SECTION 3(D) OF PATENT ACT: RELATION WITH PHARMACEUTICAL SECTOR

Ms. Madhavi Patkar, Dept. of Law
Rabindranath Tagore University, Bhopal

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 and its relation with the pharmaceutical sector.

Keywords- Section 3(d), Patentability, Efficacy.

INTRODUCTION

Section 3(d) of Patent Act, 1970, states 'what are not inventions.' Only after the year 1970 Indian pharmaceutical companies started manufacturing drugs in huge amount. As a result, India rapidly became the giant for supplying cheap drugs to a number of developing and under developed countries, however, lack of product patent production in pharmaceuticals became problem to encourage people to invest in R&D for new innovations. The Indian Parliament amended section 3(d) in 2005 that it complied with TRIPS and have no impact on the health of the public. The main object of this particular amendment of Patents (Amendment) Act of 2005 is to restrict the 'ever-greening' of drug patents and allow patents to those who have significantly shown efficacy in the actual usage of the product and not otherwise. [1] The Indian High Court's recent construction of Section 3(d) in *Novartis AG v.Union of India* raises serious concerns about where the patentability line will be drawn in the future for pharmaceuticals under the Indian Patent Act. The Court's surprising treatment of Section 3(d) in *Novartis* appears to have broad implications for innovator companies seeking patent protection for new polymorphic, enantiomeric or salt forms of known chemical entities. The Madras High Court's failure to define a clear and quantitative standard for the efficacy improvement required to meet the 3(d) threshold leaves substantial legal uncertainty around when new forms of known chemical entities will be patentable, regardless of their value to

society in terms of increased pharmacological activity or other improvements in pharmaceutical properties.[2]

IMPACT OF AMENDEMENT ON PHARACEUTICAL SECTOR

The amendment in the section 3 (d) of the Patents Acts 1970 has impacted the pharmaceutical sector severely as it promotes the innovation in the field of the pharmaceutical and it is for the welfare of the public. Here in India we have section 3(d) for the patentability of the product patent. In the case of Novartis it is seen 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 patent. There is no certain test for identifying enhanced efficacy of the product. And Novartis did not got patent even it has enhanced efficacy.[3]

Molecular combination and molecular similarity 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.[4]

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 important 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.

[1] R. Gabble and J. C. Kohler, "' To patent or not to patent? The case of Novartis'' cancer drug Glivec in India",'" *Global. Health*, 2014.

[2] C. Sermet, V. Andrieu, B. Godman, E. Van Ganse, A. Haycox, and J. P. Reynier,

"Ongoing pharmaceutical reforms in France: Implications for key stakeholder groups," *Applied Health Economics and Health Policy*. 2010.

[3] B. N. Sampat and K. C. Shadlen, "Patent watch: Drug patenting in India: Looking back and looking forward," *Nature Reviews Drug Discovery*. 2015.

[4] S. Basheer, "The 'Efficacy' of Indian Patent Law: Ironing out the Creases in Section 3(d)," *SCRIPT-ed*, 2008.