*Ibid.*

As per the relevant law in force, the following criteria must be fulfilled for a new product or process to qualify as an "invention"[284], namely:

(i) It must be newand not be anticipated;

(ii) Itmust involve an inventive step; and

(iii) It must be capable of industrial use and application.[285]

Further, for an invention to be patentable, it must not fall under the categories set out in Section 3and Section 4of the Patents Act.[286]Therefore, it is clear that under the provisions of the Patents Act, the subject matter must satisfy the twin tests of "invention" and "patentability", which in the present case, the application fails[287]. It can be argued that whereas some items may be an "invention" as the term is generally understood and yet they may not qualify as an "invention" for the purposes of the Act, others may even qualify as an "invention" as defined under the Act and yet may be denied patent protection for other larger considerations as may be stipulated in the Patents Act. However, Section 3(d) of the Patents Act, 1970 provides an explanation that salts, esters and other derivatives of known substances will be considered to be the same substance, '*unless they differ significantly in properties with regard to efficacy*', considering in future a new form of an existing product shows some increase in efficacy. It must be said that the law relating to such cases is rather untouched, and niche so far and has not been specifically dealt with in the present case.

[284] As per section 2 (j) of the Patents Act, *invention* means a new product or process involving an inventive step and capable of industrial application.

[285]Section 2 (ac) of the Patents Act, 1999.

[286]Section 3 of the Patents Act, 1999 provides a list of all inventions, which are not 'inventions' under the provisions of the Act whereas Section 4 provides that all inventions dealing with atomic energy are not patentable under the Act.

[287] Novartis AG *vs.* Union of India & Ors. (2013) 6 SCC 1; Para 195, p. 96

In Novartis AG vs. Union of India & Ors., the primary issue before the Supreme Court was whether the *beta crystalline form* of the drug sought to be patented, stands the test of patentability as specified in section 3 (d) of the Patents Act, 1970.[288]

4. BRIEF TIMELINE OF THE PRESENT CASE

Pharmaceutical conglomerate Novartis first applied for a patent for its drug *imatinib* (and other derivatives of a compound) in the United States in April 1993 and then once again in 1994, abandoning its previous application the preceding year. At this stage, the patent was commonly known as the '*Zimmermann'* patent, after the name of its inventor. At the relevant time, Novartis could not apply for a patent for its drug in India due to the non-application of the TRIPS Agreement in India[289]. However, soon after the advent of the TRIPS Agreement in India, Novartis did eventually make a patent application in India for the *beta crystalline form of imatinibmesylate* in 1998.[290] The Apex Court has noted that at the time of application of the Patent in India, the legislation governing the same was in a transitional phase, with the law being significantly different to what it stands as today[291]. Until 2005, the Applicant's application was kept in a 'mailbox'[292] and was only taken out of the 'mailbox' for consideration after certain amendments were made to the Patents Act, with effect from 1st January 2005.[293]

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[288] (2013) 6 SCC 1

[289] It must be noted that prior to the commencement of the TRIPS, member countries were barred from providing protection for a patent applied or granted elsewhere before TRIPS came into being, i.e., before 1 January 1995.

[290]Novartis' application dated 16July, 1998 was allotted application no. 1602/MAS/1998.

[291] Novartis AG *vs.* Union of India & Ors.; (2013) 6 SCC 1; Para 12, p. 8

[292] As per the relevant provisions of the TRIPS Agreement,

[293] At this stage, the patent application attracted 5 pre-grant oppositions by M/s. Cancer Patients Aid Association, NATCO Pharma Ltd., CIPLA Ltd., Ranbaxy Laboratories Ltd. and Hetro

Thereafter, the Assistant Controller of Patents and Designs rejected Novartis' application on the ground that the invention sought was obvious to a person skilled in the art in view of the disclosure provided in the *Zimmermann* patent[294] specifications and further disallowed the same as per the provisions of Section 3 (d) of the Patents Act[295]. Thereafter, against this Order of the Assistant Controller, Novartis filed an appeal before the Madras High Court, which was later transferred to the Intellectual Property Appellate Board (**IPAB)**[296]. Apart from challenging the order of the Assistant Controller, Novartis also filed two writ petitions before the Hon'ble Madras High Court[297] seeking a declaration on Section 3 (d) as unconstitutional, as it not only violates Article 14 of the Constitution of India but also not in compliance with the TRIPS Agreement. The said appeal before the IPAB was rejected on 26thJune 2009,[298] to which the Company preferred an appeal before the Supreme Court of India. The Supreme

Drugs Ltd. A hearing was given to all parties by the Assistant Controller of Patents and Designs on 15 December, 2005, as per Rule 55 of the Patent Rules, 2003

[294] The application was made on April 28, 1994 and patent was granted on May 28, 1996 under US Patent No. 5,521,184. It is from this patent that the subject matter of the present case is derived.

[295] On 25th January, 2006, the Assistant Controller of Patents and Designs passed an order rejecting the patent claim filed by Novartis on the grounds that the invention claimed by Novartis was *obvious, anticipated and that the grant of patent on the Drug is not permitted* under Section 3(d) of the Patents Act.

[296] As at that time, the appellate authority under the Patents Act had yet to become functional.

[297]Writ Petition Nos. 24759/2006 and 24760/2006

[298] With regards to Section 3 (d) of the Act, the IPAB held that "Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances."

Court of India has in its judgment[299] dated 1st April 2013 (**Judgment)** of the Division Bench of Hon'ble Justice Mr. Justice Aftab Alam and Hon'ble Justice Ms. Ranjana Prakash Desai upheld the rejection of Novartis' patent claim on the Drug

5. SUBMISSIONS OF NOVARTIS BEFORE THE HON'BLE SUPREME COURT

The primary submission of Novartis was that the beta crystalline form of the drug for which the patent was applied for in India was developed through two distinct inventions–firstly, from imatinibtoimatinibmesylate[300] and secondly, from imatinibmesylateto the beta crystalline form.The Supreme Court of India however ruled that ImatinibMesylate was a known substance at the time of application of the patent, thereby not qualifying as an 'invention' under the Patents Act and not further satisfying the criteria of therapeutic efficacy as laid down in Section 3 (d) of the Patents Act[301].The Court also recorded a finding that the pharmacological properties of Imatinib Mesylate were known in the Zimmermann patent and in an article published in a *Cancer Research*Journal[302], thereby further justifying the lack of criteria for an 'invention' in Novartis' case.

6. INTERPRETATION OF 'EFFICACY' AND 'THERAPEUTIC EFFICACY'

Section 3 of the Patents Act, 1970[303] specifically lays down what are not inventions and categorically specifies that the mere discovery of a

[299]A copy of the judgment can be found here at http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212; (last accessed 5th January, 2014)

[300]For which the patent had already been granted in USA; *Supra 20.*

[301] Novartis AG *vs.* Union of India & Ors.; (2013) 6 SCC 1; Para 157, p. 81-82.

[302]*Cancer Research,* (1996), Inhibition of the Abl Protein-Tyrosine Kinase in Vitro and in Vivo by a 2-Phenylaminopyrimidine Derivative, p. 69

[303]Section 3 (d) of the Patents (Amendment) Act, 2005, as a direct result of the Parliamentary debate centered on drugs and machinery.

new form of a known substance which does not result in the enhancement of the known *efficacy* of the substance or the mere discovery of any new property or new use for a known substance shall not be considered an 'invention' for the purposes of the Patents Act, 1970.

In a healthcare context, as is the present case, the term 'efficacy' indicates the capacity for beneficial change (or therapeutic effect) of a given intervention (e.g. a medicine, medical device, surgical procedure, or a public health intervention)[304]. In the same context, a therapeutic effect is a consequence of a medical treatment of any kind, the results of which are to be analysed and judged to be desirable and beneficial. The Supreme Court of India has held the term efficacy to mean "*the ability to produce a desired or intended result*".[305] Therefore, the test of efficacy in the context of section 3(d) would depend upon the result, the function or the utility that the product under consideration is desired or intended to produce. Consequently, the court concluded that in case of a medicine that claims to cure a disease, the test of efficacy could only be "therapeutic efficacy", i.e. the capacity of the drug for beneficial change, which must be judged strictly and narrowly.[306] The court also held that as per the explanation to the provision, a mere change of form with properties inherent to that form would not qualify as an "enhancement of the efficacy" of a known substance, thereby categorizing what is to be considered therapeutic efficacy[307].

The Apex Court also rejected Novartis' claims of better bioavailability and better physical characteristics such as better storability of the compound, requiring the same to be collaborated with necessary data in each case to justify a claim for an enhancement of therapeutic

[304] http://www.news-medical.net/health/Efficacy-What-Does-Efficacy-Mean.aspx

[305] The New Oxford Dictionary of English, Edition 1998; Novartis AG *vs.* Union of India & Ors.; Para 180, p. 90.

[306] *Ibid.* para. 181, p. 91

[307] *Ibid.*

efficacy.[308]As Novartis did not submit any material to demonstrate the same, the application failed to satisfy the test laid down in section 3(d) of the Patent Act. It has been held that Section 3(d) of the Patents Act does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances, with the determination of the same on a case-to-case basis[309]. Therefore, in interpreting cases under Section 3(d) of the Patents Act, as suggested by the Apex Court, courts in India will lay greater emphasis on the ability of the product to materially improve the therapeutic effect provided by the patented drug.

It must be noted that at the time of application of the patent, there was no criteria for any additional therapeutic benefit being derived from the product as it was only post the application, that the said criteria was introduced to Section 3 (d) of the Patents Act[310]. The apex court has remarked that the case of Novartis "*appears in rather poor light and the claim for patent for beta crystalline form of imatinibmesylate would only appear as an attempt to obtain patent for imatinibmesylate, which would otherwise not be permissible in this country*"[311].

7. SECONDARY PATENTS

Secondary Patents are essentially patents that are granted in relation to new developments or improvements of the subject matter of the primary patent, which plea in Novartis' case has been rejected by the Supreme Court. Secondary patents, which are allowed in certain cases in the United States of America and the United Kingdom when 'enhanced utility' can be proved from the base compound,[312] do not find any safeguard in the Indian Patents Act, 1970. Therefore, it is safe

[308]Novartis AG *vs.* Union of India & Ors. (2013) 6 SCC 1;para 188, p.94.
[309]*Ibid.* para. 191, p. 95
[310] As there was no statutory requirement to do so at the time in the Patents Act in 1998.
[311] Novartis AG *vs.* Union of India & Ors.(2013) 6 SCC 1;para 194, p.96.
[312]See http://www.olswang.com/pdfs/Bios_Jul03.pdf (last accessed 22 June, 2014)

to say that unless the Indian law is amended to provide for secondary patents, companies Novartis' cannot expect patent protection in India.

8. COMPULSORY LICENSING

In the present context, considering the delicacy of the legislature, had Novartis made the Patent application in the United States of America a few months later, with the advent of the TRIPS Agreement, the drug would well have been eligible for a patent in India[313].

Linking patenting to therapeutic benefit is what the Apex Court has done in its judgment in the Novartis case. The ruling is consistent with the provisions of the TRIPS Agreement and has been arrived at by following a transparent and internationally accepted legal processes that is not arbitrary. As a result, other legislations that have stricter patent regimes might also be induced to introduce similar provisions in their patent laws to make drugs more affordable.

It must be noted that the TRIPS Agreement also permits compulsory licensing, which has been granted to NATCOfor SorafenibTosylate(sold as Nexavar by the patentee, Bayer).[314]

Amongst other problems, India suffers from the problems of high prices of patented medicines and low access to generics, i.e., non-patented medicines and a compulsory license. Due to a variety of factors including poor public health facilities, and inadequate insurance facilities, drug access is trifling in India, with Indian generic companies lured by foreign markets.

[313]Section 3 (d) in the Patents Act, 1970 was only introduced by the Patents (Amendment) Act, 2005 whereas the TRIPS Agreement came in to effect from 1995.

[314]http://www.natcopharma.co.in/index.php/news-for-dump/149-natco-granted-compulsory-licence-for-nexavar
However, it must be noted that the same, when challenged was upheld by the IPAB, with certain modification with regards to royalty. http://www.ipab.tn.nic.in/045-2013.htm (last accessed 26 June, 2014)

9. REACTIONS AND REPERCUSSIONS IN THE INDIAN ECONOMY

The immediate reaction to the judgment was one of widespread acclaim and support, particularly from organisations such as the WTO and Médecins Sans Frontières (Doctors Without Borders) amongst others that welcomed the judgment as a stronghold against evergreening.[315]

The Supreme Court of India has rightly observed "*the rules and regulations of the patent systems are not governed by civil or common law but by political economy*".[316]As quoted by Michel[317], "*Patent systems are not created in the interest of the inventor but in the interest of the national economy*".[318]

It must be appreciated that in the Novartis case, the Supreme Court has taken a stance wherein it is not only justified to deny patents where incremental innovation is trivial as in the present case, but one must significantly prove and demonstrate some form of therapeutical efficacy in the product[319]. The Division Bench has given great consideration to the impact or rather damage the same, if granted would have to society and has highlighted the relevance of specific conditions of a country for deciding the appropriate patent regime.[320]

Pharmaceutical patent protection was allowed till the advent of the Patents Act, and was thereafter once again re-introduced belatedly in 2005, considering the dire consequences of non-compliance of the

[315]The following article is a comparison between the Indian and South African patent regime and worth noting. http://www.iol.co.za/lifestyle/major-victory-on-affordable-drugs-1.1495438#.UtTxUNIW0l9 (last accessed 6th January, 2014)
[316] Novartis AG *vs.* Union of India & Ors (2013) 6 SCC 1;para 36,
[317]Michel, *Principal National Patent Systems*, Vol. I, P.15
[318]Novartis AG *vs.* Union of India & Ors. (2013) 6 SCC 1;para 36, p.18
[319]Novartis AG *vs.* Union of India & Ors (2013) 6 SCC 1;para 55, page 100;
[320]*Ibid.*

TRIPS Agreement by India.[321] The intent of the same was to promote and provide a stimulus to investment and innovation in research and development in India. However, it was in the interim period that industry in India witnessed development, somewhat unprecedented, albeit in the absence of the pharmaceutical patent protection.[322] It is essential to note that prior to 1972, when pharmaceutical patent protection was provided in India, global pharmaceutical giants such as Novartis did not contribute much to innovation, market growth and development in India, as was anticipated by them,[323] and were un-inclined towards developing industry and investing in manufacturing activities in India.[324]. It has only been due to the advent of the WTO and the TRIPS Agreement that India has been forced to re-introduce the provisions for pharmaceutical patent protection in its legislature.

In the present case, the fundamental basis for rejection of the Patent application is that there is no therapeutic benefit derived from the product, thereby eliminating the need of consumers in paying exorbitant prices for the product. This will have a direct effect on 'evergreening'[325] as it will be even harder for producers to prove

[321] WTO members (India being one of them) were under an obligation to implement TRIPS provision by 2000, 2005, or 2016, depending on their level of development. India was given an extended period of time to make its patent regime complaint to the TRIPS Agreement, which it did by the Patents (Amendment) Act, 2005 which came into force on 1st January, 2005. It is through the same that India has now implemented a product patent regime and product patents in the pharmaceutical sector.

[322]Prof. SudipChaudhary has time and again reiterated that Pharmaceutical giants are keener on importing patented products and selling at high prices rather than innovating or manufacturing in the country.

[323] Based primarily on the BakshiTek Chand Committee Report (1950), the Ayyangar Committee Report (1959) and *SudipChaudhuri*, The WTO and India's Pharmaceutical Industry, (2005) Oxford University Press.

[324]*SudipChaudhary* (2012): 'Multinationals and Monopolies', Economic & Political Weekly, 24 March.

[325]Evergreening is the practice by which MNC's such as Novartis holding patents try to block or delay competition post expiry of their

therapeutic efficacy, now a strict criterion for patent protection in India. The direct benefit of the above will be to the consumer as medicines which otherwise would have been patented having high monopoly prices will now not be patentable, thereby being affordable.

The present ruling in the Novartis case is a relief to the Indian market, as pharmaceutical companies are now essentially unable to extend the life of patents by minor, trivial modifications to their protected products. Thus it paved the way for generic companies to sell the anti-cancer drug and other drugs in the future, at a fraction of the exorbitant prices charged by Novartis and pharmaceutical giants for the product. It has been suggested, although yet to be seen, that the strict patent requirement laid down by the Apex Court would actually enhance innovation as pharmaceutical companies would have to invest more in research and development to come up with new cures rather than repackage known compounds.[326]

Despite the ruling receiving stiff opposition, Novartis' sceptical approach[327] of withdrawing Research and Development initiatives in India and withholding the introduction of new drugs in the country is a knee-jerk reaction.[328] Much can be speculated of the

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patents, by getting secondary patents on minor changes to the product. This is where Section 3 (d) of the Patents Act and 'therapeutic efficacy' comes into play. As on date, the Patents Act is fully TRIPS compliant and under the same, a patent is valid for 20 years, after which competitors are permitted to manufacture the product, which naturally increased the availability of the product, leading to a fall in its price. *Schering v. Geneva(CITATION?)* is a relevant case law with regards to the same.

[326]http://www.thehindu.com/opinion/lead/why-novartis-case-will-help-innovation/article4617473.ece?ref=sliderNews (last accessed 7th January, 2014)

[327]RanjitShahani, vice-chairman and managing director of Novartis India Ltd is quoted as saying "This ruling is a setback for patients that will hinder medical progress for diseases without effective treatment options."

[328]http://www.telegraphindia.com/1130402/jsp/business/story_16736700.jsp#.UtTyttIW0l9 (last accessed 6th January, 2014)

impact of the refusal of the patent protection on the profits of Novartis. However, the same will be insignificant taking in to account the fact that the Indian market only accounts to a fraction of Novartis' emerging global market share.[329] Further, not paying much heed to Novartis' immediate reaction, an emergent market like India is too daunting and alluring for pharmaceutical giants to disregard, regardless of the company.

The beneficial aspect of the ruling is that a rationale has been set and laid down for the grant of patents, which keeping in mind the frailty of the legislature, can only be a strong hold for the same for times to come. It is suggested that the same could possibly stimulate investment for research and innovation, which is yet to be seen. The ruling in the present case seeks to achieve a perfect balance between Patent rights and interests of the society and market, often unattainable and to be fair, does considerably well in its endeavour to do so. In developing countries such as India, especially where innovation is absent or trivial, a country is justified in denying a patent protection as striking a balance between the utility of patent protection and its impact on the market becomes difficult. In the present case, the negative effect of monopoly and price-rise is much stronger than the positive effect of the grant of the patent protection in the country, thereby justifying the stance taken by the Apex Court per se. Patent rights inevitably reduce the accessibility of a product to patients in developing economies, by virtue of their inflated prices.

It must be appreciated that at present, as per India's Economic Development Stage, India is more of a net user than a developer of such life saving drugs. Therefore, the grant of patent protection in pharmaceutical products as in Novartis' case would cause greater harm to the economy than benefit as the same would essentially bereft Indian pharmaceutical companies of the opportunity of penetrating a market deep enough to sustain and grow by handing over this opportunity to a global conglomerate. India, in my opinion has the potential to provide the market and the mechanism for literally creating a pharmaceutical giant, which once is in existence, would it be

[329]See http://www.reportlinker.com/ci02257/Pharmaceutical.html (last accessed 27 June, 2014)

prudent to provide patent protection to cases like Novartis'. It is only at this stage once India starts manufacturing and developing such drugs and becomes a net-developer of the same, can it consider providing patent protection to cases like Novartis' the same. It is imperative that a balance is achieved between the grant of patent protection and the benefit of such grant on society, which the present ruling does quite well. The Division Bench is evidently justified in denying patent protection in the present case where incremental innovation is trivial, as of the application for a *beta crystalline* form of an already patent protected product. The relevance of the patenting and the net benefits to society is one that this ruling has laid great emphasis on, one that must be appreciated considering the prevalent patent regime in India.

10. CONCLUSION

The initial apprehension of the judgment enforcing a blanket ban on patent protection to all incremental inventions of chemical and pharmaceutical substances is a misplaced one. The ruling, albeit a narrow one, lays down the basis that a company must comply with in order to be afforded protection under the regime. With Indian law, fully compliant with the TRIPS and International standards, it would be fair to suggest that the judgment of the Supreme Court is a timely one, clearly establishing a foothold on the subject matter for the times to come in conformity to international standards.[330] With the stringent patent standards set across the world, given the present Economic Development Stage of India, the extent of poverty and lack of availability of affordable medicines in the country, it is only high time that India followed suit.[331] The prevalence of Section 3 (d) allows competition, which is useful as it ensures that drugs will be available at a competitive price in the market.

[330]Protection of an innovative new product as opposed to a minor change to the product

[331]http://www.mylaw.net/Article/Nothing_wrong_with_setting_high_standards_of_patentability/?past=Slideshow#.UtTzhdIW0l9 (last accessed 7th January, 2014)

The ruling, besides paving the way for easing the accessibility and availability of drugs in India, affirms and upholds the patent regime in India, thereby protecting genuine innovators in India. The impact of the judgment on other Global Pharmaceutical Companies is yet to be seen, needless to say that they would be considerably more cautious in their approach, keeping in mind the depth of the judgment in the present case. Needless to say, the repercussions of the judgment, if any, shall not be too damaging to the Indian economy, as one with the backing of a population exceeding Two Billion, shall always remain a beguiling market, which will almost impossible for Pharmaceutical corporations to overlook.

PATENTABLE SUBJECT MATTER IN THE US AFTER *MAYO V. PROMETHEUS*, 566 U. S. ____ (2012)

- **Avani Verma**[332]

Abstract

Patentable subject matter has always been a matter of debate in intellectual property laws of various countries. Especially, in the United States, this topic has become a subject of much importance due to a catena of incoherent judgments. A recent judgment in MAYO V. PROMETHEUS, 566 U. S. ____ (2012) ("Mayo"), involving a challenge to a patent dealing with a method of optimizing therapeutic efficacy for the treatment of gastrointestinal disorder, has joined the series of previous judgments. The judgment, inter alia, discussed the patentability of claims involving laws of nature, physical phenomena, abstract ideas and the applicability of the Machine or Transformation test. This judgment has been criticized as being overly broad as the effect of the judgment entails that it would invalidate almost all method claims. On the other hand, it is applauded as incentivizing research in the pharmaceutical industries. This comment discusses the position in relation to "patentable subject matter" before Mayo and the effects on the position of the U.S. courts on "patentable subject

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