CASE ANALYSIS OF NOVARTIS AG V. UOI.-PEOPLE'S RIGHT V. COMMERCIAL INTEREST

Harpal Parmar[*]

ABSTRACT

In the world over millions of suffer due to lack of cure for the concerned diseases or either that medicine is affordable due to the patent over the product that leads to increase in price of the medicine depriving the poor people. The innovation or invention are for the benefit of the people and should not be used as a tool of exploitation to the vulnerable. It is indeed a great measure by the government

In maintaining the harmony with the International Agreement after the amendments. In the recent times after the patent regime has gained international postulate it was dominated by the giants of the developed countries aimed at gaining profit in developing countries which sometimes minor innovation were also protected by the patent and developing the concept of eve-greening. The patent not only aims at providing benefit to the inventor but also it must be in the national interest which should not be barrier, specifically in the case of drugs, for the promotion of the public health. It is also moral duty of the patentee not to abuse the patent as it is a human right aspect dealing with the life of the person. The Appellant (Novartis International AG) couldn't prove the therapeutic effect of drug (crystalline form of imatinib) before the court, which is cure for chronic myeloid leukaemia , where the Supreme Court of India applied stricter interpretation of the provision by disallowing mere modification in the product to be patented that does not results in enhancement of efficacy. The paper analysis the constitutional validity of the *Novartis AG v. Union of India*[1] case judgement.

INTRODUCTION

A patent is a monopoly right granted to the person who has invented a new and useful thing or an improvement of a new article or new process of making an article[2]. A landmark judgement was delivered by the Supreme Court of India in the case of Novartis vs. Union of India. Novartis has challenged the Intellectual property appellate board (IPAB) under section 3 (d) of the Indian Patent act, 1970. The tussle was due to the drug called Glivec (beta crystalline form of imatinib mesylate), an anti-cancer drug used to treat chronic myeloid leukaemia, developed by the Novartis claiming it

[*] 4th year, B.com LLB (hons.), R.N. Patel Ipcowala School of law and justice, Sardar Patel University, **E-mail:** harpalparmar95@gmail.com, **Address:** 3, shiv Shakti hill park Shakarpur road khambhat, Di-Anand 388620 Gujarat

to an invention but was struck down by the Apex court being not eligible for the patent. The applicability of the patent must be justified in the courts of law in order to ensure that there is no pro-longed tussle between the governments who always wants the availability of the drug at cheaper rate and to the masses while the pharmaceutical giants are profit-driven industry who cares only profit. The patent in dispute needs to pass judicial scrutiny for its validity. Initially the patent law was governed by the Patents and Designs Act, 1911 that contained provision for both products as well as process patent. It was needed in more precise manner to protect the invention and to promote scientific research and development in the country instead of benefiting the rich knowledge of nation to the foreigners which will lead to industrialization prosperity in the near future, so the Patent act 1970 was enacted.India have its own patent act which is The Indian Patent act, 1970 (here after will be referred as 'the act'), to deal with the patent policy, and further in 2005 it was amended to make it in compliance with TRIPS agreement[3] that is it included product patent. It describes what can be called as patent and what invention cannot be.[4] This particular judgement has resulted in prevention of ever-greening[5] of their patent, which is seen in pharmaceutical industry and is commonly referred as abuse of patent system.

FACTS OF THE CASE

Novartis International AG is Swiss multinational pharmaceutical company who has patented this controversial drug in over 35 countries who deals with the treatment of chronic myeloid leukaemia.[6] As India did not allowed patent on products during those time, it couldn't able to patent the Glivec (the drug), even though Novartis applied for the grant of patent in march 1998, but the application remained in the mail box with the others until in 1st January 2005, the Indian Patent act, 1970 was amended to be in compliance with the TRIPs agreement and only then those application were taken into consideration. Further for the same Exclusive marketing right (EMR) was granted under the said act. Subsequently after revising the law, the Madras patent office refused to grant patent for the drug Glivec due to the reason that it does now show any major changes on its existing form. India had a unique system of pre-grant opposition where before the grant of patent the interested parties can make opposition for the product or process going to be patented. In the present case the pre-grant opposition was made by the five pharma companies. The patent office upheld the opposition application and thus rejected the application of the Novartis for the grant of patent, it did not fulfil the condition required under section 3 (d) of the act which states that *"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 known 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".

Aggrieved by this, Novartis filed writ two writ petition in the madras High court in 2007 contending that the impugned section 3 (d) of the patent act is violative of article 14 of the constitution which is vague and unambiguous in nature and secondly is not in harmony with the TRIPS agreement. Subsequently the writ was rejected was rejected. Appellant went to the IPAB for appeal where again the patent was rejected, but it considered the beta-crystalline form of imatinib mesylate as new and an inventive step. Finally the matter reached the Supreme court in 2009 by the way of special leave petition. The main issue before the honourable was that whether the beta-form can be regarded as the invention and whether it qualifies the test of novelty of the said product and whether it is consistent with section 3 (d) of the patent act, 1970. Unfortunately it couldn't establish the newness of the medicine thus enhanced therapeutic efficacy and was entitles to get patent protection under the Act.

The court observed that according to section 2 (1) (j) of the act Invention refers to *a new product or process involving an inventive step and capable of industrial application*. The court in its verdict concluded that Imatinib Mesylate as well its beta form are not an invention thus are not capable of being patent under the act while referring to the Zimmerman patent.[7] The case longed from the year 1998 to 2013 till the final pronouncement by the Apex court of India.

CASE COMMENT

The matter before the court was of a life-saving drug and the interpretation of Section 2(1) (l), 2 (1) (j) and Section 3 (d) of the Act. The compound doesn't shows any newness as the imatinib was contained in Zimmerman patent and had the anti-tumour properties too. Further the same was even published in the article of the journal 'Cancer research' (1996). It also had only 30 percent of increasedbioavailability which is not effective in, and only determining bioavailability is not suffice to prove the effectiveness. Not all a properties of a new form (such as improved process ability or flow characteristics, storage potential, etc.) ought to qualify under section 3(d), but only those properties that have some bearing on efficacy. It is laudable precedent by the Supreme Court of India to which is tend to shape future pharma policies in terms of regulation of price, and made clear that only innovative medicines could be patented and not mere improvement of known substance which by this particular case was prohibited to grant patent where there is mere enhancement of efficacy i.e. if a medicine claiming to cure the disease, the test of "therapeutic

efficacy" should be fulfilled that defines beneficial change made by drug and by applying these test the compound does not fit in the arena of patent. The court concluded that the properties of more beneficial flow and better thermodynamic stability would result only in its physical efficacy not its therapeutic efficacy.Thus only real innovative medicines to be protected vis-à-vis patented. Therefore Apex court is justified in non-granting of the patent confirming the intention of the legislature.

CONCLUSION

The instant case resembles the approach by the India in dealing with the pharmaceutical patent regime. The Supreme court's interpretation of the patent legislation seems to more favourable on the citizens right rather than commercial interest for the deprived people in India which forms majority in the masses of the population, which is ought to deliver access to medicine at reasonable price.It is caution and not the verdict to forbid the protection under the act. On the other it set to impact research investment policy of the giant pharma in India because it discourage them for the differentiated law in India from that of U.S.A and other countries where the same drug was allowed to be protected under patent.After the amendment in 2005, the patent in India has requirement of higher standards of inventive steps, what is patentable in other countries may not be patentable in India.The right to health[8] is duly protected in a way towards Trade Related Intellectual Property Rights (TRIPS) agreement by giving nod to life saving drug. As India is a developing nation it is necessary that the medicines to be available at cheap and affordable price, the poor cannot be put at the risk of life when there is adequate cure exist.

REFERENCES

[1] *Novartis AG v. Union of India* , AIR 2013 SC 1331

[2] P. NARAYANAN, PATENT LAW, (4th ed. 2006)

[3] India-Patents (Amendment) Act, 2005 (Act No. 15 of 2005), http://www.wipo.int/wipolex/en/details.jsp?id=2407

[4] The Indian Patent act, 1970 Section 3 and 4

[5] It is an act where in order to increase the tenure of patented product or process which is generally 20 years in India by making minor modification in the original product which is done several times by the patent holder to gain more patent period as to have the monopoly in the market for longer period to earn more profit.

[6] A type of cancer that affect the blood and bone marrow. In Chronic myeloid leukaemia the bone marrow produces too many white cells called granulocytes and these cells generally crowd the bone marrow, interfering with the normal blood cell production.

[7] An application for grant of patent for the Zimmermann invention (Pyrimidine Derivatives and Processes for the Preparation thereof) was filed in the United States of America on April 2, 1993, by Ciba Geigy (US Patent Application No. 08/042, 322).

[8] In Murlidhar Dayandeo Kesekar v. Vishwanath Pandu Barde [1995 Supp (2) SCC 549], the Hon'ble supreme court held that Article 21 of the Constitution assures right to life. To make right to life meaningful and effective, this Court put up expansive interpretation and brought within its ambit right to education, health, speedy trial, and equal wages for equal work as fundamental rights. Articles 14, 15 and 16 prohibit discrimination and accord equality. See also Constitution of India, 1950, Article 38, 39 (e), 41, 42, 47 and 48A under part IV (Directive principle of State Policy).

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