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Section 3(D) Of Patent Act: Problem or Beneficial To Pharmaceutical Sector

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Abstract

Section 3(d) of the Indian Patent Act states patentability of the product where the product can be patented or not. Section 3(d) was amended in 2005 and from then it was the main issue in the cases of applications for Pharmaceutical Patents. In this research paper the researcher tried to cover the Perspective of Indian Courts regarding section 3(d) of Patent Act, few cases where section 3(d) is interpreted, analysis of those cases, what problems are there in the present section 3(d) and how Indian courts are missing the key points while deciding the cases, effect of the interpretation on pharmaceutical industry in India comparing with condition in USA.

Keywords; *Section 3(d), Patentability, Efficacy.*

I. INTRODUCTION

Section 3(d) of Patent Act, 1970, states 'what are not inventions'. Indian pharmaceutical corporations started industrial drugs in huge amount only after early 1970s[1]. As a result, India speedily developed as a country which is a most important supplier of inexpensive drugs to a expanse of emergent and under developed countries, however, lack of product patent production in pharmaceuticals became problem to encourage people to capitalise in R&D for new innovations. Main phase in expansion of India's patent system happened after India joined World Trade Organization (WTO) in 1995. Trade connected aspects of Intellectual Property Rights (TRIPS) agreement was employed on 1st January 1995 which is one of the substantial provisions of WTO Agreement[2].

This is done to comply with TRIPS, India required to revise its patent law to give product patent protection for pharmaceuticals. The Indian Parliament amended section 3(d) in 2005 that it complied with TRIPS and also did not negatively impact public health efficacy in the actual usage of the product and not otherwise. The Indian High Court's recent manufacture of Section 3(d) in *Novartis AG v.Union of India* increases thoughtful apprehensions about where the patentability line will be haggard in the forthcoming for pharmaceuticals under the Indian Patent Act. The Court's surprising treatment of Section 3(d) in *Novartis* appears to have comprehensive insinuations for innovator companies seeking patent protection for new polymorphic, enantiomeric or salt forms of known chemical entities. The Madras High Court's failure to describe a vibrant and measureable standard for the effectiveness improvement obligatory to meet the 3(d) threshold leaves considerable legal indecision around when innovative forms of known chemical things[3] will be patentable, regardless of their worth to society in terms of augmented pharmacological activity or supplementary perfections in pharmaceutical properties.

In this research paper the researcher will analyse interpretation given by Indian courts of section 3(d) of Patent Act and will see whether this interpretation is harming the ecosystem of Indian pharmaceutical sector[4] or benefiting it, whether this interpretation

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providing environment for new innovations or it is restricting the growth of inventions. Part I of the research paper is dealing with introduction, part II deals with cases for interpretation and Analysis of the cases, part III deals with Effect of Interpretation on Pharmaceutical sector[5] in India, Part IV is conclusion of the research paper.

II. PERSPECTIVE OF INDIAN COURTS REGARDING SECTION 3(D) OF PATENT ACT

Cases where Section 3(d) is interpreted

Novartis AG, the land mark case in the interpretation of section 3(d) of Patent Act, Novartis filed the application for patent in 1998 for beta version named as "Gleevec" of already patented salt "Imatinib", a cancer curing drug, and was kept for examination till 1st January 2005 as per TRIPS regulations. In 2001-03 Novartis got Exclusive Marketing Rights under section 24(A) for applied patent, because of this other companies making generic product were stopped from making generic version of the patented salt and thereafter they filed case against Novartis on the ground that the salt applied for the patent lacks novelty. Novartis product got five pre-grant oppositions for the applied patent by Cancer Aid Association[6], NATCO Pharma, Cipla, Ranbaxy Laboratories and HetroDrugs.

Assistant Controller of the Patent rejected the grant of Patent on the basis of not having novelty[7] as per section 3(d) of Indian Patent Act and thereafter High Court of Madras and Supreme Court also rejected the grant of Patent on the same estates.

In the case of Frensenius Kabi Oncology Limited v Glaxo, Intellectual Property Appellate Board (IPAB), rejected the grant of patent of "Quinazoline Ditosylate Salt Compounds" where the case was filed by Frensenius Kabi an Indian Pharma company against GSK on the ground that the product applied for the patent lack novelty and does not stand in the meaning of Invention according to section 3(d) of Patents Act. Chairman of IPAB rejected the application for patent on the same ground as prescribed by the opposition that, the product applied for patent is not an invention in the meaning of section 3(d) of Patent Act.

In the case of Ajanta Pharma Ltd v Allergan, Ajanta Pharma an Indian company filed complaint against Allergan Inc. an USA company. The application for patent was filed by Allergan for "Ganfort" and "Combigan" drugs that are employed in the treatment for "Glaucoma". The use of the drugs was to reduce the pressure in eyes. The complaint filed by Ajanta on the ground that patent application does not comply with provision laid down in section 8 of the Patent Act and is obvious and mere combination and mere discovery of recognised substance in the context of section 3(d). The chairman of IPAB repudiated the grant of patent to Allergan for the said drugs used in the treatment on Glaucoma on the ground that it is just combination (mixture) of the known drugs and was obvious and not patentable according to the section 3(d) of the Patent Act.

In the case of Xtandi (Enzalutamide), Enzalutamide a drug invented by California University Los Angeles for treatment of Prostate Cancer. The drug was marketed by Japanese company named as Astellas and the drug was granted patent in more than 50 jurisdictions worldwide. There was pre-grant opposition filed Fresenius Kabi Oncology Limited (FKOL) and BDR Pharmaceutical International Private. Ltd. (BDR), one by the Indian Pharmaceutical Alliance (IPA) and by two individuals on the ground that there was structural similarity between already known drug and applied patent. IPO rejected the application on the ground that section 3(d) does not allow to grant patent to the structural similar product.

III. ANALYSIS OF THE CASES

In the Novartis AG case, Novartis filed application for Patent for drug "Gleevec" which was the beta version of the drug "Imatinib Mesylate". Imatinib was the free base which was developed by Novartis

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and formed into a particular salt and named that as Imatinib Mesylate which was less stable. After the modification and research Novartis formulated a stable salt which was pharmaceutically useful out of Imatinib which was a specific polymorphic form named as beta crystalline form and the drug was named as Gleevec. Gleevec, an anticancer drug was patented in forty jurisdictions at that time and Novartis filed application for patent of Gleevec in India in 1999 in "mailbox" applications. India didn't had patent for drugs till 2005, after the amendment of 2005 in patent regime the mailbox opened and the application of Novartis was inspected. The grant of patent for Novartis drug Gleevec was opposed by several Indian drug corporations and NGOs on numerous grounds together with lack of novelty, lack of efficacy etc. Assistant Controller of Patents rejected the application on 25th January 2006 of patent on the ground that is the new version of old molecule and lacks novelty and was obvious.

In May 2006, Novartis filed appeal in the Madras High Court against Union of India, the Controller General of Patents and others. The contention of the Novartis was that the Controller failed in interpretation of enhanced efficacy standards according to section 3(d), the scope of 3(d) is very vague and ambiguous. And controller disregarded the test conducted by Novartis showing that the drug had 30% more bioavailability than the previous drug and it can be benchmark in the view of section 3(d) as enhanced efficacy.

In 2007 case transferred to IPAB according to the Notification 117G by Central Government.

On 26th June 2009 IPAB gave order against the Novartis, rejecting the application for Patent saying application was barred from patentability according to section 3(d).

On 1st April 2013, Supreme Court gave concluding order against Novartis saying that there is no enhanced efficacy in the drug and Novartis is marketing old drug and court certainly not said that modification in bioavailability may at no time outcome in enhanced efficacy.

If relied on the definition given by Madras High court the scope for the derivatives to be patented narrows down and the definition does not talk about the bio-availability can be considered as therapeutic efficacy or not as contested by Novartis.

And most importantly court did not take into consideration that checking enhanced efficacy there should be prior drug and court compared imatinib with Gleevec where imatinib was by itself was not physiologically not feasible for ingestion.

In the case of Frensenius Kabi Oncology Limited v Glaxo the application for patent was for enhanced efficacy of the drug "Quinazoline Ditosylate Salt Compounds" where patent applicant contested that the product for which the application is filed is therapeutically efficient than the previous drug, because the new drug has greater moisture sorbing properties and more stable than the previous drug. The important point here it that, where, the more stability and more moisture absorbing property can be therapeutic efficacy or not because there are some countries where because of environmental conditions medicines does not survive. Because of non-survival of drug increases the prices for transportation and causes death of several peoples. It should have been considered when testing the enhanced efficacy of the product.

But, here, in this case IPAB stated that this cannot be a therapeutic efficacy and the drug produced was obvious and not patentable under section 3(d). But in this case IPAB gave some guidelines when handling the cases of opposition under section 3(d), like the opposition has to provide evidence that the product applied for patent is obvious or structurally similar or not an invention according to section 3(d).

In the case of Ajanta Pharma Ltd v Allergan, the patent application was for drugs Ganfort and Combigan employed in the curing of Glaucoma. The point of dispute in this case was where the

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combination of the drugs having enhanced effect can be patented or not. Here these drugs used for hypertension (glaucoma) reduced the side effects which was causing by previous drugs. But IPAB did not considered it as an efficacy and said that it is mere combination and was obvious under section 3(d) and it cannot be patented.

In the case of Xtandi (Enzalutamide), the application filed for the patent of drug Enzalutamide which was prescribed for treating men with metastatic castration-resistant prostate cancer. In this particular case opponent filed opposition on the ground that the applied drug molecule is structurally similar with the already known drug. In this case applicant failed to differentiate between the structural differences although the drug having different applications and treatments the patent was rejected. Here the patent for enzalutamide is given in more than 50 jurisdictions. The patent was rejected by IPO on the ground of lack of novelty.

Problems Relating To Section 3(D) And Effect On Pharma Industry

Problems in section 3(d)

The idea or the concept behind introducing section 3(d) is to stop "Evergreening of Patent" by pharmaceutical industries. If this section is removed or was absent in the Act then the effect of evergreening cannot be stopped in our country.

From above case of Novartis, we can say that there is no clear-cut definition provided for therapeutic efficacy. No one can understand or apply standards for what therapeutic efficacy or enhanced efficacy. In this case court did not look upon what is being compared, court compared non druggable molecule with a druggable molecule and their efficacy and bio-availability. The court did not say anything about increase in the bio-availability i.e. mixing of drug in the blood can be considered as enhanced efficacy or therapeutic efficacy.

According to the section 3(d) if "X" is a recognised drug rummage-sale to treat blood cancer and "Y" is the new form of X which is correspondingly effective in curing blood cancer and it is observed that Y also precisely operational in treating bone cancer i.e. in other words Y has new utilization as compared to X, here Y cannot be patented because Y and X are equally effective in blood cancer and Y does not make evident an enrichment in "Known efficacy".

In this provision the enhanced efficacy of known product and different product is not differentiated. If the product for example drug was improvised and by changing structure showing same efficacy and Improved structure showing enhanced efficacy then what will be the solution? Whether it will be considered as new drug for treating the same disease or second will get enhanced efficacy patent or will be rejected by obviousness test and on the basis of structural similarity? As done in the case of Frensius Kabu and Xtandi where the drug was modified and had enhanced efficacy but was rejected the grant of patent on the basis of obviousness in the case of Quinazoline Ditosylate Salt Compounds and on the ground of structural similarity in the case of enzalutamide. But in the both cases drugs were sufficiently efficient to pass the test of enhanced efficacy.

Effect On Pharma Industry

Here in India we have section 3(d) for the patentability of the product patent. As we have seen in above cases because of the strict interpretation and narrow interpretation of the section 3(d) Novartis did not get patent for the drug Gleevec and for the same drug Novartis got patent in other countries. It is not that case that other countries did not have stricter laws regarding patentability, but in India for restricting evergreening of the patent there is a condition of therapeutic efficacy or enhanced efficacy by which most of the drugs which are new, invented are not getting paten. There is no certain test for identifying enhanced efficacy of the product.

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And Novartis did not have patent although the drug had 30% efficacy than the patented molecule which was not druggable, why any company would then will invest in the R&D for preparing molecule which is druggable and have more efficacy.

Any company has a moto to develop a drug and get patent for it that's why they invest so much in research and development, if this condition is there that company would not get any patent for having increased efficacy then why any company would will try to innovate anything. 30% increased in the bio-availability of drug is not a thing which can be just achieved in couple of minutes or in couple of attempts. And 30% is how much efficient should be asked to the patient who is suffering.

Molecular combination and molecular similarity[8] can be of enhanced efficacy and of new therapeutic use or it can be a new form of a drug, but under section 3(d) mere combination or a drug having molecular similarity cannot be patented. It is another problem like, in simple example of fructose and glucose while share same structure but one causes sugar (disease) and another doesn't. Thus, in India companies are demotivated for making or innovating new drugs and will only make generic drugs and this is the condition present now days.

Condition In Usa

Manual of Patent Examining Procedure, Part II Patentability of Inventions and Grant of patent deals with the inventions which are patentable. More specifically Chapter 10 of the Manual and sections 100,101,102,103 deals with the provisions relating to what can be patented and there is no definition or condition of enhanced efficacy such as mentioned in section 3(d) of Indian Patent Act.

Title 35 U.S.C.101 states that invention should be novel, non-obvious, utility. 2100 states non-patentable subject matters and USC title 35 describes types of patent which can be granted: 1) Utility Patent, 2) Design Patent, 3) Plant Patent.

Under US laws patent can be granted to same molecular structural drug and for combination of drugs but following the condition of non-obviousness and novelty.

According to the research conducted and data collected by Risa Kumazava, in between 1999-2012 pharmaceutical patent applied by USA in Triadic patent office are 2581.06, in EPO patents are 3925.56 and in USPTO 9435.44. And of India is in Triadic Patent are 70.55, in EPO 160.64 and in USPTO it is 241.89 only. By this data it clearly seen that India is far behind the Patent filing and in innovation there may be other reasons behind this but one of the major issues is of Patentability of product and mainly section 3(d) of the Patents Act. Pharmaceutical application in PCT in 2010 India filed 145 applications and USA filed 3302 applications and in 2011 India filed 143 patents and USA filed 3221. In total period from 1999 to 2012 USA filed averagely 207,246.78 patents and India filed 6150.04 Patents. All above data clearly shows that India is far behind in patent filling and in Innovations.

The primary object behind establishing the company or industry was to make profit out of it by making new product or making innovations. But Indian patent regime does not provide environment for taking an effort to innovate something in pharmaceutical industry as we have seen from above cases and it is exactly opposite in USA where they give patent for small advancement and Utility Patent. And it can be understood from above given analysis of data that USA is much more ahead in filling the patent application and granting the patent. And it is clear that India does not have environment for growing pharmaceutical industries in regard with patents.

Right To Health And Provision Of Section 3(D)

Wider interpretation of Article 21 includes right to health which further includes right to have affordable medical services, and as of above

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discussion section 3(d) is restricting the growth of innovations which leading to import of drugs and then increase in prices, then there should be changes incorporate or amendments made in section 3(d) to avoid the violation of Article 21 i.e. Right to Health.

IV. CONCLUSION

Though the idea behind including section 3(d) in Patents Act was to stop the evergreening of the patents but now it is leading to the lack of interest of Indian pharmaceutical companies in investing in R&D to make new products and innovations. It is imperative to amend some provisions of Section 3(d) to make an ecosystem which will increase innovations in pharmaceutical industry and will make Indian Pharma sector strong.

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