NOVARTIS CASE : IMPACT OF SECTION 3(D) OF TRIPS ON INCREMENTAL PHARMACEUTICAL INVENTION

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ABSTRACT

The TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement came into force on 01-01-1995. India being the Founder member of the WTO (World Trade Organization) the umbrella Organization, had to sign and ratify the TRIPS agreement which was an international agreement among the members of the WTO on the governance and regulation of intellectual property rights. Within the ten years transition period, India carried out three amendments in the patents Act 1970 i.e. 1999, 2002 and 2005 to make its patent law fully compliant with TRIPS agreement. By 2005 patent amendment product patent was introduced by deleting Section 5 of the patents Act 1970 and section 3(d) of the Act was also amended. This section 3(d) was amended to reject all those patents which were claimed to be new forms of a known substance unless they displayed enhanced efficacy over the previous one. This paper argues that section 3(d) encourage real inventions including incremental invention. This paper is confined to the examination of the question "whether increased bioavailability of the drugs can be included as an enhanced therapeutic efficacy under section 3(d)." This paper will try to answer this question by examining and discussing the landmark judgment of the Supreme Court in Novartis A G versus Union of India & other along with its broad implications on the Pharmaceutical innovator companies.

Keywords : TRIPS, Novartis AG Versus Union of India, Pharmaceutical Section 3 (d) and Efficacy.

INTRODUCTION

The Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement is an international multi-lateral agreement on Intellectual property rights which came into existence on 01-01-1995 at the end of the Uruguay round of the GATT (general agreement on tariffs and trade) leading to the establishment of the World Trade Organization (WTO). Annexure 1 C of the Marrakesh agreement which created the World Trade Organization (WTO) was compulsorily binding on the member countries of the WTO to sign and comply with the TRIPS agreement before becoming a member of the WTO.

India being the founder member of the WTO had also to sign, ratify and comply with the TRIPS agreement. within the ten years of transition period allowed to all the developing countries including India, India carried out three amendments in the patents Act 1970 i.e. 1999, 2002 and 2005 to make its for patent law fully compliant with the TRIPS agreement. By 2005 patent amendment product patent was introduced by deleting Section 5 of the patents Act 1970 and section 3(d) was also amended. This section 3(d) was amended to reject all those patents which were claimed to be new farms of known substance unless they displayed enhanced efficacy over the previous one.

This paper argues that section 3(d) encourages real inventions including incremental inventions. This paper is restricted to the examination of the question "whether increased the bioavailability of a drug can be included as an enhanced therapeutic efficacy under section 3(d)." This question will be answered on the basis of the findings and conclusion recorded and made by the supreme court in the landmark judgment of Novartis AG v/s Union of India decided in the year 2013.

SECTION 3 (D) AND ITS EFFICACY

Section 3 (d) has been at the center of controversy following the 2005 patents amendment in the patents Act 1970. Many Pharmaceutical multinational companies time and again have raised their concern with regard to the language of section 3(d) being ambiguously drafted.

Their primary concern is related to the enhanced efficacy aspect of section 3(d) which is the basic requirement of patentability of a new form of known substance. therefore; if the new form of a known substance does not quality the test of enhanced efficiency over the already known efficacy of the previous substance then the new form in question will not be considered a new product and will therefore; not be patentable under section 3(d) .

Section 3(d) is being reproduced here under for our examination:

Section 3(d) "What are not inventions"

The following are not inventions

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

EFFICACY UNDER SECTION 3 (D)

The word efficacy has been used first in the substantive text of section 3(d) and thereafter, the same has been used in the explanation appended to Section 3(d). According to the new Oxford dictionary the word efficacy means "the ability to produce a desired or intended result."

NOVARTIS AG V/S UNION OF INDIA

(A) Facts of the case

The Novartis AG (Appellant) filed an application no. 1602/MS/1998 on 17-07-1998 seeking a patent for its product "Imatinib Mesylate" in beta crystalline form before the patent office at Chennai claiming as follows:

i. It has more beneficial flow properties.

ii. It has better thermodynamic stability.

iii. It has lower hygroscopicity than the alpha crystal form of the product.

Further, the Appellant Novartis claimed that these above-mentioned properties made the invented product "new", superior, and easier to process with better process ability and storage.

Since the Indian patent law was in transition at that particular time; therefore, the Appellant Novartis had resorted to the "mailbox procedures" and it was granted "EMR" (Exclusive marketing rights) on its so-called new product on 10-11-2003 by the patent office.

After coming into force the 2005 patent amendment, Novartis" application was taken up for consideration and the application on for grant of patent was rejected by the assistant controller of patents and designs on 25-01-2006 on the following grounds:

1. Novartis invention was anticipated by prior publication, i.e. the Zimmermann patent
2. The invention was obvious to a person skilled in the art
3. The invention in question was hit by section 3(d) and hence not patentable.

Novartis challenged the order of assistant controller by way of filing writ petitions directly before the madras high court on the ground that section 3(d) of the patents Act 1970 was unconstitutional and violative of article 14 of the constitution of India and also on the ground that the said section 3(d) was also violative of the TRIPS Agreement as it was not compliant with the agreement. The write petitions were dismissed by the madras high court holding that section 3(d) was not violative of article 14 of the constitution of India. So for as the challenge of section 3(d) "compatibility with the TRIPS was concerned, the madras high court did not touch this dispute on the ground that domestic courts did not have jurisdiction to resolve disputes regarding municipal law" compliance with an international agreement.5

The other five writ petitions were transferred to the IPAB (intellectual property appellate board) after its formation and were registered as appeals. The appellant Novartis "appeals were also dismissed by the IPAB on 26-06-2009.however, the findings of the Assistant controller were reversed by the IPAB and the IPAB held that Appellant" invention satisfied the test of novelty and non-obviousness.

The IPAB, however, categorically held that the subject product in question of the Appellant was not patentable as it was hit by section 3(d) of the Act.

Now the Appellant Novartis challenged the order of IPAB by filing SLP (Special Leave Petition) under article 13 of the constitution of India. Now this paper will discuss and deal with the findings of the Supreme Court made in this case on significant aspects of section 3(d).

(B) Section 3(d) and interpretation of Efficacy

While dealing with the controversy with regard to the meaning and interpretation of the term "Efficacy" under section 3(d) the supreme court held that since the term "Efficacy" means the ability to produce a desired result or the result intended to be achieved, the test of efficacy under section 3 (3) would depend on the function, utility or the purpose of the product in question. Therefore, if the product in question was a drug or medicine to cure an ailment; in that cash the efficacy wold be "therapeutic efficacy" only the supreme court, thereafter, moved on to the next important question as to what would be the basis of Judging. The therapeutic efficacy and the question whether every advantage and benefits can be considered while judging the enhancement in the therapeutic efficacy. the supreme court held that the amended section 3(d) clearly and unambiguously uses the worlds "enhancement of the known efficacy" and also in the explanation, the requirement of the derivative to "differ significantly in properties with regard to efficacy" Makes section 3(d) crystal clear and leaves no room for any doubt that it intends to consider only the advantages which improves. Upon or enhances the therapeutic efficacy of the known product.

Now the controversy with regard to the interpretation of efficacy under section 3(d) is no more res-integra after the Novartis case.

(C) Section 3(d) encourages inventions including incremental inventions

After 2005 patent amendment which introduced novel standards of patentability by way of amended section 3(d) , there was a widespread atmosphere of fear and transitions among the multinational Pharma Companies with regard to their intellectual property rights and the fear of rejection of their patent applications as they viewed section 3(d) as a big impediment in the way of their patent rights designed and devised in such a crafty way that it was found by these multinational companies to be obscure especially in terms of the test of "Enhanced efficacy" These MNCs raised Their concerns and objected to the parameter of "Enhanced Efficacy as they found it demoralizing and discouraging to the research and development activities further saying that section 3(d) would discouraging new inventions and the MNCs would not be investing in the R&D. In India.

The Novartis case is further a big setback to these MNCs I do not find the fears and apprehensions of these multinational companies to be valid rather these fears and apprehensions are misplaced. India amended section 3(d) for the purpose of putting a check on take inventions popularly known as "evergreening". India has designed section 3(d) in such a unique Fashion that it does not discourage real inventions.

This section 3(d) prescribes a unique test of "enhanced efficacy" over the efficacy of known product and that test has to be qualified before being entitled to be patentable. So has been categorically held by the Supreme Court. Therefore, the Supreme Court judgment has put the controversy of enhanced efficacy test at rest.

In my considered view, section 3(d) encourages real inventions including incremental inventions. Now the MNCs as well as domestic players will have to spend time and money in inventing new products and putting genuine efforts in research and development will bring new efficacious drugs and medicines for the benefit of the public at large.

(D) Increased bioavailability of a drug as an incremental invention and section 3(d)

One of the objectors in the Novartis case argued that in the field of Pharmaceuticals action of a drug is explained by "Pharmacokinetics" (effect of the body on the drug) and "pharmacodynamics" (effect of the drug on the body)

According to the objection raised by this objector "Pharmacodynamics property" was the drug "efficacy in terms of producing the desired result. The objector relied upon the Goodman and Gillman, according to them, "the generation of response from the drug receptor complex is governed by a property described as efficacy" He further relied upon Dorland" medical dicnary to define the word efficacy as the "ability of the drug to produce the desired therapeutic effect".

It was, therefore, argued by this objector that bioavailability was a pharmacokinetic property and not pharmacodynamics property. As per Goodman and Gillman, bioavailability is the "term used to indicate the fraction extent to which a dose of drug reaches its site of action or a biological fluid from which the drug has access to its site of action"

The Appellant Novartis claimed that its beta crystalline form of Imatinib Mesylate had 30 percent increased bioavailability as compared to Imatinib in free phase form.

Therefore, the appellant claimed its product to have an enhanced efficacy. Now the Supreme Court had to deal with and adjudicate upon this very moot question as to "Whether a mere assertion of increased bioavailability of a drug can lead to an inference of enhanced therapeutic efficacy?"

To address this issue, the court attention was invited to a quotation from a commentator as under:

"It is not the intent of a bioavailability study to demonstrate effectiveness, but to determine the rate and extent of absorption. If a drug product is not bioavailable, it cannot be regarded as effective. However a determination that a drug product is bioavailable is not in itself a determination of effectiveness."

The Supreme Court after careful consideration of the submissions made come to conclusion as under:

"The position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research date. In this case, there is absolutely nothing on this score apart from the adroit submissions of the Council. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or Superior efficacy (Therapeutic) on Male culer basis then what could be achieved with Imatinib free base in Vivo animal model"

Therefore, the above Conclusion and finding of the Supreme Court is crystal clear. The court has nowhere said that all the cases of increased bioavailability of drugs would fail the test of enhanced therapeutic efficacy under section 3(d).

The court clarified further that any case of increased bioavailability of a drug or medicine could quality the test of enhanced therapeutic efficacy. Provided the drug or the medicine in question was claimed specifically to have such enhanced therapeutic efficacy and proved as such by reliable research data.

Therefore, This paper reaches the unambiguous conclusion on the basis of the findings of Novartis AG case that even an increase in the bioavailability of a drug can be accepted as an incremental invention which deserves to patentable under section 3(d) provided.

This increase in bioavailability leads to an undoubted and genuine enhancement in the therapeutic efficacy of that drug on the human body and clearly established and proved as such by research data.

The Supreme Court went further to even express its views as under:

"We have held that subject product, the beta crystalline form of Imatinib Mesylate, does not quality the test of section 3(d) of the Act but that is not to say that section 3(d) bars patent protection for all incremental invention of chemical and Pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of Section 5 from the parent Act. This is not said in this judgment.

On the basis of above Court findings, This paper also concludes that section 3(d) promotes and encourages real inventions including real incremental inventions section 3(d) is no bar to genuine inventions including incremental inventions there is no doubt that section 3(d) serves the purpose it was enacted in a unique fashion i.e. to curb evergreening of patents on minor modification.

FUTURE IMPLICATIONS OF NOVARTIS CASE

The Novartis judgment, being the landmark case on the scope, application and interpretation of enhanced efficacy aspect of section 3(d) will undoubtedly have broader implications on the future prospects of pharmaceutical companies including both multinational and domestic.

Now following the Novartis case, there remains no ambiguity with regard to the patentability criteria under section 3(d) and its enhanced efficacy to mean the enhanced Therapeutic efficacy of drugs and medicines. Therefore, the Novartis case will now create an atmosphere of genuine research and development activities among the pharmaceutical companies leading to more genuine efforts in carrying out real research and development of new drugs, Thereby promoting an atmosphere of competition between the Pharma Companies. This judgment will also encourage domestic Pharma Companies to get into rigorous research and development activities and bring out new inventions. This judgment will also pave the way for bringing out real and genuine incremental invention.

The Novartis case is for sure to have both domestic as well as Global Impact on the Pharmaceutical sector. According to Gangte in domestic Pharmaceutical sector, the Novartis reling has definitely paved the way for cheaper casts of life saving drugs following the Novartis ruling by the Supreme Court two significant studies have been conducted in last five years into the pattern of granting patents by the patent office of India. The first study found the rejection of patents on the basis of section 3(d) which was the basis of rejection in 69% of the cases. Whereas the rejection of the patents was not found on the basis of section 3(d) as it was not resorted to in an effective manner as per the second study in April 2018 report.12

So far as the Novartis ruling "Global Impact is concerned we

come across the report of United Nations regarding access to medicines.13 This report suggests to the WTO members to fully utilize the TRIPS flexibilities provided and article 27. Further suggestion to apply the same. Recent examples are South Africa and Columbia. Thailand" civil society groups are also pushing for a measure on the line of India section 3(d) .

Prior to Novartis case. India had issued 1001 drugs patents between April 2010 and March 2013 out of which 771 patents had gone to the foreign drug manufacturers mainly from United States and Europe as per the Indian Patent office report of data.14

CONCLUSION

Section 3(d) is a novel act of parliament introduced by India by way of its third and the last patent amendment of 2005 in full compliance with the TRIPS amended using to the hilt the flexibilities available under article 27 of the TRIPS agreement. This section 3(d) introduces novel patentability standards.

The purpose of this section was to check foreign drug manufacturers from obtaining endlessly the patent rights over their year already patented products on minor modifications. The said purpose has been achieved by India

The Novartis verdict has adjudicate upon and interpreted the enhanced efficacy to mean enhanced therapeutic efficacy. The Supreme Court has made it clear that section 3(d) nowhere bars incremental invention mainly the enhanced bioavailability of a drug provided it scientifically and with the scientific evidence and data displays and proves the enhanced therapeutic efficacy over the already known efficacy of the known product.

As such the Novartis ruling has paved the way for real incremental inventions to be created by all the pharmaceutical companies including foreign and domestic players. The Novartis Verdict will have a positive effect on future research and development activities that will bring out real and genuine new drugs for the Welfare of the public at large. The Novartis ruling will also promote a competitive environment among the foreign and national drug manufacturers which may lead to reduction of cost of life saving medicines.

There are still great challenges ahed. India will have to ensure that the Novartis verdict is implemented effectively in the days to come looking to the mounting pressure of U.S and Europe to dilute the spirit of enhanced efficacy aspect. Which is the soul of section 3(d) and the back-bone of the Patents Act 1970.

REFERENCES

- Gopa kumar G. Nair http:// shodhganga. inflibnet.ac.in/ bitstream/10603/21666/9/chapter-vi.pdf.
- www.wto.org/ english/ tratop_e/ trips_e/ ta_docs_e/ modules1_e.pdf.
- The New oxford Dictionary of English, Edition 1998.
- Novartis AG v/s Union of India: Supreme court of India.nic.in/outtoday/patent.pdf, April 01, 2003.
- Susan Fyan: Pharmaceutical patent protection and section 3(d) A comparative look at India and the US: Virginia Journal of Law & Technology Fall 2010 vol. 15, No. 198.
- The New oxford Dictionary of English, Edition 1998.
- Goodman and Gilman in CPAA, compilation, vol. 9, page 22, LHC.
- Dorland Medical Dictionary, vol. p, page 19.
- Goodman and Gilman in CPAA, compilation, vol., page 4.
- 42 FR 1640 (1977). C.f. Moffitt, jane, Appropriateness of Bioavailability and Bioequivalency as pre-market clearance consideration.34 Food drug cosm. L.J. 640 (1979).
- makemedicinesaffordable.org/en/fiveyears after indian-supreme-courts-Novartis-Verdict.
- makemedicinesaffordable.org/en/fiveyears after indian-supreme-courts-Novartis-Verdict.
- makemedicinesaffordable.org/en/fiveyears after indian-supreme-courts-Novartis-Verdict.
- C.H. Unni Krishnan: Foreign drug makers won 77% of all patents in last 3 year.
- http:// googleweblight.com/i? U=www.livemint.com/ industry.