THE TEST OF EFFICACY IN PATENT LAW

Written by ***Siddhant Saroha***

Final Year student, 3-Year LL.B programme, Jindal Global Law School, O.P. Jindal Global University

INTRODUCTION

The purpose behind patent law is that a patent must be granted to an applicant when the invention of some product is useful and new. Further, the product must have utility and novelty. The object and purpose behind a patent is to encourage industrial progress, scientific, technological research etc. For a patent to be valid, the product must be the discovery of the inventor and should not be a corroboration of something that was already in existence before date of the patent.[i] A patent confers the right to the patentee to exclude others from making, importing, using, selling the invention etc. during its term.[ii]

Section 3(d) of the Patent Act, 1970 has stated that the mere discovery of a newer form of a substance which has already been discovered, which however does not lead to enhancement of the efficacy of the newer form of substance, shall not be considered as a new invention in the eyes of the law and would not be patentable. Section 3(d) has dissuaded evergreening and has stopped the newer forms of substance which are similar to already patented substances from getting a patent unless there is a significant differentiation in the properties of the substances with regard to efficacy.[iii]

The Court in the case of *Novartis AG vs Union of India*[iv], stated that while interpreting section 3(d)[v], it was clear that this section has given significance to efficacy and a duty to show that there has been enhancement of a known efficacy of a substance while discovering it, is directed towards the patent applicant. If the discovery of the newer substance has resulted in nothing except than the derivative of a known substance, then it is also the duty of the patent applicant

to show the properties of the derivative are different from the known substance with regard to efficacy.[vi]

While considering a new pharmaceutical product which is a substance with known efficacy, it must be noted that it must pass section 2(1)(j)[vii], 2(1)(ja)[viii] and the test of enhanced efficacy under the purview of section 3(d)[ix]. While discussing the term 'efficacy', the Hon'ble Supreme Court held that the test of efficacy would have a different meaning with regards to Section 3(d)[x], it would depend upon the result that the product has intended to deliver.[xi] The Hon'ble Supreme Court also stated that if such patents which do not have different properties with regard to efficacy have been granted, then would lead to a lot problems for the people of India as such pharmaceutical products would then be sold at a higher price and would not be affordable for a majority of people.[xii]

In case of a medicine, the therapeutic efficacy must be taken seriously and must be given a narrow and strict analysis, and such is construed on external as well as internal factors. Also, there may be multiple properties in the newer substance which may be beneficial or may have certain advantages to it but the properties that are promptly correlated to efficacy are only to be considered relevant.

The Hon'ble Supreme Court also stated that it must be noted that unless the mentioned substance has properties which are not inherent to a known substance with regard to efficacy, it cannot be construed as an invention and shall not qualify as enhancement of efficacy.[xiii] Section 2(1)(j) of the Patent Act, 1970 has clearly stated that invention is only when there is either a new produce or process has enough inventive step it and is also capable of industrial application.

The law and purpose behind such laws is that a patent should only be granted to the applicant when the invention of the said product has been found to be new and useful, it is also important for the invention to have utility and novelty.[xiv] If the inventor was known to have prior public knowledge about the said invention, then he/she shall not be eligible for a patent of the said invention. Inventions made in pharmaceuticals does not imply that it has to be something completely new or something unaccustomed or something that has never existed before, but it

has to be something diverse from a previous invention or it has to be better than what was invented before.

COGENT OPINION

In my opinion, the interpretation given by Section 3(d)[xv] has clearly stated that there must be differentiation in properties of a newer substance than from a known substance. Such interpretation is essential as it would prevent patent applicants from getting patents for work which is already in existence and would also further motivate other innovators to work on products that are new and unique and even if they are not new or unique, the innovators would still be motivated to make sure that these new inventions have different properties with regard to efficacy which is an important aspect in getting patents especially for pharmaceuticals.

I think that the concept of therapeutic efficacy might not be too beneficial for the medical industry as the criterion is too strict to adhere to. There may be some properties which are essential and might have certain advantages to it but may not be considered relevant according to the criterion. Such properties though considered irrelevant still could be beneficial for the industry as these properties are still made by innovators who are considering aspects which are important in general. Innovators make these inventions considering the problems of the society as a whole and not case by case that is why many innovations fail the criterion which might not be fair to them.

Also, I think that the concept of evergreen which was used by the Courts in the cases of *F. Hoffman*[xvi] and *Novartis AG*[xvii] is very significant. Such use by the Courts will make sure that the innovators do not make minor changes to a known product or substance in order to claim a patent for the same and market it as a new invention as such might be harmful not only to the pharmaceutical industry but to the people as well and it would also demotivate inventors to work on new things.

ENDNOTES

[i] *Bishwanath Prasad Radhey Shyam vs Hindustan Metal Industries*, (1979) 2 SCC 511).
[ii] *F. Hoffmann-La Roche Ltd. vs Cipla Limited*, 148 (2008) DLT 598.
[iii] *F. Hoffman-La Roche Ltd vs Cipla Limited*, 2012 (52) PTC 1 (Del.)
[iv] (2007) 4 MLaJ 1153.
[v] The Patent Act, 1970.
[vi] Intellectual Property Rights in India (2nd Edition), VK Ahuja, page 467.
[vii] The Patent Act, 1970.
[viii] The Patent Act, 1970.
[ix] The Patent Act, 1970.
[x] The Patent Act, 1970.
[xi] *Novartis AG vs Union of India*, (2013) 6 SCC.
[xii] *Novartis AG vs Union of India*, (2013) 6 SCC.
[xiii] *Novartis AG vs Union of India*, (2013) 6 SCC.
[xiv] *Bishwanath Prasad Radhey Shyam vs Hindustan Metal Industries*, (1979) 2 SCC 511.
[xv] The Patent Act, 1970.
[xvi] *F. Hoffman-La Roche Ltd and Another vs Cipla Limited*, 2012 (52) PTC 1 (Del.)
[xvii] *Novartis AG vs Union of India*, (2013) 6 SCC.