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JUDICIAL INTERPRETATION OVER THE REJECTION OF PATENT APPLICATION WITH REFERENCE TO NOVARTIS AG v. UOI & Others

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ABSTRACT

The study analyses about the judicial interpretations behind the rejection of patent application for Gleevec (beta crystalline form of imatinib mesylate) in India. Gleevec is a product of the Swiss pharma company, Novartis. The patentable and related subject matters were dealt under the Indian Patent Act of 1970, which had its latest amendment in 2005, which took the major role in this case. Under this act, the person who holds the right of patentability has the exclusive right over the subject matter which allows him to use, produce or sell the same which is valid for up to 20 years. The study extends its view, to know the footprints of the Novartis case; to analyse the interpretations made by patent officers and judicial authorities and to analyse the applicability of TRIPS Agreement in Indian patent law. The interpretation also extends to the concept of Anti Evergreening, patentability of invention, interpretation of sec 3 (d) of Indian Patent Act and its compliance with TRIPS Agreement, promotion of innovative technology and applicability of stringent patent law. This analytical study is a doctrinal study and related information is gathered using secondary sources such as articles, books, judgements etc. The analysis concluded by saying that since the drug is just the modification of existing imatinib, which already got its patent right, the second-generation patent right cannot be provided to the same.

Keywords: - Novartis, Patent, Gleevec, Myeloid Leukaemia, TRIPS Agreement, Anti-Evergreening.

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LIST OF ABBREVIATIONS

WTO – World Trade Organisation

EMR – Exclusive Marketing rights

HC – High Court

SC – Supreme Court

Act –Indian Patent Act

US – United States of America

Sec – Section

CML –Chronic Myeloid Leukaemia

GIST – Gastrointestinal Stromal Tumours

SLP – Special Leave Petition

IPAB – Intellectual Property Appellate Tribunal

Art – Article

LEGAL PROVISIONS

Indian Patent Act 1970

Indian Patent (Amendment) Act 2005

Indian Constitution 1950

Ayyangar Committee Report 1959

1. INTRODUCTION

Novartis case is nicknamed by some people as 'patents vs. Patients case'. More than 40 countries gave patent protection to Gleevec, but India refused. Keeping this is mine, let us see and facts and interpretations made in the case.

In this case, Novartis AG v. UOI & Others, three forms of imatinib (i.e., imatinib free base, imatinib mesylate non-crystalline and imatinib mesylate beta crystalline) were considered for interpretation under the section 3(d).

In 1993, the first form of imatinib got patented in more than 35 countries including the US, which

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however was not tested in humans. At that time Indian Patent law provides patentability for only processes and not products and also it didn't provide pharma patents till 1995, hence it was not patented in India. Later, to improve it, 2nd form of imatinib was identified, which further extends the research for the identification of the third form of imatinib which is used to produce Gleevec[1].

In 1998, one of the largest international pharmaceutical companies was Novartis. In July 17, 1998, it applied before Chennai Patent office for patent protection of third form of imatinib, i.e., beta crystalline form of imatinib mesylate and also pointing out its application in Gleevec, which can be used to treat CML and GIST through 'mail box'.

Since India is about to come up with a product patent from 2005, based on TRIPS Agreement, applications were received through 'mail box', which would be further examined after the enactment of the act. In the meantime, 2002-2003, Novartis got EMR for its product under sec 24A of the act. After the Patent Act was amended in 2005, Novartis' patent application was considered and received opposition from Cancer Patients Aid Association, NATCO, pharma, Cipla, Ranbaxy Laboratories and Hetro drugs.

In January 25, 2006, its application for patentability of 'Gleevec' was scrutinised based on oppositions and the patent officer rejected the application based on section 3(d) stating following reasons – there is no enhanced therapeutic efficacy; no new innovation is involved and since already patented, ever-greening of same is prevented.

Then, Novartis approached Madras High Court through writ petitions under Article 226 of the Indian constitution, and put forth three contentions, they are

i. Sec 3(d) seems contrary to the TRIPS minimum requirements which also violated Art 14 of the Indian Constitution and it also looks vague,
ii. 30% increase in bioavailability between the patented first form and present form of imatinib was evidently proved in rats which was not regarded by the patent officer,
iii. The controller also made errors in interpreting the enhanced efficacy of the product.

[1] Liu, Jodie, *Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Section 84 and 3(d) of the Indian Patent Act*, Vol. 56, HARVARD INTERNATIONAL LAW JOURNAL 207, 207-228 (2015).

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In August 6, 2007, Madras HC held that sec 3(d) is not violating Article 14 and also further forwarded the case to IPAB, in April 2007 under sec 117G, along with other pending cases[2], to deal with other issues, since it had no jurisdiction on the subject matters.

Further, IPAB reserved the decision of the patent officer i.e., assistant controller, and also allowed process patent for the product on June 26, 2009.

Then, unsatisfied with the decision of IPAB, Novartis approached SC through SLP under Art 136 on August 11, 2009. SC order was passed on April 1, 2013, which had gone through various interpretations which would be discussed in this research paper, further.

1.1 RESEARCH PROBLEM

If patentability is allowed for inventions, which are the modifications of the previous patented inventions, then it will decrease the effective participation towards innovative technologies.

1.2 RESEARCH OBJECTIVES

- To prove the compliance of Sec 3 (d) of the Indian Patent (Amendment) Act 2005 with TRIPS Agreement;
- To identify the use of uniformity or non-uniformity of patent regime in WHO member countries;
- To analyse the need for stringent standards for patent protection in pharmaceutical industries.

1.3 RESEARCH QUESTIONS

1) Whether section 3 (d) of Indian Patent Act is noncompliance with the TRIPS Agreement?
2) Whether the TRIPS Agreement mandates a uniform patent regime for member countries of WTO?
3) Whether a more stringent standard that requires non obviousness and Anti-Evergreening can contribute to the promotion of innovative technology?

[2] https://www.iralr.in/post/efficacy-in-pharmaceutical-products-novartis-ag-v-union-of-india

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1.4 HYPOTHESIS

Objective of the TRIPS Agreement should be prevailed in Sec 3 (d) of the Indian Patent (Amendment) Act 2005 otherwise it will be held unconstitutional.

1.5 SCOPE AND LIMITATIONS OF STUDY

The Scope of the study extends to Indian Patent (Amendment) Act and TRIPS Agreement in relation to Novartis AG Case. Hence, the scope of the study also extends to historical background of the case, judicial decisions and interpretations.

The study is limited to Indian law for patentability and there is no possibility of comparing with other countries Law and the participants of the study are Novartis pharmaceutical company, patent officer, HC and SC. Since it is also a part of academic work, researcher's time of doing research is also limited to five months, which restricts the researcher from doing comparison with other countries' patent laws.

1.6 METHOD OF RESEARCH

The study follows *Doctrinal Method of Study* using secondary sources such as articles, books, judgements, news etc. To have better analyses of sources, the researcher also adopted Qualitative, Descriptive, Explanatory and Secondary methods of study.

1.7 REVIEW OF LITERATURE

- In **Oke, Emmanuel Kolawole, in 2013[3],** the author stress that, Novartis failed to meet the requirements given under sec. 3 (d) of the Indian Patent Act - though Novartis has 30% enhanced efficacy, it failed to provide evidence that add more value to the invention in judicial interpretation; Novartis failed to give access to the generic drugs in affordable price; further this section prohibits evergreening to promote more innovative inventions, but Novartis tries to ever-greening its product.
- In **Thambisetty, Siva, (2013)[4],** Some effects from Novartis case were given, which remains the landmark case, in doubting the effective implementation of patent law in other member

[3] Oke, Emmanuel Kolawole, *The Indian Novartis Case: Finding the Right Balance between Access and Innovation* (August 28, 2013).
[4] Thambisetty, Siva, *Novartis v Union of India and the Person Skilled in the Art: A Missed Opportunity* (September 19, 2013).

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countries of WTO. If it had a great effect in the US, many people would ask for revocation of patents for life saving drugs in the US.

- In **Kumar, Shanti and Shukla, Nitin and Sangal, Tanushree, (2009)**[5] discussed the prevention of Evergreening of patents, which is supported using sec 2 (1) (1), sec 2 (1) (ja) and sec 3 (d) of Indian patent act. Authors also explained clearly how Novartis lost its efficacy test. Inconsistency of section 3 (d) with TRIPS Agreement also has the major role in this research work.

2. JUDICIAL INTERPRETATION

The SC, to interpret this case, traced the importance and evolutions undergone in Indian patent law from 1949 to amendment in 2005.

- First, it looked into recommendations of Ayyangar committee report, which leads to the enactment of the Patent Act 1970;
- It then traced the effects of the enactment of 1970 act on the Indian pharmaceutical companies in comparison with MNC pharmaceutical companies;
- Then, it searched for the reason behind non permissive of patentable rights on pharmaceutical, chemical and food products till 2005;
- Then it looked into the product patent based on the obligations of TRIPS Agreement of WTO and other relevant provisions of TRIPS Agreement and also the necessary flexibilities under Doha Declaration;
- And finally, SC looked into the case and its facts where the problem arises on correct interpretation of sec 3(d) of the act, which also includes the subsequent debates that took place in the parliament and letters that are received from organisations like WTO and others.
- Tracing the above said subject matters, following issues were framed in this case, to pass the judgement after interpreting,

2.1. How sec 3(d) is interpreted with the invention in this case?

The aim of section 3(d) is to encourage innovations by preventing ever-greening of already patented inventions. In parliamentary debate on March 22, 2005, it was stressed that there is some purpose

[5] Kumar, Shanti and Shukla, Nitin and Sangal, Tanushree, *Evergreening of Patents and Indian Patents Law* (June 15, 2009).

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hidden behind the sec.3 (d) of the Act which aims at preventing practice of ever-greening in the field of pharmaceutical industry, which is discussed in the following chapter.

2.2. Whether invention qualifies the test of novelty and inventive step?

Test of invention and patentability

Sec 2(1) (j) and Sec 2(1) (ja) of the patent act laid down some conditions, satisfying which, any subject matter will be considered as invention;

- Novelty
- Industrial application and
- Inventive step

After passing the test of invention, the same subject matter should also pass the test of patentability which is not exclusively given in law, but subject matters which are not patentable are listed under sections 3 and 4 of the acts.

Novartis failed to show novelty in the product, hence it didn't pass the test of invention and subsequently it cannot be patentable.

2.3. Whether increase in bioavailability of the existing substance amounts to enhanced efficacy?

To define the term 'efficacy', SC used Oxford dictionary's meaning and also observed in this case that 'efficacy is the capability to give a desired result'[6].

A known substance which is developed into a new form is not an invention, unless it shows enhanced efficacy. Here efficacy means therapeutic efficacy. But there is no evidence provided by Novartis to evident enhanced therapeutic efficacy of the product, by administering in human body[7].

3. RESEARCHERS INTERPRETATION INCONSISTENT WITH JUDICIAL INTERPRETATION

[6] Chandru, Ajay and Gokhale, Gowree, *Novartis Indian Supreme Court Judgment: what is efficacy for pharmaceutical invention?* Vol.2, MANUPATRA INTELLECTUAL PROPERTY REPORTS 165, 165-172 (May 2013).

[7] Arcuri, Alessandra and Castro Bernieri, *Rosa Julieta, How Innovative is Innovative Enough? Reflections on the Interpretation of Article 27 TRIPS from Novartis v. Union of India*, SOCIETY OF INTERNATIONAL ECONOMIC LAW (SIEL) INAUGURAL CONFERENCE 2008 PAPER (July 14, 2008).

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3.1 Whether section 3 (d) of Indian Patent Act is noncompliance with TRIPS Agreement?

India signed the TRIPS Agreement in 1995 and agreed to give patent protection for products also, in accordance with the Art 27 of the TRIPS Agreement for the enhancement of the pharmaceutical industries. Since India needs some time to understand and adopt the minimum standards, it postponed till 2005 for granting product patents until applications are welcomed through 'mail box' and granting of EMR is also provided till 2005, which is considered as transitional period. By the expiration of the transitional period, a bill was passed by the Indian parliament and adopted the TRIPS standards through Indian patent (Amendment) Act 2005.

To answer the research question, whether section 3 (d) of Indian Patent Act is noncompliance with TRIPS Agreement? Article 27 is looked into which consists of three paragraphs;
Second sentence of the first para, allows national laws to be different without showing discrimination;

- Further Paras 2 and 3 gives circumstances for non-patentability of inventions which is given in a broad manner.

Like, it allows non patentability of circumstances like public health, which allows restriction on patentability of pharmaceuticals that causes great impact on the public.
{Hence TRIPS Agreement allows nationals to have stringent standards for patentability of pharmaceutical products since it affects the public at large.}

3.2. Whether the TRIPS Agreement mandates a uniform patent regime for member countries of WTO?

First para of Article 27 of TRIPS Agreement laid conditions for patentability of inventions, which should have novelty, incentive steps and industrial applicability.

- The condition 'Inventive step' is not specifically explained in the agreements, which gives open access to interpretation, hence its meaning 'non-obviousness' is observed in the Indian patent Act, likewise other countries can adopt their own interpretation of the term 'inventive step'.
- Again, for interpreting the same 'inventive step', the objectives of the TRIPS Agreement started under Art 7 is looked into, which aims at promoting technological innovation and it

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depends on the social and economic welfare of the country which won't be the same for all the member countries'.

- Thus, the degree of stringency may vary in patent law from one country to the other depending on its social and economic welfare.

[Hence TRIPS Agreement not mandates a uniform patent regime for member countries of WTO]

3.3. Whether a more stringent standard that requires non obviousness and Anti-Evergreening can contribute to the promotion of innovative technology?

To consider the stringency of non-obviousness of the patent law, Art 7 and 8 of TRIPS Agreement are looked into which tells about its objectives and principles. It is observed that the stringency of the non-obviousness promotes the technological innovation in the country which should also be used for social and economic welfare of the respective country. Therefore, to have an innovative technology, a stringent non obviousness standard helps to achieve the goal, which is there in sec 3(d) of the Indian patent act.

Evergreening is the process by which patentees will get patentable rights to their invention which would show only minor changes from the previous invention. This process of Evergreening will fail to bring more innovative technologies. Hence non patentability of Evergreening of Gleevec is also acceptable, which will retain further innovations and also will try to present competition to attain Monopoly right. Thus, Anti Evergreening promotes innovative technology.

4. CONCLUSION

Novartis' case remains as a good interpretation of the scope and the applicability of the sec 3(d) of the act. The judgement passed in this case encourages the inventions with more innovations rather than having minute changes in previous inventions, thus leading the environment to have more genuine researchers.

The Novartis case showed a serious effect in WTO member countries. Médecins Sans Frontières, released a statement relating to this Novartis case, that he called it as 'Attack on the pharmacy of the

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developing country[8]'. With the effect of this case, US blacklisted Indian trade, which forced other countries to have more focus towards innovation. 170 US congress members, write to President Obama to look into the necessity of life saving drugs to revocate their patentability. Thus, though the Novartis case was the first product patent case in India, the interpretation in this case made other countries look into the same to promote innovative technology.

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[8] THAMBISETTY, SIVA, *supra* note 4, at 8.

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