Page 174 - 181 **DOI:** *https://doij.org/10.10000/IJLSI.11913*

INTERNATIONAL JOURNAL OF LEGAL SCIENCE AND INNOVATION

[ISSN 2581-9453]

Volume 3 | Issue 4

2021

Novartis Case: An Analysis of Section 3(D)

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ABSTRACT

Recent Judgment of the High Court of Madras in India (known as the Novartis case) many questions have been raised about international law and the compatibility of Indian patents Law (Amendment) Act 2005 to the Agreement on Intellectual Aspects of Trade World Trade Organization (WTO) property rights (TRIPS agreement).The Indian Parliament passed the Patents (Amendment) Act 2005 to comply with it TRIPS promises for the introduction of the product patent system in India for the first time. Protection in India of patent protection for pharmaceuticals and the WTO had agrochemicals (known as patented processes) at one of the main reasons for this.

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" 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.

I. INTRODUCTION: THE NOVARTIS CASE

The Novartis case dates back to 1997, when a patent application was filed Novartis AG for P-crystalline imatinib mesylate (Glivec brand),a slightly different version of their 1993 patent, an essential drug for leukemia, filed in Chennai Patent Office (Madras).[2]The petitioner claimed that they had Ne crystalline beta salt from the imatinib free base. In 2003, Glivec EMR was granted in the Indian market. Novartis received orders prohibiting several generic drug companies from doing so Manufacture of generic equivalents of Gleevec in India. Soon Novartis was selling Gleevec at $ 2,666 per patient per year. Generic companies had sold their own Generic versions for $ 177-266 per patient per month.

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[2] The petitioner holds patents for "Pyrimidineamine Derivatives" in countries like Canada (Patent No. 2093203) filed on 1-4-1993 and granted on 26-11-2002 and the European Union (Patent No. EP0564409), Patent No. US5521184.

 [ISSN 2581-9453]

Natco Phar objected to approvals Natco Pharma Ltd., Cipla Ltd., Hetro Drugs Ltd. into counter approvals. Cancer Patient Assistance Association and Ranbaxy Laboratories Ltd., India and in one order dated January 25, 2006, Assistant Controller of Patents and Designs, Chennai Novartis application was rejected by the patent office. Novartis AG and its Indian subsidiary Novartis India Ltd. submit written petitions in the Madras High Court challenges the governor's decision.[3] The petitioner alleged Section 3 (d) of the Patents Act 1970 as amended by Patents (Amendment) The 2005 law is invalid, illegal and unconstitutional because it is arbitrary power of the executive under article 253 in conjunction with article 73 there of Constitution of India.

The petitioner also argued that Article 3 be accepted the Patents Act, the legislature completely disregarded the underlying reasoning Articles 253 and 51 (c) of the Constitution of India which allow Parliament model local law in accordance with international treaties such as the TRIPS Agreement of which India is a part.[4]

On the other hand, the granting of a patent for the invention of Novartis the assistant controller relied on the following points: Section 3 (d) suggests that there was little difference between the compound in question Properties in terms of efficacy compared to the known compound despite the bioavailability of the material was found to have increased by 30%Binding to the known substance. Anticipation by prior publication, the compound in question is already discussed

A. Patenting under the TRIPS Agreement and Section 3 (d) of the Indian Patents (Amendment)Act, Article 27 (1) of the TRIPS Agreement provides:

- Patents must be available for all inventions, whether products or processes. Areas of technology; and
- Patent rights must be exercised without discrimination in the field of technology.

The TRIPS Agreement does not specify what constitutes an invention. National laws may define this concept according to the standards that are generally applied, that is to say tests Originality, ingenuity and industrial application. It is also necessary to have patents available and patent rights without discrimination regardless of their location Invention whether the products are imported or manufactured locally. There is no obligation adopt a broad concept of invention in the context of TRIPS. “Unlike the patent law of 1970, India was the1911 law does not impose the obligation to be useful in defining this Invention. However, the courts

[3] *Novartis AG* v. *Union of India*, 2007 SCC Online Mad 658 : (2007) 4 Mad LJ 1153.
[4] Art. 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*.”

have always considered it a patentable invention.

It should also be useful from a new manufacture. An invention or invention is an ‘invention’ An operation to discover something new; the process of invention and production something that was not previously known or existed as a result of exercising independence Investigation and experiment. “Some countries may decide not to protect new plant uses, for example: medicinal plants. The exclusion may also be related to the protection of new plant uses, orthe second use of known patented drugs. It is accepted in most developed countries. Computer programming must be the same it is not considered patentable, as in most countries around the world. There is no single definition of the distinction between Invention and discovery. According to the basic principles of patent law, the first is patentable and the latter not. Discovery is usually considered simple Acknowledge what already exists. Therefore, India can take a definition correctly of the invention, which largely excludes existing materials. For example, Argentine patent law does not include “any Type of living material or substance existing in nature”. Especially the definition the invention is explained negatively, i.e., which cannot be regarded as Inventions.

The Indian Patents (Amendment) Act 2005 defines a new invention. The definition of invention and inventive stage clearly indicates that the existing knowledge or the thing cannot be patented. Excluded discoveries are therefore subject to patent in Section 3, other than the practice of granting patents on discovery in the United States Conditions. Section 3 (d) sets out the conditions that must be met in order to patent an invention. Efficiency is the criterion is discussed in detail in this section. “Only a new form of a known non - resulting substance was found an improvement in the known efficacy of this substance, or a simple discovery any new property or any known or simple use of a known substance Process, machine or device, provided that such a recognized process does not result in a new product or use at least one new reagent.

Explanation - For the purposes of this clause salts, esters, ethers, polymorphs, Metabolites, pure form, particle size, isomers, isomer mixtures, complexes, Combinations and derivatives of other substances are considered to be known the same substance, unless their properties differ significantly in terms of Efficiency.”

In parallel, the term discovery refers to “the action, process or something an example of getting information or recognizing in advance that something is there unknown or unrecognized. "Discovery is basically about discovering something existing in nature, but not yet recognized or unrecognized. Therefore, it is different from an invention involving a new

product or an inventive process Degrees and industrially applicable Section 2 (1) (1) provides that a new invention means "any invention or technology" it was not intended to be published in a document or used in the country or elsewhere in the world before the date of filing of the patent application at full specifications, d. H. the article did not enter the public domain or any such thing it is not part of the state of the art. "When protein is developed the biotechnological process of human intervention (subject to other conditions prescribed by law) is not a simple discovery. It should be viewed as an invention, but it should the issue raised in the case of Novartis was the patentability of a new form of it known chemicals.

II. THE MADRAS HIGH COURT JUDGMENT

The petitioner asked the Court to clarify section 3 (d) of the patents the (Amendment) Act, 2005, as inconsistent with and in breach of the TRIPS Agreement Article 14 of the Constitution of India. The second prayer was to allow the petitioner Patent application number 1602 / NAS / 98 were filed with Madras patent office Apply for a patent. Total arguments for infringement of Article 14 there of the Constitution of India were based on an arbitrary choice given to the patent Controller to determine the improved efficiency. Respondents argued that Section 3 (d) complied with the TRIPS Agreement and the High Court did not the appropriate forum to determine the problem, other than the WTO Dispute Settlement Body (DSB) the appropriate forum. It has been argued that members are free to adopt Laws under the TRIPS Agreement and their adoption and implementation national policy, such as the right to health of its citizens.

The Court dealt primarily with the question of jurisdiction. The petitioner stated the resolution the decision of the board in *R. v. Secretary of State for Employment ex p (Equal Opportunities)*[5]

In this case, the question was the judicial one. The review is available to support a statement that some United the primary law of the Kingdom is incompatible with European Community law. The petitioner suggested and emphasized a similar statement in this case Section 3 (d) was inconsistent with the TRIPS Agreement. But the high court agreed with the defendants' argument that the Equal Opportunities Commission was a case they can be differentiated on the basis of the facts and cannot be said to be applicable in this case. In this case, community regulations were implemented through various national regulations. Laws were enacted, but the TRIPS agreement was never adopted in India and India.

In fact, the current patent law of 1970 was amended to comply with its obligations of the

[5] (1995) 1 A.C. 1: (1994) 2 WLR 409: (1994) 1 All ER 910

TRIPS Agreement. Respondents state a decision *Solomn v Commissioner of Customs*[6], found by national court, if any It is challenged to challenge a local law on the grounds that it violates international law, So the law is the remedy against lies in a jurisdiction rather than a national jurisdiction.

The High Court has ruled on this jurisdiction: Any international agreement has the fundamental nature of any international agreement Treaty and whether the courts respect the choice of jurisdiction established between them we see no compelling reason to depart from these legal proceedings. Approach if we consider the choice of forum reached in international treaties. Since we decided that this tribunal has no jurisdiction to rule on the validity of the Article amended in breach of Article 27 of the TRIPS Agreement

The High Court refused to consider whether a private party is a party the right to enforce an international agreement or if there is a patent law (amendment), 2005 is compatible with the TRIPS Agreement. For confirmation Jurisdiction of the court after reference to previous decisions of the Supreme Court India considered that the petitioner would have no use for this and therefore for the petitioners. The petitioner is not entitled to a declaration measure. Another important issue considered by the High Court was the lack Guidelines in section 3 (d) on how to improve efficiency a known substance from which new discoveries and substances are made. In orderin order to understand the meaning of the word efficiency, the Tribunal looked at meaning demonstrated efficacy in the field of pharmacology as discussed in Darlands Medical A dictionary that defines it as “the ability of a drug to produce the desired therapeutic agent Effect”, if the efficacy is independent of the efficacy of the drug the term therapeutic term means “cure of diseases - with a good effect on the Body”.

The Court also rejected the petitioner's argument that it was discretionary Patent examiners may be abused and the petitioner may reject the petitioner's patent decision the request arose because of the discretion placed on the law authority and thus infringes Article 14 of the Constitution of India. It was held this way the amended provision cannot be revoked on the sole ground of possibility of abuse of power. Before dismissing the petitions, the Court of Justice

The implications of this judgment at the procedural and industry level remain unresolved to evaluate. Pharmaceutical companies spend billions of dollars on research to build a business unique product. A company has to spend around $ 800 million and 15 years placing a drug on

[6] [1966] 2 All ER 340: [1966] 3 WLR 36.

the market.[7]It is estimated that out of a thousand potential drugs when screened, only four to five reach the clinical trial stage and only one actually receives approved for marketing[8]. Exclusive rights for pharmaceutical companies as patent holders for 20 years, allowing them to easily recoup their investments. Such prices medications depend on pricing strategies and profit margins. It can lead to itprices of unusable patented medicines in developing countries.

The product patent system, which did not previously exist in India, through patents (Amendment) The 2005 law gave EMRs multinational rights Drugs in India. This means that the makers of the generic version had to abandon their own. Manufacture of patented medicines. The controversy is not about patenting, but about pricing these drugs. The law authorized the granting of compulsory licenses for certain patented drugs certain circumstances. India has rarely used this provision against pharmaceuticals Companies. Other countries such as Brazil have announced the compulsory licensing of some countries retrospective drugs distributed free of charge through the public health system. The Drug Price Control Order 1995 serves as a strong antidote to overvaluation Medications in India. However, only 74 drugs were included on the list500 commonly used gross drugs. The government got the powers in accordance with the regulations of the National Pharmaceutical Pricing Authority (NPPA) for the Prices of drugs.

III. ANALYSIS AND CONCLUSION

The Novartis case again raised the question of the reasonableness of the patenting prices of drugs. It is an open secret that drug companies get try to keep protection by making your patents greener and greener through incremental innovations. Despite new drug inventions and life expectancy rates, most people are making countries do not have access to these drugs, mainly due to tariff barriers. On the Novartis, on the other hand, says: “Patents save lives through innovation”.[9]

The WHO Constitution emphasizes the need for access to medicines for the poor. In 2005, the World Health Assembly considered a proposal for medical research and development contract (MRDT).[10]Its main purpose the contract was to create a new legal framework to encourage research and development drugs and other medical treatments are available as alternatives patents and drug price monopoly. Such international efforts can be influence on

[7]RogerPilon, “China's Viagra Test”, Apple Daily (Hong Kong) www.cato.org/cgibin/scripts/printech.cgi/dailys/08-13-04.html,

[8] 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

[9]“India Glivec patent case” <http://www.novartis.com/newsroom/india-glivec-patent-case/index.shtml,

[10] ibid

pricing strategies of multinational companies.

It is alleged that the judgment of the Madras High Court in the Novartis case reads as follows: in the right direction. Patent law is emerging in India and is in Indian courts followed a strict interpretation of Indian law requiring compliance with international agreement. In history, all monopoly and power have been abused the monopoly of the patent is no exception. Cancer patients are more interested important as monopoly rights. However, the ambiguities raised in this case must be taken into account to be supplemented by appropriate amendments to patent law in India. Patent monitors

The decision to refuse the request is fully justified on the following grounds:

(i) Novartis did not meet the conditions for patenting, namely a new comer, inventive stage and invisibility.

(ii) The invention is published in advance by means of patent applications filed in priority by many countries, including Canada and the United States Swiss applications filed in 1992.

(iii) The patent application does not require any additional therapeutic efficacy a- Installation shape revealed in previous applications. Hence the patent application they cannot pass the Section 3 (d) examination of the Indian Patents Act 2005.Governments can improve access to patented medicines in three ways. At the start, you can take advantage of the flexibility already included in the TRIPS Agreement and the Doha Declaration on Public Health, e.g.

A compulsory license has been issued for the manufacture of generic drugs. Secondly, they can certain mechanisms such as price information, price competition and price support Negotiate with public contracts and covers insurance system Affordability of drugs. Third, governments can negotiate a lower price with the government Pharmaceutical companies, as an incentive, with an extended term of more than 20 years,

This is the minimum set out in the TRIPS agreement. WHO can create a global database on drug prices and patent expiration period for readily available data on price competitiveness

Medications worldwide. Developing countries need cheaper drugs to fight it Endemics such as HIV / AIDS, malaria, etc.

On the other hand, if Article 3 (d) is interpreted as strictly as Madras High does Novartis, manufacturers of Indian generic drugs will never invest in drugs Research. There should always be an incentive for innovation and research Maintain the balance between property rights and social interests. After that in this case, Novartis has announced that it will discontinue all investments in India and move to another location where it does. Get

protection. India should commit to protecting and promoting intellectual property long - term investments in the pharmaceutical sector. Short-term protection will act as a deterrent multinational company in India do not invest and this will affect the availability new drugs for future patients. In addition, it raises serious issues Intellectual property protection issues, generally international Standards. On the other hand, pharmaceutical companies should introduce differentiated prices in developing countries to make medicines more affordable. At the same time, Innovation and research in the pharmaceutical sector should be appropriate compensation. Current experience shows that the level of intellectual property protection is higher it means a higher barrier to accessibility. Economists agree with the suggestion that "Monopolies have a negative effect on efficiency and can raise prices." This theory it seems more precise considering that 75% of antidepressants are Drugs are controlled by monopolies.

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 [ISSN 2581-9453]