

INTERPRETATION OF SECTION 3(D) IN THE INDIAN PATENTS ACT 2005: A CASE STUDY OF NOVARTIS

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§ Introduction

A recent judgment¹ of the Madras High Court in India (referred to as *Novartis* case) raised many questions of international law and the compatibility of the Indian Patents (Amendment) Act, 2005 with Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs agreement) of the World Trade Organisation (WTO). The Patents (Amendment) Act, 2005, was passed by the Indian Parliament to comply with the TRIPs obligations leading to the introduction of the product patent system in India for the first time.² The loss in the *India–Patent Protection for Pharmaceutical and Agricultural Chemical Products*³ (referred to as Patent case) at WTO was one of the main reasons for this.⁴ Even though India was a founder member of the WTO since 1995, it had opted for the Mail Box system according to Article 70(8) of the TRIPs⁵ agreement During the transitional period, between 1995-2005, Exclusive

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¹ *Novartis AG represented by it's Power of Attorney Ranjna Mehta Dutt v. Union of India (UOI) through the Secretary, Department of Industry, Ministry of Industry and Commerce and Ors.*, (2007) 4 MLJ 1153, decided on 6 August 2007.

² The Uruguay Round commitments compelled India to amend its patent regime in 1999, 2002 and 2005.

³ *India–Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50, WT/DS79.

⁴ The US and EU complained to the WTO Dispute Settlement Body (DSB) regarding the absence of either patent protection for pharmaceutical and agricultural chemical products or formal systems in India that permit the filing of patent applications for pharmaceutical and agricultural chemical products and that there is a need to provide for the grant of exclusive marketing rights for such products.

⁵ The “mail box” system is a TRIPs-imposed obligation on developing countries that wished to benefit from the TRIPs transitional period by delaying granting of patents for pharmaceutical products until 2005. In exchange for not granting patents, these countries had to establish a “mail box” system for receiving and filing patent applications from the beginning of the transitional period in 1995.

Marketing Rights (referred to as EMRs)⁶ were to be granted for a period of five years from the date of obtaining marketing approval in any country or until a product patent is granted or rejected, whichever was shorter with a cut off date from January 1, 1995. India granted only few EMRs for pharmaceuticals and agrochemicals during the transition period. Under this scheme, the following companies got marketing approval:

- Novartis AG for anti-blood cancer medicine, *Glivec/Gleevec* (beta crystalline form of imatinib mesylate).
- Eli Lilly & Company, USA for erectile dysfunction medicine, *Cialis (Tadalafil)*.
- Wockhardt for *Nadifloxacin* under the brand name NADOXIN.
- United Phosphorus for *fungicide saaf*, a combination of *carbendazim and mancozeb*.⁷

Civil society organisations raised serious questions regarding the access to medicines in India especially in the treatment of grave diseases such as cancer and HIV/AIDS, after the adoption of the product patent regime. The introduction of the product patent system had adversely affected many generic pharmaceutical companies in India which hitherto supplied low priced medicine to many developing countries in the world. In November 2003, the Controller General of Patents & Trademarks of India granted EMR to Novartis A.G. for *Glivec*, the blood cancer drug for a period of five years. In 2004, Novartis approached the court for restraining generic manufacturers from producing the generic version of the drug. Once the generic manufacturers stopped producing *Glivec*, the

⁶ Exclusive Marketing Rights were applied in case a product “waiting for a patent in the “mail box” obtained marketing approval before the “mail box” is opened and a decision is made on whether or not to grant the patent. In such a case, the manufacturer could request exclusive marketing rights for up to five years or until a decision is rendered on the patentability of the product, whichever is shorter. However, exclusive marketing rights were subject to two preconditions: a patent should have been granted for the same product in another WTO member country after 1995 (the date of entry into force of TRIPs), and marketing approval should have been obtained for this product in the other member country. EMRs were supposed to prevent others from coming onto the market until the patent would be granted or rejected. It is not surprising that in India the only drug that got exclusive marketing rights was *Glivec*.

⁷ George Kutty, “India Patents - Exclusive Marketing Rights (EMR)”, [http://ezinearticles.com/?India-Patents---Exclusive-Marketing-Rights-\(EMR\)&id=79426](http://ezinearticles.com/?India-Patents---Exclusive-Marketing-Rights-(EMR)&id=79426). (Last visited on December 27, 2007).

price of the drug rose from approximately Rs.10,000 for a month's requirement to a whopping Rs.1,20,000/-⁸ and thereby, leading to the question of the social cost of protection of higher intellectual property and the ability of the government of a developing country to maintain public health. This is a contentious issue and reflects the growing crisis of a developing country's preparedness in fighting diseases like cancer and HIV/AIDS.⁹

The debate on the accessibility to medicines, in the WTO Doha Ministerial conference led to the adoption of the Doha Declaration on TRIPs and Public Health, in order to help the least developed and developing countries that do not have sufficient manufacturing facilities of essential medicines. The Doha declaration states: "*We agree the TRIPs Agreement does not and should not prevent a Member from taking measures to protect public health*"¹⁰. However, the problems of developing countries are not addressed by multinational pharmaceutical companies. The *Novartis* case in India is only a starting point in its innings. The case raised substantial questions of TRIPs Agreement compliance and interpretation of international law by national courts.

§ The *Novartis* case

The *Novartis* case can be traced to 1997 when a patent application was filed by Novartis AG for the β -crystalline of imatinib mesylate (brand name *Glivec*) which was a slightly different version of their 1993 patent,¹¹ a vital anti-leukaemia drug, filed in the Chennai (Madras) Patent Office.¹²

The petitioner claimed that they had invented the beta crystalline salt from the free base of imatinib.¹³ In 2003, *Glivec* was granted EMR in

⁸ *The Hindu Business Line Daily*, Delhi, June 7, 2007.

⁹ Frederick M. Abbot and Jerome H. Reichman, "The Doha Round Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions," *Journal of International Economic Law*, Vol. 10, p. 927.

¹⁰ Declaration on the TRIPs Agreement and Public Health, Doha, 9-14 November, 2001 WT/MIN(01)/DEC/W/2,

<http://www.who.int/entity/medicines/areas/policy/tripshealth.pdf>.

¹¹ It was α - form of imatinib mesylate.

¹² The Petitioner holds patents for "Pyrimidineamine Derivatives" in countries like Canada (patent No. 2093203) filed on April 1, 1993 and granted on November 26, 2002 and the European Union (patent No. EP0564409), Patent No. US5521184.

¹³ See Annexure I and II for the chemical composition of the compound.

the Indian market.¹⁴ Novartis obtained orders preventing some of the generic manufacturers from producing the generic equivalents of *Glivec* in India. Soon, Novartis was selling *Gleevec* at USD 2666 per patient per year.¹⁵ Generic companies had been selling their generic versions at USD 177 to 266 per patient per month.¹⁶

Pre-grant oppositions were filed by Natco Pharma Ltd., M/s Cipla Ltd., M/s Hetro Drugs Ltd., M/s Cancer Patient Aid Association and M/s Ranbaxy Laboratories Ltd., India and in an order dated January 25, 2006, the Assistant Controller of Patents and Designs, Chennai Patent Office rejected the Novartis application.¹⁷

Novartis AG and its Indian subsidiary, Novartis India Ltd., filed writ petitions, in the Madras High Court challenging the decision of the Controller.¹⁸ The petitioner alleged that Section 3(d) of the Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005, is invalid, illegal and unconstitutional on the ground that there is arbitrary power vested in the executive according to Article 253 read with Article 73 of the Constitution of India. The petitioner, further, submitted that when enacting Section 3(d) of the Patents Act, the legislature had completely ignored the rationale underlying Articles 253 and 51(c) of the Indian Constitution,¹⁹ which allows the Parliament to mould municipal law in harmony with international treaties like the TRIPs Agreement of which India is a party.

¹⁴ According to Article 70 (9) of TRIPs, during the transitional period, Exclusive Marketing Rights (EMR) have to be granted for a period of five years from the date of obtaining marketing approval in that country or until a product patent is granted or rejected, whichever is shorter. India opted for EMR and "mailbox" facility for all applications for pharmaceuticals and agro-chemicals from 1 January 1995. This was expressly provided for under the Patents Act, 1970 in Section 24A of Chapter IVA of the Act added by the Patents Amendment Act (17 of 1999).

¹⁵ The drug is marketed under the brand name *Glivec* in Europe/Australia and *Gleevec* in the US.

¹⁶ The Novartis drug costs Rs.1, 20,000 per month in India. At the same time, the generic versions are available in the country which cost only Rs.8000 to Rs.10, 000/month.

¹⁷ Petitioner's patent application No.1602/MIS/1998 was for the beta crystalline form of imatinib mesylate sold under the brand name *Glivec* used for treating blood cancer (leukaemia) and Gastro-Intestinal Stromal Tumours (GIST).

¹⁸ *Novartis AG represented by its Power of Attorney Ranjna Mehta Dutt v. Union of India (UOI) through the Secretary, Department of Industry, Ministry of Industry and Commerce and Ors.*, (2007) 4 MLJ 1153.

¹⁹ Article 51(c) of the Indian Constitution provides for "foster respect for international law and treaty obligations in the dealings of organised people with one another."

In India, international treaties are not directly enforceable at the domestic level. Enabling legislations like the Patents (Amendment) Act, 2005, are necessary in order to fulfill international obligations. It can be argued that the treaties are not binding on Indian courts. However, the Constitution of India permits the Parliament to make any law for the implementation of an international treaty, to be enforced at the domestic level.²⁰ However, Article 253 is not an overriding power given to the Central Government to make laws to give effect to any treaty. It is subject to the other provisions of the Constitution and judicial decisions. For instance, Article 253 is subject to the “Doctrine of Basic Structure.”²¹

Sovereignty of a nation implies absence of any control of internal affairs by a foreign nation or agreement. A sovereign nation is free to make any laws to achieve its social, political and economic goals. Critics of the General Agreement on Tariffs and Trade (GATT) accuse that by acceding to the TRIPs Agreement, India’s sovereignty has been curtailed.²² Article 13 of the Constitution declares that any laws inconsistent with or in derogation of the fundamental rights under Part III of the Constitution of India, are void.²³ Justice V.R. Krishna Iyer, a former judge of the Supreme Court of India, explains the impact of WTO and the TRIPs Agreement on our economy in the following words: “*the thrust, of course, was the capture of world markets by the international corporate power incarnate, under the hegemony of America Incorporated. The GATT became an instrumentality for the implementation of this planetary big business agenda.*”²⁴ In *D.S. Nakara v. Union of India*,²⁵ the Supreme Court held that the basic framework of socialism is to provide a decent standard of life from cradle to grave to the working class. This kind of socialism, a blend of Gandhian and

²⁰ Article 253 of the Indian constitution reads – “*Legislation for giving effect to international agreements: Notwithstanding anything in the foregoing provisions of this Chapter (Part XI, Chapter 1-Legislative Relations), Parliament has power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country or countries or any decision made at any international conference, association or other body*”.

²¹ The ‘Basic Structure’ doctrine is the judge-made doctrine whereby certain features of the Constitution of India are beyond the limits of the powers of amendment of the Parliament of India. The Supreme Court laid down this theory in *Keshavananda Bharati v. The State of Kerala*, AIR 1973 SC 1461.

²² Manabendra Kumar Nag, “Indian Constitution, Tipped by the GATT, the TRIPs and the Indian Patent Law,” in Shiv Sahai Singh (ed.), *The Law of Intellectual Property Rights*, (New Delhi: Deep and Deep Publications 2004), 87.

²³ Article 13 of the Indian Constitution.

²⁴ V.R. Krishna Iyer, *Off the Bench*, (New Delhi: Universal Law Publishing), 2002 102.

²⁵ AIR 1983 SC 130.

Marxian socialism, has to be established in our country. This has been articulated in Part IV of the Constitution of India elaborating on the directive principles of State policy. Article 47 of the Constitution of India casts a duty on the State to raise the level of nutrition and the standard of living and to improve public health.

Similar provisions can be seen in the Constitutions of developed countries to safeguard the interests of the people. For example, Article 2 of the American Constitution.²⁶ Section 102(a) of Uruguay Round Agreement Act reads as follows: "*Section 102(a) (a) Relationship of Agreements to United States Law: (1) US Law to Prevail in Conflict: No provision of any of the Uruguay Round Agreements nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.*"²⁷ Therefore, any treaty law which is in conflict with the domestic law will be void and cannot be implemented. Unquestionably the legal position is clear that unless and until a treaty or convention has been given due effect in India under Article 253 of the Constitution of India, it has no binding value except as a moral appeal. A law may be enacted by the Parliament to give effect to an international treaty and the same may have received the approval of the President of India, however, it can still be struck down by the Supreme Court or High Courts of India as unconstitutional, if it violates any of the fundamental rights of citizens. In fact, courts in India have liberally invoked the international treaties and conventions for interpreting fundamental rights in an expansive and harmonious manner on many occasions.

On the other hand, on the question of granting patent to the invention of Novartis, the Assistant Controller relied on the following points:

Section 3(d) holding that the subject compound did not differ significantly in properties with regard to *efficacy* as compared to the known compound despite recording that there was a 30 per cent increase in bio-availability of the subject compound over the known substance.

²⁶ Article 2 of the American Constitution provides that "*He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur...*"

²⁷ Uruguay Round Agreement Act,
<http://www.copyright.gov/title17/92appiii.html#a3-1>
(Last visited on July 6, 2008).

Anticipation by prior publication, *i.e.*, the subject compound is already discussed in public documents and, thereby, destroying the novelty of the invention.

On the question of obviousness, the Assistant Controller has held that the subject compound is in the obviously naturally occurring form and there was no inventive step involved.²⁸

On the basis of the aforementioned reasons, the Assistant Controller concluded that imatinib mesylate was already known from prior publications because Claims 6 to 23 of the U.S. Patent application, a pharmaceutically acceptable salt of the base compound and the patent term extension certificate, specifically mentions imatinib mesylate as the product in the earlier patent application. Furthermore, the U.S. Patent discloses methanesulphonic acid as one of the salt forming groups and the patent specification clearly states that the required acid addition salts are obtained in a customary manner. Also that imatinib mesylate normally exist in the beta crystals form, which is thermodynamically a very stable product and, thus, the invention is obvious and anticipated by prior publication. For these reasons, it is not an invention under the Indian Patents Act, 2005.

The petitioner alleged that the decision of the Assistant Controller violated the principles of administrative law crystallised and reiterated by the decisions of the Supreme Court of India, in particular the *Wednesbury* principle.²⁹ However, in this particular case, it was held that the court would only intervene to correct a bad administrative decision on the grounds of unreasonableness. This position was reaffirmed in the *Council of Civil Service Unions v. Minister for the Civil Service*³⁰ case. According to Lord Diplock, the court will only intervene if the matter is “so outrageous in its defiance of logic or accepted moral standards that no sensible person who had applied his mind to the question to be decided could have arrived at it.”³¹ The discretionary powers of patent examiners are not discussed here and not warranted in this discussion.

²⁸ *Novartis Case*, (2007) 4 MLJ 1153, 5.

²⁹ *Associated Provincial Picture Houses Limited v. Wednesbury Corporation*, (1948) 1 KB 223, (1947) 2 All ER 680, per Lord Greene MR.

³⁰ (1985) AC 374.

³¹ (1985) AC 374, 410.

A. Patentability under TRIPs Agreement and Section 3(d) of the Indian Patents (Amendment) Act, 2005

Article 27(1) of the TRIPs Agreement provides that:

- Patents shall be available for any inventions, whether product or process, in all fields of technology; and
- Patent rights shall be enjoyable without discrimination in the field of technology.

The TRIPs Agreement does not specify what an *invention* is. National laws can define this concept according to the standards generally applied, that is, the tests of novelty, inventiveness and industrial application. It is also required that patents be available and patent rights enjoyable without discrimination irrespective of the place of invention, whether products are imported or produced locally. There is no obligation under the TRIPs to adopt an expansive concept of *invention*. While implementing Article 27(1) of the TRIPs Agreement, each country should carefully consider the economic, legal and ethical aspects involved in the patenting of living materials or certain types thereof.

Section 2(8) of the Patents and Designs Act, 1911, of Bangladesh defines *invention* in the following words: “*Any manner of new manufacture and includes an improvement over an allied invention.*” Unlike the Patents Act, 1970, in India, the 1911 Act does not specify the requirement of being useful in the definition of *invention*. But the courts have always held the view that a patentable invention, apart from being a new manufacture, must also be useful.”³² An “*invention is the act or operation of finding out something new; the process of contriving and producing something not previously known or existing, by the exercise of independent investigation and experiment.*”³³

Some countries may decide not to confer protection on new uses of plants, such as medicinal plants. The exclusion may also be on protection of new uses of plants, or *second uses* of known medicinal products, the patentability of which has been accepted in most industrialised countries. Likewise, computer programmes should be deemed not patentable, as in most countries of the world.

³² *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries*, AIR 1982 SC 1444.

³³ *Smith v. Nichols*, 88 U.S. (21 Wall.) 112, 22 LED.566; *Hollister v. Benedict & Burnham Mfg. Co.*, (1885), 113 U.S. 59, 5 S. ct. 717, 28 Led.901.

There is no uniform definition available which relates to the distinction between *invention* and *discovery*. According to the basic principles of patent law, the former is patentable and the latter is not. A *discovery* is commonly considered as the mere recognition of what already exists. Therefore, India can legitimately adopt a definition of *invention* that broadly excludes materials pre-existing in nature.

For instance, Argentina's Patents Law excludes from the concept of invention "*any kind of living materials or substance already existing in nature*".³⁴ Mostly the definition of invention is explained in the negative, *i.e.*, what cannot be considered as inventions.

The Indian Patents (Amendment) Act, 2005, defines what a *new invention* is.³⁵ The definition of *invention* and *inventive step* makes it clear that any existing knowledge or thing cannot be patented. Therefore, discoveries are excluded from patenting, subject to Section 3, unlike the practice of granting patents for a discovery in the United States. Section 3(d) stipulates the conditions to be fulfilled for patenting of an invention. The *efficacy* criterion is discussed elaborately in the section.

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations

³⁴ Article 6(g) of Patent Law, 1995, http://www.jpo.go.jp/shiryuu_e/s_sonota_e/fips_e/pdf/argentine_e/e_tokkyo.pdf. (Last visited on July 6, 2008); Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries, The TRIPs Agreement and Policy Options*, (Malaysia: Zed Books, 2000).

³⁵ Section 2(1)(l) defines "*new invention mean any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art*". Section 2(1)(ja) defines "*inventive step, as a "feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

In the common parlance, the expression *discovery* refers to “the act, process or an instance of gaining knowledge of or ascertaining the existence of something previously unknown or unrecognised.”³⁶ A discovery essentially refers to finding out something which already exists in nature but was previously unknown or unrecognised. Therefore, it is unlike an invention which refers to a new product or process involving inventive steps and capable of industrial application.³⁷

Section 2(1)(l) provides that a *new invention* means “any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of the patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the prior art.”³⁸ If a protein is engineered by biotechnological process with human intervention, it is not a mere discovery (subject to other conditions in the Act). It should be considered as an invention, but the question raised in the *Novartis* case was the patentability of a new form of already known chemical substances.

B. Novelty and Obviousness

In the *Novartis* case, the petitioners claimed that they had invented a particular form of methanesulfonic acid addition salt of a particular Pyrimidineamine Derivative (Imatinib Mesylate) in the crystal form. Additionally, it was claimed that the petitioners had invented the substance in two forms – *Alpha* and *Beta*- of which the *Beta* form can be stored easier, is less hygroscopic, easier to process and guarantees a constant quality of the final drug product. The *Beta* crystalline form of imatinib mesylate also results in higher bio-availability over the 1993 compound and, hence, differs significantly in properties with respect to *efficacy*.³⁹ The *Beta* crystalline form of imatinib mesylate was being

³⁶ The Webster’s Third International Dictionary of the English Language.

³⁷ Section 2(1)(j) of the Patents Act, 1970; Swarup Kumar, *Intellectual Property Watch*, June 2007.

³⁸ Section 2(1)(l) of the Patents (Amendment) Act, 2005,

http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf. (Last visited on July 6, 2008).

³⁹ See Annexure I for the chemical combination of the α and β -form of imatinib mesylate.

produced and sold on a commercial scale in India from 2003 after getting EMR.⁴⁰

The generic manufacturers and civil society organisations alleged that Novartis' *invention* lacked novelty, and was obvious to a person skilled in the art, and that it was merely a new form of a known substance that did not enhance the *efficacy* of the substance, and therefore, it was not patentable under Section 3(d) of the Patents Act. Different crystalline forms of imatinib mesylate did not differ in properties with respect to *efficacy*, and thus, the various forms of imatinib mesylate must be considered the same substance under Section 3(d). These arguments were based on the fact that Novartis had already been granted a patent in 1993 for the active molecule, imatinib, and that the present application only concerned a specific crystalline form of the salt form of that compound. It should be observed that Novartis' 1993 patent disclosed both the free base, imatinib, and the acid-addition salt, imatinib mesylate and the crystalline forms of imatinib mesylate claimed in the application in question do not significantly differ in properties with respect to *efficacy*.

Novartis claimed that "*The 1993 patent was for synthesizing the molecule of imatinib; this molecule, however, could not be administered to patients and represented only the first step in the process to develop Glivec. We developed the mesylate salt of imatinib and then the beta crystal form of imatinib mesylate to make it suitable for patients to take in pill form. Glivec was launched globally in 2001, and this is the only form of Glivec we have marketed.*"⁴¹ The petitioner also claimed that the price issue was immaterial since 99 per cent of the patients in India were getting free *Glivec* through their *Glivec* International Patient Assistance Program (GIPAP).

The petitioners alleged that the subject compound is two step removed from the prior art as it is a two-fold improvement over the prior art- first, the imatinib free base had been chemically changed into a salt form (the methanesulfonic acid addition salt) and second, a particular crystal form of this salt, *i.e.*, the *beta* crystal form which had been made through ingenuity and human intervention. Interestingly, the petitioners

⁴⁰ The EMR was intended to be in force for a maximum period of 5 years or until grant or rejection of Petitioner's product patent application (Black Box application) for the said drug whichever was earlier.

⁴¹ "Glivec Patent Case in India: FACT vs. FICTION", www.novartis.com/downloads/about-novartis/facts-vs-fiction-india-glivec-patent-case.pdf, (Last visited on October 25, 2007).

claimed that even if it were a discovery of a new form of a known substance, they could claim the patent because, it had resulted in the enhancement of the known efficacy of the known substance, *i.e.*, imatinib free base, thereby making the subject compound more efficacious. Since the expression *discovery* has not been defined in any section of the amended Patents Act, it could be construed in the ordinary meaning.⁴²

The law of novelty was recently explained by the House of Lords in *Synthon BV v. Smithkline Beecham Plc*.⁴³ There are two requirements, first, the matter relied upon as prior art must disclose the subject matter which, if performed, would necessarily result in an infringement of the patent. Second, the said disclosure must have been enabling, that is to say that an ordinary skilled person would have been able to perform the invention if he attempted to do so by using the disclosed matter and common general knowledge. The court also held that enablement and disclosure were distinct concepts and each had to be satisfied separately. For the purpose of disclosure, the prior art had to disclose an invention. Once the subject matter of the invention has been disclosed by the prior art then consideration has to be given to whether it can enable an ordinary skilled man to perform the invention. In *Generics (UK) Ltd. v. H Lundbeck A/S*⁴⁴, the court held that the claims were too broad and invalid for insufficiency. The court interestingly held that “The first person to

⁴² In the case of *Gopi Lal v. Lakhpat Rai* 1923 PC 103, it was held that the use before the date of the patent negates the novelty criteria in the invention. In this case, a letters patent was granted in respect of improvements in the manufacture of a medicinal preparation which was an improvement in the treatment of a substance found in the interior of some bamboos and known as ‘tabakshir’ or ‘bamboo mannah’ for the purpose of refining the same when in the raw state and to convert it into a nutritious and saleable article. The medicinal preparation was named and marketed as “banslochan” and admittedly had sold throughout India for a long time. The letters patent was granted for the improvements alleged to have been discovered by the respondents. This proposition was confirmed in an old case of *Patterson v. Gas Light & Coke Co* (1887) 3 AC 239, 244. It confirmed this position in *Bombay Agrarwal Co., Akola v. Ramchand Diwanchand* AIR 1953 Nag 154. Mere arrangement or re-arrangement or duplication of a known device or material cannot be patented- *Standpick (P) Ltd. v. Oswal Trading Co. Ltd.*, 1999 PTC (19) 479. It was very clear that in the present case also, the ‘same’ medicine, whether it was beta or alpha crystal form of imatinib mesylate (Pyrimidineamine Derivatives), which was used for curing the same disease is available in the market from 1993, hence the so called ‘new’ material could not be patented. The mere carrying forward of an original patented thing is like a workman carrying forward old ideas without any innovations *Smith v. Nichols*, 88 US 112. The novelty criterion is crucial in all patent applications.

⁴³ [2005] UKHL 59; [2006] RPC 10.

⁴⁴ [2007] RPC 32.

find a way of achieving an obviously desirable goal is not permitted to monopolise every other way of doing so.”⁴⁵

Mere obvious extensions of inventions are not patentable under any law, because most of the countries patent law rewards only the inventions that are new, useful and non-obvious advances. Indian law also incorporates the requirement of non-obviousness. Section 2(ta) of the Indian Patents Act, 2005, defines *pharmaceutical substance* as “any new entity involving one or more inventive steps”. Section 2(1)(ja) specifies that an *inventive step* refers to “a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance or both and that makes the invention not obvious to a person skilled in the art.” The U.S. Supreme Court, in *Graham v. John Deere Co*⁴⁶, laid down a four pronged test (Graham test) which laid out the basic standards for determining *obviousness*. The following are the determinants:

- The scope and content of the prior art.
- The structural similarity between the prior art and the claimed invention.
- Indication of non-obviousness and commercial success.
- The level of ordinary skill in the pertinent art.

But this test was converted into a synergism of the existing product or at least produces a synergistic effect in the *Burland v. Trippe Manufacturing Co.*⁴⁷ but the Supreme Court affirmed the *Graham test*. It seems that the *Graham test* is still valid today and adopted in India also.⁴⁸ However, obviousness rests on prior art and the structure of each

⁴⁵ *Ibid.*, para. 265.

⁴⁶ 383 U.S. 1, 17-18 (1966).

⁴⁷ 43 F. 2d 588 (7th Cir. 1976).

⁴⁸ The US Supreme Court in the famous case of *KSR International Co. v. Teleflex Inc.*, et al 127 S. Ct. 1727 (2007), analysed the test of obviousness and held that “In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under §103 of US Patent law. One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims. The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading [a prior art patent] with a sensor.”

chemical compound and a new compound's enhanced bio-availability and efficacy.⁴⁹

In the case of pharmaceuticals and chemical compounds, proving novelty is very difficult. In *In Re Williams*⁵⁰, the Board of Appeals rejected a claim on a single-enantiomer compound on the grounds of lack of novelty as well as lack of invention. Rejection on the basis of lack of novelty was based on a prior art reference that disclosed the production of a compound having a formula identical to the claimed compound.⁵¹ In the case of chemical compounds, in *In re Henze*,⁵² it was held that if the compound is closely related to the prior art compound, a presumption in favour of obviousness or a *prima facie* case of obviousness arises. This particular case established that, unless an applicant showed that the prior art compound lacked the property or advantages asserted for the claimed compound, the presumption of unpatentability was not overcome.⁵³ Finally, in *In re Merck & Co.*⁵⁴, the prior art not only disclosed a similar compound but “expressly stated that [the claimed compound] was expected to resemble [the prior art compound] clinically, in its depression alleviation effects.”⁵⁵

Recently, in *Angiotech Pharmaceuticals v. Conor Medsystems Inc.*,⁵⁶ it was held that the question of invention depends on many factors, especially what is claimed and what is prior art. Obviousness always depends on technicality rather than commercial considerations.⁵⁷ In *Teva Pharmaceutical Industries Limited, Teva UK Limited v. Merrell Pharmaceuticals Inc, Aventis Inc., Sepracor Inc.*⁵⁸, the court considered the question of ever greening of a patent in the anti-histaminic drug called terfenadine and its acid metabolite, terfenadine carboxylate, which also has the generic name fexofenadine. The court rejected the claims on the ground of lack of novelty.

⁴⁹ Jonathan J. Darrow, “The Patentability of Enantiomers: Implications for the Pharmaceutical Industry,” *Stanford Technology Law Review*, 2007, vol. 2, p. 10.

⁵⁰ 171 F.2d 319 (C.C.P.A. 1948).

⁵¹ 171 F.2d 319 (C.C.P.A. 1948).

⁵² 181 F. 2d 196 (C.C.P.A 1950).

⁵³ Elizabeth Verkey, *Law of Patents*, (Lucknow: Eastern Book Company), p. 45.

⁵⁴ 800 F.2d 1091.

⁵⁵ *In re Merck & Co.*, 800 F.2d 1091, 1096.

⁵⁶ [2007] EWCA Civ 5, para. 45.

⁵⁷ *Dyson v Hoover* [2002] RPC 22 at paras 56-67.

⁵⁸ [2007] EWHC 2276 (Ch).

In other jurisdiction, like the European Union (EU), courts have held, as in *Bayer AG (Meyer's) Application*⁵⁹, that a new use of a known substance is patentable if a newly discovered technical effect is described in the patent application. In *Ciba-Geigy's (Durr) Application*,⁶⁰ the plaintiff discovered that a known chemical could be used as a selective weed killer to kill monocotyledonous weeds occurring in a monocotyledonous crop and they sought a packed claim. It was held that a pack containing only a well-known and admittedly old material, has not by the words used, in any way, modified their pack or qualified it for the purpose for which the material is intended to be used. It was also held that one cannot have a patent for the new use of an old product unless there is an invention in the adaptation of the old product to the new use.⁶¹ A patent that did not reflect any new scientific insight but the manufacture of a known product from known materials, selected to achieve commercially acceptable efficiency loss, was considered as not patentable.⁶² It can be concluded that some times novelty and obviousness are misnomers when the properties and structure of the compound are similar. An increased *efficacy* of a known compound may not satisfy the novelty and obviousness criteria, but even then it is patentable under Section 3(d) of the Indian Patent Act, 2005. A significant improvement in the activity level may be considered as an increased *efficacy* level. However, exactly what is the level of improvement required for meeting the *efficacy* criterion under Section 3(d) is a question of public policy.

C. Efficacy

In the present case, the petitioners held patents for a form of *Pyrimidineamine Derivatives* which was patented in many countries (*Alpha* crystal form). Thus, the subject matter of the patent was already in the public domain and had already been published. The petitioners claimed that the new medicine developed from the *Beta* crystalline form showed a 30 per cent increased bio-availability over the known substance of the 1993 patent. The US Patent and Trademark Office (USPTO) issued a certificate to extend the patent validity of Patent No.5521184, based on the same product (*Gleevec*) imatinib mesylate patented in 1996.⁶³ This

⁵⁹ [1984] RPC 11 (UK Pat Ct).

⁶⁰ 1977 R.P.C. 83, CA.

⁶¹ *Acetylene Illuminating Co. Ltd. v. United Alkali Co. Ltd.*, (1904) 22 RPC 145.

⁶² *NV Philips v. Mirabella*, (1992) 24 IPR 1.

⁶³ In India, the medicine was marketed under the name of *Glivec*.

clearly shows that the same product was anticipated and published.⁶⁴ The Novartis' argument that Section 3(d) discriminates between pharmaceutical inventions and other inventions also did not hold good, because, the chemical combinations used for pharmaceutical purposes are required to meet a higher level of *efficacy*. The petitioner also claimed that the present application is for the *Beta* crystal form that they had invented in 1997 and that the earlier version was the *Alpha* crystal form. The petitioners claimed that imatinib mesylate exists in several forms including *alpha*, *alpha 2*, *beta* and H1 form. No teaching or suggestion existed in any prior art document to identify and anticipate the favourable properties or characteristics of the *beta* crystal form of Imatinib mesylate prior to it being invented. It is possible to obtain a patent for the first medical use of a known substance or composition, where this substance or composition was not previously known to have any medical application.⁶⁵ However, in the present case, the Imatinib mesylate was used in the manufacture of *Glivec* and therefore, it was obvious.

The most pertinent question was not whether the patented subject matter was an *invention* or mere *discovery*, but about the significantly increased level of *efficacy* of the new substance. In the case of pharmaceutical substances, the crucial question is with regard to its increased *efficacy* rather than the new substance. It is true that the standard of *efficacy* is neither prescribed in Section 3(d) nor under the Rules. It is vague and not in accordance with the policy of the country which is vigorously going for more and more foreign investment in the pharmaceutical sector and increased level of patent protection.

The earlier provision, Section 3(d) in the Patents Act, 1970, provided that "*the mere discovery of any new property of new use for a*

⁶⁴ The efficacy criterion has not been discussed in any of the popular patent legislations such as in the US or in the EU. The US patent law defines invention as a term meaning invention or discovery, Title 35, Part II, Chapter 10, § 100. Unlike in India, discoveries also can be patented in the US. The patentability criteria are loosely defined in the US law. It provides that "*whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.*" But the patentability criteria laid down that if the invention was known or used by others in the country or published in a printed format within or in a foreign country or in public use for more than one year prior to the filing of the application, then they are not eligible for a patent in the US. The non-obviousness clause also says, "*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title...*" We can see the similar language used in the Indian patent law also.

⁶⁵ Sopharma SA's Application, [1983] RPC 195.

known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant." It clearly excludes "mere discovery of any new property of new use" from the ambit of patenting. The explanation to Section 3(d) of 1970 Act also excludes derivatives of known substances of esters and salts from patenting unless the new substance significantly differs in properties with regard to *efficacy*.

The objective of repealing and including a new criterion in Section 3(d) of the 2005 Act was to increase the ambit of patenting. Under the new provision, the legislators intended to include the discovery of a known substance which has higher *efficacy* than the known substance. However, the Act never fixed a standard definition of *efficacy* for the patenting of such substance. The history of the TRIPs negotiations also does not imply any obligation on the WTO members to implement a uniform standard of inventions.⁶⁶ The lack of a uniform definition for an *invention* suggests that the Members of TRIPs Agreement can adopt a definition which is not inconsistent with Article 27(1) of the TRIPs Agreement.

The *efficacy* criterion has to be discussed in detail in the light of Section 3(d) of the Indian Patents Act, 2005. On this aspect, due to the dearth in domestic judicial exegesis, one has to examine cases from the United States for a better understanding of the key issues. In *Bristol-Myers Squibb Company v. Baker Norton Pharmaceuticals Inc. & Napro Biotherapeutics Inc.*,⁶⁷ the plaintiff was the proprietor of a European patent, EP 0 584 000, with a priority date of August 3, 1992.⁶⁸ The patent

⁶⁶ *Bridges Weekly*, Vol.11, No.1, <http://www.iprsonline.org/ictsd/news/bridges11-1.pg15-16.pdf>. (Last visited on October, 2007).

⁶⁷ [2000] E.N.P.R. 57.

⁶⁸ The EU Patent Convention stipulates that "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step." Discoveries, scientific theories and mathematical methods are specifically excluded. The novelty criterion in Article 54 stipulates that "an invention shall be considered to be new if it does not form part of the state of the art." It includes any kind of publication to the public prior to filing of an application. Invention shall be considered as involving an inventive step if it is not obvious to a person skilled in the art. There is no provision with regard to *efficacy* in the US or EU patent law. However, the EU Regulation 2309/93 with regard to the marketing authorisation of medicinal products, Article 11(1) provides that "a marketing authorisation shall be refused if it appears that the quality, the safety or the efficacy of the medicinal product have not been adequately or sufficiently demonstrated by the applicant." Recital 7 of Council Directive 2001/83/EC provides: "the concept of harmfulness and therapeutic efficacy can only be examined in relation to each other and have only relative significance depending on the progress of

claimed the administration of taxol in certain dosages to humans by infusion, for 3 hours or less, following a regime of premedication. The patent disclosed that a 3-hour period of infusion of taxol was safe and more efficacious than a 24-hour infusion period because it produced less neutropenia. In this case, Justice Jacob held that:

*“I finally come to obviousness. I think this is a very plain case. Winograd had disclosed 3-hour infusion with pre-medication was safe from the point of view of toxic shock. It was unknown how efficacious the 3-hour treatment was, save for Winograd’s hint that there were ‘responses in all arms.’ But there was every motive to find out. And in further testing of 3-hour infusion you would surely test for neutropenia. As I have said blood tests were routine in this sort of clinical trial. There simply cannot be any invention in pressing on with the OV.9 trial and finding out about the comparative levels of neutropenia.”*⁶⁹

Accordingly, the court rejected the application for want of novelty and obviousness.⁷⁰

On a closer look, Section 3(d) not only permits patenting of pharmaceutical products, but also new forms of known substances, provided there is a higher standard of *efficacy* of the new product. Neither the Act nor international practice gives a clear definition of *efficacy*. It can be construed that the intention of the legislature, when they re-drafted Section 3(d) in 2005, was to prevent pharmaceutical companies from ever

scientific knowledge and the use for which the medicinal product is intended. The particulars and documents which must accompany an application for marketing authorisation for a medicinal product demonstrate that potential risks are outweighed by the therapeutic efficacy of the product.” Annex I of Council Directive 2001/83/EC states that “... the treatment of the control group will vary from case to case and also will depend on ethical considerations and therapeutic area; thus it may, in some instances, be more pertinent to compare the efficacy of a new medicinal product with that of an established medicinal product of proven therapeutic value rather than with the effect of a placebo.” It is clear that the marketing approvals of a medicine are subject to its “efficacy” and “safety” of the product.

⁶⁹ *Ibid.*, para. 68 and 69.

⁷⁰ The same situation arose when China invalidated Pfizer Inc.’s second use of VIAGRA patent in 2004. Companies like Eli Lilly, Glaxo-SmithKline and Bayer waged legal wars with Pfizer’s VIAGRA patenting. Australia, Canada, Japan, and South Africa, UK and EU invalidated VIAGRA patent citing obviousness and lack of novelty. Richard A. Castellano, “Patent Law for new Medical Uses of Known Compounds and Pfizer’s Viagra Patent,” *The Intellectual Property Law Review*, 2006, Vol. 46, p. 283.

greening their patents by re-combining known substances.⁷¹ The High Court also suggested that *efficacy* can be defined as “*the ability of a drug to produce a desired therapeutic effect.*”⁷² It did not provide any guidance on how enhancements might be quantified, such as in terms of fewer side-effects or lower dosages.

1. The Madras High Court Judgment

The complainant prayed to the Court to declare Section 3(d) of the Patents (Amendment) Act, 2005, as inconsistent with the TRIPs Agreement and violative of Article 14 of the Indian Constitution. The second prayer was to allow petitioner’s patent application bearing No.1602/NAS/98 filed before the Madras Patent Office seeking patent. The whole argument with regard to the violation of Article 14 of the Constitution of India was based on arbitrary discretionary power vested in the Patent Controller in the determination of enhanced *efficacy*. The respondents argued that Section 3(d) has complied with the TRIPs Agreement and that the High Court was not the right forum to determine the issue rather the WTO Dispute Settlement Body (DSB) would be the appropriate forum. It was argued that the Members are free to adopt laws within the framework of the TRIPs Agreement, and to adopt and implement national policies, like, the right to health for its citizens.

The Court mainly considered the jurisdictional issue. The petitioner cited the Privy Council decision in *Equal Opportunities Commission & Another v. Secretary of State for Employment* (referred to *Equal Opportunities Commission case*)⁷². In this case, the question under consideration was whether judicial review is available for the purpose of securing a declaration that certain United Kingdom primary legislation is incompatible with European Community Law. The House of Lords held that this is a private law claim and dismissed the appeal, but declared the Employment Protection (Consolidation) Act, 1978, was

⁷¹ In the U.S. also, it is mandatory to submit evidence of effectiveness of clinical trial, effectiveness of the product and dose comparison trials for getting marketing approval of the drug, Centre for Drug Evaluation and Research Guidance Document, U.S. Food and Drug Administration, <http://www.fda.gov/cder/guidance/2097fnl.htm>, (Last visited on October 6, 2007). Bio-availability and bioequivalence studies in clinical trials of the drug are required for marketing approval, comparing performance of the formulation or dosage form used in clinical trials have to be submitted to the CDER. In India, the therapeutic efficacy, bio-availability studies and bioequivalence data have to be submitted along with the application for marketing approval. However, in none of the regulations the standard of efficacy is clearly defined or distinguished.

⁷² (1994) 1 All ER 910.

incompatible with Article 119 of the EEC Treaty and Council Directive (EEC) 75/117 and Council Directive (EEC) 76/207.

The petitioner argued for a similar declaration in this case, emphasizing that Section 3(d) was not in consonance with the TRIPs Agreement. But the High Court agreed with the respondents' argument that the *Equal Opportunities Commission* case can be distinguished on facts and cannot be said to be applicable in the present case. In that case, the EC Regulations were made applicable through various domestic legislations introduced but the TRIPs Agreement was never adopted in India and in fact the existing Patents Act, 1970, was amended in order to comply with its commitments under the TRIPs Agreement. The respondents cited the decision of *Salomn v. Commissioner of Customs*⁷³ in which it was held that if any domestic court is approached challenging a municipal law on the ground that it violates international law, then, the remedy for the lies in a forum other than the domestic court.

The High Court on that jurisdiction point held that:

*"... any International Agreement possesses the basic nature of an ordinary contract and when courts respect the choice of jurisdiction fixed under such ordinary contract, we see no compelling reasons to deviate from such judicial approach when we consider the choice of forum arrived at in International Treaties. Since we have held that this court has no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of TRIPS..."*⁷⁴

The High Court refused to look into the question of whether a private party has a right to enforce an international agreement or whether the Patents (Amendment) Act, 2005, is compatible with the TRIPs Agreement. With regard to the declaratory jurisdiction of the court, after referring to earlier decisions of the Supreme Court of India, it held that it is not going to be of any use for the petitioner and so the petitioner is not entitled for any declaratory relief.

Another important question considered by the High Court was, in the absence of guidelines under Section 3(d), how to establish the enhancement of *efficacy* of a known substance from which discoveries and new substances are made. In order to understand the meaning of the

⁷³ 1966 (3) A.E.R 871.

⁷⁴ *Novartis case*, (2007) 4 MLJ 1153, para 8.

word *efficacy*, the Court looked at the meaning of the expression *efficacy* in the field of Pharmacology, as explained in Darland's Medical Dictionary, which defines it as "*the ability of a drug to produce the desired therapeutic effect*" where *efficacy* is independent of the potency of the drug. The dictionary meaning of *therapeutic*, is the "*healing of disease - having a good effect on the body*,"⁷⁵

The Court also rejected the argument of the petitioner that the discretion vested in the patent examiners can be misused and the decision to reject the petitioner's patent application was due to the excess discretionary power entrusted with the statutory authority and, thus, it violates Article 14 of the Constitution of India. It was held that the amended provision cannot be invalidated solely on the ground that there is a possibility of misusing the power.⁷⁶ Before dismissing the petitions, the Court observed that the "*...object which the Amending Act wanted to achieve was namely, to prevent ever-greening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to it's citizens.*"⁷⁷

The implications of this judgment, at the procedural and industrial level, are yet to be assessed.

Pharmaceutical companies spend billions of dollars on research for developing a single product. A company has to spend approximately \$800 million and 15 years to bring a drug into the market.⁷⁸ It is estimated that, of every thousand potential drugs screened, only four to five reach the clinical trial stage and only one actually gets approved for marketing.⁷⁹ The exclusive rights given to pharmaceutical companies as patentee for 20 years, facilitates them to recover their investments. The prices of such medicines depend upon the pricing strategies and profit margins. This may lead to unaffordable prices of patented medicines in developing countries. The introduction of the product patent system, which did not exist in India earlier, through the Patents (Amendment) Act, 2005, gave multinational companies, EMRs rights over patented drugs in India. This means that the generic version manufacturers had to

⁷⁵ *Novartis case*, (2007) 4 MLJ 1153, para 13.

⁷⁶ *Novartis case*, (2007) 4 MLJ 1153, para 18.

⁷⁷ *Novartis case*, (2007) 4 MLJ 1153, para 19.

⁷⁸ Roger Pilon, "China's Viagra Test", Apple Daily (Hong Kong)

www.cato.org/cgi-bin/scripts/printtech.cgi/dailys/08-13-04.html, (Last visited on August 11, 2004).

⁷⁹ Andrade C, Shah N, Chandra S., "The New Patent Regime: Implications for patients in India," *Indian Journal of Psychiatry*, 2007, vol.49, pp. 56-59.

stop their production of a patented drug. The controversy is not on patenting, but the pricing of such medicines. The Act allowed compulsory licensing of certain patented medicines in certain circumstances.⁸⁰ India hardly used this provision against pharmaceutical companies. Other countries like Brazil announced compulsory licensing of several retroviral drugs which were distributed free of cost through its public health system. The Drugs Price Control Order, 1995, works as a strong deterrent of overpricing of medicines in India.⁸¹ However, only 74 medicines have been kept in the list, out of 500 commonly used bulk drugs. The Government has been vested with the powers under the Order in the National Pharmaceutical Pricing Authority (NPPA) to control the prices of medicines.

2. Implications of the Judgment and the Way Forward

The *Novartis* case once again raised the question of rationality of patenting and pricing of medicines. It is an open secret that the pharmaceutical companies always try to continue the protection through ever-greening of their patents by incremental innovations. Despite new drug inventions and life expectancy ratios, most of the people in the developing countries do not have access to these medicines mainly due to price barriers. On the other hand, Novartis argues, “*patents save lives by innovations.*”⁸² The Constitution of the WHO emphasises the need to have access to medicines for the poor. In 2005, the World Health Assembly considered a proposal for a Medical Research and Development Treaty (MRDT).⁸³ The main objective of this treaty was to set-up a new legal framework to promote research and development for pharmaceuticals and other medical treatments that function as an

⁸⁰ The law provides for compulsory license under Section 84 of the Indian Patent Act, 1970, to prevent the abuse of patent as a monopoly and to make way for commercial exploitation of invention by an interested person. Under this section, any person can make an application for grant of compulsory licence for a patent after three years, from the date of grant of that patent.

⁸¹ The Drugs Price Control Order (DPCO), 1995 is an order issued by the Government of India under Section 3 of the Essential Commodities Act, 1955 to regulate the prices of drugs. The Order inter alia provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention.

⁸² “India Glivec patent case”

<http://www.novartis.com/newsroom/india-glivec-patent-case/index.shtml>, (Last visited on July 7, 2008).

⁸³ However, after the 2005 initiative not much work has been done to achieve the objectives of the treaty to establish a common fund for innovation and research under the WHO.

alternative to patents and the monopoly drug pricing. Such international efforts may make an impact on the pricing strategies of the multinational companies.

It is submitted that the judgment of the Madras High Court in the *Novartis* case is in the right direction. Patent law is emerging in India and the Indian courts have followed a strict interpretation of an Indian statute which involves compliance with an international agreement. In history, every monopoly power has been abused and patent monopoly is not an exception. The interests of cancer patients are more important than monopoly rights. However, the ambiguities raised in the case should be filled by appropriate amendments to the patent law in India. The Patent Controller's decision to reject the claim is fully justified on the following grounds:

- (i) Novartis had not satisfied the pre-requisites for patenting, *viz.*, novelty, inventive step and non-obviousness.
- (ii) There is prior publication of the invention through patent applications filed in many countries, including Canada and U.S., in 1993, by taking priority from the Swiss applications filed in 1992.
- (iii) The patent application does not claim any added therapeutic efficacy from the α -crystal form disclosed in the earlier applications. Hence, the patent application cannot satisfy the scrutiny of Section 3(d) of the Indian Patents Act, 2005.

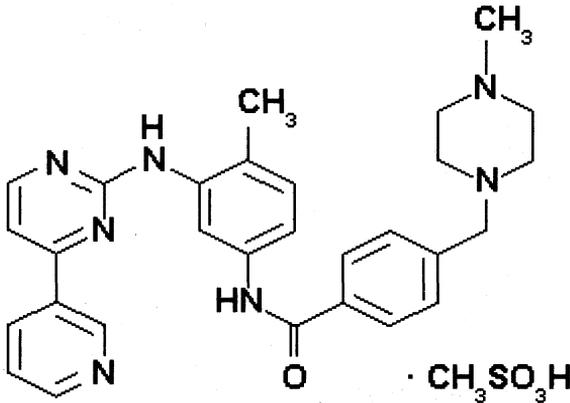
Governments can improve access to patented pharmaceuticals in three ways. First, they can utilize the flexibilities which are already embedded in the TRIPs Agreement and Doha Declaration on public health, such as making it mandatory to have a compulsory license issued in order to manufacture generic drugs. Second, they can adopt some mechanisms, such as price information, price competition and price negotiation with public procurement and an insurance scheme, which will enhance the affordability of the drugs. Third, governments can negotiate for a lower price with the pharmaceutical companies, as an incentive extended period of more than 20 years, which is the minimum stipulated under the TRIPs Agreement, can be allowed. The WHO can create a global database of the prices of drugs and the expiry of patent period so that there will be readily available data on the competitiveness of prices of medicines all over the world. Developing countries need cheaper medicines for fighting endemics like HIV/AIDS, Malaria etc.

On the flip side, if Section 3(d) is interpreted as rigidly as done by the Madras High Court in the *Novartis* case, Indian generic companies will never invest in drug research. There should always be incentive for innovation and research and the maintenance of equilibrium between proprietary rights and social interests. After the judgment in the case, Novartis announced that they will stall all investments in India and transfer it anywhere else where they would get protection. India should commit to intellectual property protection and promote long term investments in the pharmaceutical sector. Short term protection will deter multinational companies from investing in India and, thus, it will affect the availability of new medicines to patients in the coming future. Moreover, it raises serious questions of intellectual property protection, in general according to international standards.

On the other hand, pharmaceutical companies should implement differential pricing in developing countries in order to facilitate affordability of medicine. Simultaneously, innovation and research in the pharmaceutical sector should be adequately compensated. The present experience is that higher intellectual property protection means a higher barrier to accessibility. Economists also agree with the proposition that "*monopolies discourage efficiencies and potentially increase prices.*"⁸⁴ This theory seems more accurate when looking into the fact that 75 per cent of anti-retroviral drugs are controlled by monopolies.

⁸⁴ Tejas Sathian, "Patients vs. Patents", <http://hprsite.squarespace.com/patients-vs-patents-012007>, (Last visited on July 7, 2008)

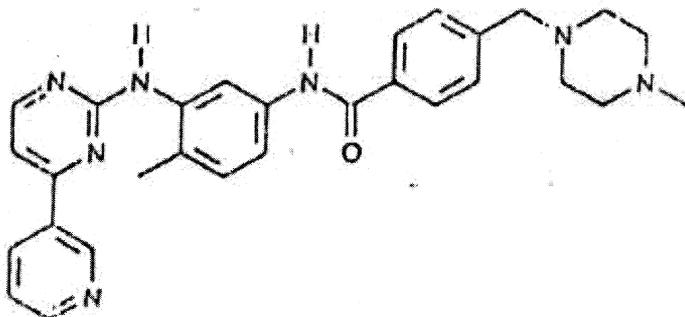
Annexure - I

DESCRIPTION of α -form

Source: fda.gov

Gleevec (imatinib mesylate) film-coated tablets contain imatinib mesylate equivalent to 100 mg or 400 mg of imatinib free base. Imatinib mesylate is designated chemically as 4-[(4-Methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-phenyl]benzamide methanesulfonate and its structural formula, Imatinib mesylate is a white to off-white to brownish or yellowish tinged crystalline powder. Its molecular formula is $\text{C}_{29}\text{H}_{31}\text{N}_7\text{O} \cdot \text{CH}_4\text{SO}_3$ and its molecular weight is 589.7.

Imatinib mesylate is soluble in aqueous buffers \leq pH 5.5 but is very slightly soluble to insoluble in neutral/alkaline aqueous buffers. In non-aqueous solvents, the drug substance is freely soluble to very slightly soluble in dimethyl sulfoxide, methanol and ethanol, but is insoluble in n-octanol, acetone and acetonitrile.

The Patent Claim on β Modification of Methanesulfonic Acid.

Source: Novartis Claim Petition

The β -crystal form of the 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino]phenylbenzamide.