International Journal of Applied Social Science
Volume 6 (6), June (2019) : 1654-1658
Received : 25.04.2019; Revised : 09.05.2019; Accepted : 25.05.2019

RESEARCH ARTICLE
ISSN : 2394-1405

Ever-Greening of Patents of Drugs and Right to Health: A Conflicting Interest

IMRAN AHAD
Ph.D. Research Scholar
Department of Law, University of Kashmir, Srinagar (J&K) India

ABSTRACT

Forever greening of patents, the most common practice associated with the pharmaceuticals industries, refers to the strategy of obtaining multiple patents which cover the different aspects of the same pharmaceutical products, typically by obtaining patents on improved versions of the existing products. Evergreening of patents is not a formal concept of law; rather it is an idea refer to the innumerable ways in which the pharmaceutical companies use the law and related regulatory processes to extend their high rent earning intellectual property rights, otherwise known as "intellectual monopoly privileges.[1]

Key Words : Product patent, TRIPS agreement, Life-saving drugs, Parma Patents

INTRODUCTION

In India, the first patent law, which came into being in 1852, was aimed solely toward favoring the foreign pharmaceuticals companies. Though, in post-independence phase, the Indian Patent Act 1970 was enacted for providing medicines at affordable prices to the masses, apart from giving encouragement to research and development and domestic competition while protecting interests of the patent holders. The concept of process patent remained in vogue in order to ensure the availability of medicines at affordable prices to the public. Then came to the TRIPS agreement under the auspices of WTO and our Patent Act was made compliant with the TRIPS agreement. Whereas the Indian Patent Act was being amended by the government under the pressure from WTO, appeals were coming from not only within India but even from other countries including WHO to safeguard public health. Therefore, in the year of 2001, the WTO members adopted a special ministerial declaration at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the TRIPS Agreement. Doha declaration on public health is a victory for the developing countries like India who are demanding the WTO council to consider the public health measures in the developing and the least developed countries on TRIPS minimum standards for a patent. In light of the issues and the increasing evidence that patent protection was negatively affecting world health by erecting a barrier between sick people and the medication they need, the WTO amended TRIPS under the Doha Declaration to broaden the criteria to facilitate compulsory licensing of patented pharmaceuticals for countries facing a public health crisis. Furthermore, countries that lack domestic pharmaceutical production abilities may import these medications from countries that produce medications for them for this purpose.[2] India, under

1. Martin G, Sorenson C. and Faunce T., Balancing intellectual monopoly privileges and the need for essential medicines, Globalization and Health, 2007, available on http://www.globalizationandhealth.com/content/3/1/4, on 7/5/13 at 11:00 am.
2. Aileen M. Me Gill, Compulsory Licensing of patented pharmaceuticals: why a WTO administrative body should determine what constitutes a public health crises under the Doha Declaration, 10 Wake Forest Intellectual Property Law Journal 73 (2009); cited in http://www.scribd.com/doc/53318704/pharmaceutical-patent-in-issues-and-concerns; accessed on 7/5/13 at 12:15 PM.

How to cite this Article: Ahad, Imran (2019). Ever-Greening of Patents of Drugs and Right to Health: A Conflicting Interest. *Internat. J. Appl. Soc. Sci.,* **6** (6) : 1654-1658.

severe criticism from different quarters, was forced to introduce amendments in the Indian Patent Act, so as to allow the existing domestic production of medicines to continue despite the Patent.[3] The Patents Amendments Act of 2005 has introduced another provision to discourage the continuation of patents rights beyond the prescribed term of patent protection by preventing the grant of evergreening.[4]

Ever Greened Patents Vs. Right to Health:

Despite the fact that the patents law regime allows investors to obtain patents upon improvements, the evergreening of patents by the pharmaceutical industry creates controversies. The specific reasons are the traditionally resource-intensive nature of research and development activities and the continuing public outrage over the very high cost of drugs and thus adversely affecting the right to health. The duration of patent protection, which extends for maximum for a period of 20 years from the date of filing of the patent, is effectively extended by way of evergreening. Critics assert it as an abusive practice by pharmaceutical industries that conflict with the concept of limited monopoly under patents law.

The evergreening of patents of drugs by pharmaceutical industries is not a new practice. It was started far back in the year 1983 by the US pharmaceutical companies to retain the profits from the "blockbuster" high selling drugs for as long as possible. When the original patent over the active component of such high selling drug is about to expire, these companies cleverly claims a number of complex and highly speculative patents. Than the patentee of such evergreened patents over drug use to threaten the producers of generic equivalent of such drug by seeking a court order for preventing their marketing approval. The result is the exorbitant prices of essential and lifesaving evergreened drugs.

The high cost of evergreened drugs and its inaccessibility to the mass is causing maximum sufferance to the inhabitants of the least developed and developing countries, wherein the people are denied with their basic right to health in the form of non-access to the essential drugs. Right to health is an internationally recognized human right covered by several international human rights instruments, including the International Covenant on Economic, social and Cultural Rights (ICESCR).[5] The Committee on Economic, Social and Cultural Rights in its General Comment[6] extensively set out the obligation of States parties, under which countries are bound to respect, protect and fulfill the right to health. Access to adorable drugs is one of the significant attributes of the right to health. Further on the competition posed by the pharmaceuticals companies producing generic drugs[7] is the key to adorable drugs. The right to health, the internationally recognized human rights, is how conferred with the status of fundamental right under the Constitution of India. The right to health is now included to be the part of Article 21 of the Constitution[8] and is directly enforceable through domestic courts in the absence of contradictory domestic law.[9] Despite the recognition of the right to health as legally enforceable right the people in the developing countries, including India, are dying of diseases like HIV/AIDS, Cancer, Tuberculosis, etc.,

3. Supra note 23.
4. Section 3(d) of the Indian patent act prevents the ever greening of patents. It provides 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 known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant Explanation: for the purpose 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.
5. Article 12 establishes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
6. General Comment 14, the right to the highest attainable standard of health, UN Doc. E/C. 12/2000/4, 11 August 2000.
7. As defined by the Centre for drug evaluation and research, US. Food and Drug Administration, the generic drug meant for a drug product that is comparable to brand/reference listed drug product in dosage from, strength, route of administration, quality and performance characteristics, and intended use. It also refers to a drug marketed under its chemical name without advertising.
8. Paschim Bang Khet Mazdoor Samiti vs. State of WB (1996) 4 SCC 37; Surjit Singh vs. State of Punjab (1996) 2 SCC 336.
9. Vishaka vs. State of Rajasthan (1997) 6SCC 241.

because of non-access to affordable drugs. Many of the drugs used to treat these diseases (particularly the anti-viral drugs used in HIV/AIDS therapy) – are still under patent.

Ever-Greening of Patents upon Drugs – A Threat to the Producers of Generic Drugs:

A patent provides the owner of an invention with the legal means to prevent others from selling it for a period of 20 years. In return, the patent holder must disclose details of the invention. The exclusivity provided by a patent allows pharmaceutical companies to recoup their investment in developing a new medicine. Once the patent expires on a drug, other manufacturers are free to step-in and manufacture so-called generic versions of the drug. Generics are usually far cheaper than in-patient drugs since generic manufacturing is a competitive business and the companies do not have to worry about recovering research and development (R&D) costs.[10] Generally, the generic drugs are being produced upon the expiry of the period of patent protection. There are also certain other circumstances when generic drugs can be produced without patent infringement, *viz.,* – (a) when the generic company certifies the brand company's patents as either invalid or unenforceable (b) when the generic version is for drugs which have never held patents, or (c) when the generic version is produced in countries where the drug does not have current patent protection.

In India, the TRIPS-compliant patent law regime has incorporated the concept of product patent over drugs. It provides for the patent protection in cases where there is no domestic production of that product and even the patent protection on the import. Thus it is threatening the producers of generic drugs. Though TRIPS agreement contains the provisions of "compulsory licensing"[11] and "parallel importing"[12] which allows the member countries to manufacture or buy the generic drugs in exceptional situations. Yet, the above-stated safeguards in the form of "compulsory licensing" and "parallel importing" has not been used successfully by a developing nation to access inexpensive medicines. Among the likely reasons for this are: (a) the fear of bilateral trade disputes; (b) the lack of legal resources to interpret and implement the agreement; (c) the lack of the infrastructure needed to dispense drugs; and (d) the implications of declaring a national emergency.[13]

The judgment of Novartis Case – A Vanguard to the Patients in Immense Need of Life-Saving Drugs:

The Novartis applied for a patent for 'imatinib' in the USA in the year of 1994 and it had started marketing a derivative of it, viz., imatinib mesylate' as an anti-cancer drug under the brand name of Glivec or Gleevec. Novartis could not apply for a patent for imatinib mesylate in India because, from 1972 to 1995, it did not recognize product patent protection in pharmaceuticals. When India introduced product patents, Novartis could not apply for a patent for imatinib mesylate because patents are given only for new substances and not for known substances. Therefore, Novartis in the year of 1998 had again applied for the patent of the new form of imatinib mesylate, *i.e.* – a beta crystalline form of imatinib mesylate. As per the arrangement in India in compliance with the TRIPS agreement, the application of Novartis was kept in the mailbox. In the year 2005 onwards, when the examinations of patents application were started, the application of Novartis was rejected by the patent office on the ground that it did not satisfy the 'efficacy' criteria as laid down in section 3(d) of the Indian Patents Act.[14] Though, Novartis argued before the patent office that the invented

10. www.parliament.uk/post/home.htm; accessed on 4/5/2013 at 10:45 am.
11. Compulsory Licensing allows the government to permit use of a patent without the consent of the owner in certain circumstances, viz.- where a company/person has already attempted to gain a voluntary license from the patent holder on reasonable commercial terms; or in the event of national emergencies or in other circumstances of extreme urgency; or for public non-commercial use. Compulsory licenses are being issued after the payment of adequate remuneration to the patent holder. In cases of compulsory licensing, a single license cannot be given exclusivity and the production is primarily for the supply to the domestic market.
12. Parallel importing refers to products marketed by the patent owner in one country and imported into another without the patent owner's approval.
13. Supra note 28.
14. http://www.rediff.com/money/interview-novartis-ruling-is-not-an-anti-patentjudgement/20130410.htm, accessed on 7/5/13 at 1:00 pm.

product, the beta crystalline form of Imatinib Mesylate, has more beneficial flow properties, better thermodynamic stability, and the lower hygroscopicity than the alpha crystalline form of Imatinib Mesylate. It further claimed that the aforesaid properties make the invented product new and superior as it "stores better and are easier to process" at that time the appellate authority under the act had yet to become functional. The appellant, therefore, challenged the orders passed by the Assistant controller in writ petitions filed directly before the Madras High court. Apart from challenging the orders of the Assistant Controller, the appellant also filed writ petitions seeking a declaration that section 3 (d) of the Act is unconstitutional because it not only violates Article 14 of the Constitution of India but is also not in compliance with TRIPS. After the formation of the Intellectual Property Appellate Board (IPAB), the writ petitions challenging the orders of the Assistant Controller were transferred from the High Court to IPAB. The appellant's appeals against the orders passed by the Assistant Controller were finally heard and dismissed by the IPAB in the year of 2009.[15]

The IPAB held that the patentability of the subject product was hit by section 3(d) of the Act. Referring to section 3(d) the IPAB observed:

> "Since India is having a requirement of a higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of the amended section 3(d) of the Act is nothing but a requirement of a higher standard of inventive step in the law particularly for the drug pharmaceutical substances".[16]

The IPAB also referred to the judgment of the Madras High Court, dismissing the appellant's writ petitions challenging the constitutional validity of section 3(d) where the High Court had observed:

> "We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening, to provide easy access to the citizens of the country to life-saving drugs and to discharge their constitutional obligation of providing good health care to its citizens."[17]

Against the order of the IPAB, the appellant came directly to this Court in a petition under Article 136 of the Constitution. On 1 April 2013, the Supreme Court rendered the judgment confirming that the beta crystalline form of imatinib mesylate failed the test of section 3(d). The Supreme Court interpreted the meaning of "efficacy" in section 3(d). It said that the new form of a drug must demonstrate an improvement in its therapeutic effect or curative property as compared to the old form in order to secure a patent. Though, Novartis offered evidence that the beta crystalline form differed regarding certain properties relating to production and storage. The Court held that these properties may be important from a storage point of view, but would not be relevant to showing "enhanced therapeutic efficacy". The Court discussed at some length the meaning of therapeutic efficacy in respect to pharmaceutical products and observed that there are different possible meanings. The definition may be limited only to action resulting in a curative effect, or it might be more broadly extended to cover improved safety or reduced toxicity. The Court decided to leave open what is the appropriate definition of enhanced (therapeutic) efficacy – the narrower or broader interpretation – because it did not need to reach that question in this case. Novartis had provided no evidence that the beta crystalline form of imatinib improved the therapeutic effect of the drug. There was nothing to measure.[18] Novartis had also shown that imatinib mesylate had a 30% increase in bioavailability[19] compared with imatinib. However, the Supreme Court decided to not consider this sufficient to meet the "enhanced efficacy" requirement as laid down in the Indian Patent Act.[20]

Finally, the Supreme Court has said that it appeared that Novartis was, in fact, marketing an older form of the drug and not the beta crystalline version and that it

15. Novartis AG vs. Union of India; Civil Appeal Nos. 2706-2716 of 2013 (Arising out of SLP (C) Nos. 20539-20549 of 2009).
16. Ibid.
17. Ibid.
18. http://www.ip-watch.org/2013/04/04/the-judgement-in-novartis-v-vwhat-the-supreme-court-of-india-said/; accessed on 9/5/13 at 2:20 pm.
19. Bioavailability stands for the proportion of the drug absorbed in the blood stream.
20. http://www.medscape.com/viewarticle/775186_3, accessed on 9/5/13 at 2:30 pm.

appeared that Novartis may have been trying to use a patent in India to cover a drug that it was not actually selling. It suggested that this showed Novartis "in rather poor light".[21]

In this way, the Supreme Court of India, in Novartis case judgment has adopted a standard for patenting of drugs, which is much stricter than that followed in the USA & European Union countries. While applying for patents for drugs in India, the claimant must have to show that the new form of compound to be patented is different from the old form and at the same time it must be resulting into improvement in the treatment of the patient.

Accessibility of life-saving drugs:

India will respect product patents. However, the patents so respected will only be those issues in India. Product patents will be respected for a period of twenty years from the time of application not from the time of grant of the patent. About ten thousand applications for patents were pending with the government in 2005, these date back to 1995 and are designated as mailbox application when the mailbox application is cleared and patents awarded newly introduced generics in the Indian market may have to be withdrawn.

Conclusion:

The Novartis ruling by the Supreme Court of India is a breakthrough, which has laid down the yardstick against which the medicines will be measured before the grant of patents. This is also the first drug patent-related case after the Patents Amendment Act, 2005 meant for honoring product patents. In the case of patenting of drugs, the concern should be that a monopoly could not price the drug beyond the reach of patients. The Novartis judgment comes on the heels of other judgments in the country that ruled in favor of public health. The said judgment is affirming to the fact that India has adopted a standard of drug patenting which is stricter than that followed by the United States of America or the European Union. For the grant of a patent for the drug in India, the applicant must not only show that a new form of the known compound is different than an old form, rather the modification will result in an improvement in the treatment of the patient. Now, the consumers in India will have to pay for expensive patented products only when those products represent a genuine advance over older versions. The Novartis ruling will also benefit the generic companies in India, which are fully capable of manufacturing generic Imatinib Mesylate at par to global standards. Apart from this, the companies in countries where Glivec is not patented could also manufacture and export to India. Thus, the said ruling leads to the recognition of the right of patients to access affordable medicines over the profitability of big pharmaceutical companies through patents.

****

21. Supra note 42.