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Patent Ever Greening

[1]Chinmaya Kumar Mohapatra

Abstract--- *Patent is an exclusive privilege to reward the true and first inventors of new inventions. To be patentable, an invention must be novel, involving inventive step and of industrial application. Theoretically patents exist to promote the diffusion of innovative knowledge. The patent system provides necessary incentives for investment in research and encourages inventors to engage in new lines of R & D, thus it stimulating further creativity. It is considered as exclusive right and not as a monopoly, because in the scheme of patents there are inbuilt checks and balances to prevent the abuse of patents such as compulsory licensing, permitted use etc. However, the recent trend in the patent system shows that there is a tendency to evergreen the patent rights, especially in the pharmaceutical sector, by making trivial modifications and changes. Drug companies generally do ever-greening, by filing new patent applications, tweaking existing molecules to show novelty. Ever-greening of patent is a phrase used to label practices that have developed in certain jurisdictions wherein a trifling change is made to an existing product, and claimed as a new invention. The present paper discusses about the patents with a special emphasis on ever-greening of patents. The landmark judicial decision in Novartis A G v. Union of India will also be analyzed.*

Index Terms--- *Patent, Ever greening, Novartis, Pharmaceuticals.*

I. INTRODUCTION

Intellectual property (IP) refers to knowledge and information that can be incorporated and exploited commercially in tangible objects. It is a collective term used to denote independent rights such as patents, trademarks, copyright, industrial designs, geographical indications, confidential information and layout designs. Each right's nature, scope, content and length varies from property to property. The main justifications for intellectual property rights (IPRs) are: IP protection is an incentive to human creativity; to human creativity; it provides the necessary stimulus for new R&D ; it serves as an instrument for cultural, social, economic and technological development.

Patent is one of IPR's strong forms. Countries patent new inventors to be awarded. The patent law acknowledges a patent proprietor's exclusive right to profit directly from his invention. A patent is an exclusive right granted to the owner of an invention by a country to make, use, manufacture and market the invention, provided that the invention meets certain stipulated condition.1

There are various statutory criteria to be fulfilled to obtain a patent. Patent as a right is an exclusive privilege to reward the true and first inventors of new inventions. To qualify for patent protection, an invention must fall within the scope of patentable subject matter and must meet the three statutory requisites of novelty, inventive step and industrial application.

[1] Amato, Anthony D' & Long, Doris Estelle, International Intellectual Property Law, Kluwer Law International

Department of Law, Siksha 'O' Anusandhan (Deemed to be University), Bhubaneswar, chinmayamohapatra@soa.ac.in

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This means that invention to be patentable should be novel, non-obvious by involving an inventive step and must also have an industrial; application. The novelty requirement is by and large, satisfied as long as the patent applicant was the first to invent the claimed invention.

The industrial design criterion implies that the product must be useful to the industry and that it must meet a minimal human need. The criterion for innovative phase (non-obviousness) excludes patentability if the discrepancies between the claimed invention and the related prior art were such that the claimed invention would have been apparent at the time the invention was made to a person with common expertise in the art to which the subject-matter relates.2

The innovation can be a product or process and its reach applies to all technical fields. The inventor must reveal the invention and also identify the process of conducting it in order to obtain immunity. The patent gives the patent proprietor the right to exclude others from making, using or selling the invention, among other things.3

Countries may exclude such innovations to protect public order or morality or to protect human, animal or plant life or health or to avoid serious harm to the environment from patentability, given that such exclusion is not made solely because exploitation is prohibited by the municipal laws of those countries.

The purpose of patent law is to promote scientific research, new technology and advancement of industry.4 The patent system is based on the reasonable assumption that when the government takes further steps to encourage the creation, marketing and disclosure of new inventions, the public will enjoy additional benefits.

The basic argument is that society benefits when people formulate new inventions, create and sell new products implementing these inventions, and disclose information about their inventions to the public, so that others can learn from these inventions and improve them. It often takes a substantial investment in knowledge, energy and resources to create something new. The revealed technology helps to inspire further creativity and creative ideas. The economic value of patent information is that it offers information technology that can be used for commercial purposes to industry. There may be a significant incentive to take a free ride on someone else's investment if there is no protection. This free-riding potential reduces the incentive to invent something new as the inventor may not be able to recover the investment.

Patents are also meant to remedy a deficiency of the sector. The failure of the market leads to sub-optimal investment rates in technological practices and emerges because companies who can use an invention without incurring research and development costs will always have a competitive advantage over businesses who innovate and incur these costs. As a result, there will be no incentive to innovate. Patents reward innovators with a temporary monopoly on the intellectual property they have created. In order to promote the dissemination of knowledge, the patent holder is required to disclose the scientific knowledge that emphasizes innovation to the public.

Therefore, patent grants new inventions inventors property rights. Among all forms of IPRs, the patent is considered to be the most economically possible form of IPR, having a direct effect on a country's scientific and technological growth and having a significant influence on a nation's public health policy. The innovation per se may not be patentable, as the discussions above show, even though it passes the triple patentability test. The invention must not have been exempt from

[2] Bainbridge, David I, Intellectual Property, Pitman Publishing
[3] Black, T, Intellectual Property in Industry, Butterworth & Co, (Publishers) Ltd
[4] Groves, Peter J, Source Book on Intellectual Property Law, Cavendish Publishing Ltd.

patentability, i.e. a non-patentable invention in the country concerned must not be the subject of the patent.

According to clauses 2 and 3 of Article 27, the TRIPS Agreement provides sufficient flexibility for its Member States to exclude such innovations from patentability, inter alia to protect public order or morality or to protect human, animal or plant life or health. Furthermore, for these appropriate purposes, each country has the right to exclude certain inventions from patentability. In India, to provide for non-patentable inventions, section 3 of the Indian Patent Act has been amended. It enlists inventions that are not patentable but otherwise that fulfill the patent prerequisites.5

II. PATENT EVER GREENING

Patent ever greening is an infringement and misuse of the patent system. It's the eternal patent extension. It denotes the practice of pharmaceutical companies seeking additional patents on minor variations of the original drug–new forms of release, new dosages, new combinations or variations, or new forms, changing a drug from a tablet to a capsule, etc. A trifling alteration in an existing product is made in this process and it will later be listed as a new invention. Drug companies typically change existing molecules to demonstrate novelty by submitting new patent applications. Patent ever greening is a term used to mark procedures that have formed in some jurisdictions in which an existing product is made a trifling improvement and asserted as a new invention. The coverage / protection offered by the supposed new invention is then used to expand the exclusive rights of the patent proprietor over the drug, thus preventing competition. Usually, these changes are made to blockbuster products just before their patents expire.6 In many countries such as Australia and the US, ever-greening is possible as their legal standard for securing a patent is very weak. Different methods of drug delivery have been known for decades (such as extended release, for example). Patents for new use facilitates ever greening directly or indirectly in developed nations. The low standard US benchmark for innovative moves and utility allows for meaningless patents on medicines. National Institute of Health Care Management on Pharmaceutical Innovation reports that over 75% of the patented drugs are new forms of known substances, thus eliminating competition, extending monopolies, making.

There are many negative impacts of ever greening. Ever-greening increases the exclusivity period of the market. This requires the generic supplier to wait for all the patents to expire indefinitely and delays the generic market launch. It adversely affects public health and plays a negative role in shutting out the demand for domestic generic medicine, providing access to essential prescription or life-saving medicines at affordable prices to lower sections of society. The patented drug' Gleevec,' for instance, cost Rs. 4,115/-per tablet in India. Resonance and Indian generic drug company are offering their generic version in India at Rs. 30/-per tablet. While the Gleevec's annual cost in India is Rs.15,00,000/-19, its generic versions cost just Rs.10,000/-per year. When patents for a widely used drug expire, the price drops to 95%. Allowing patents for new use of pharmaceuticals directly or indirectly encourages ever-greening in the developed nations.

III. PHARMACEUTICAL PATENTS AND PUBLIC HEALTH ISSUES

Pharmaceutical patents are designed to stimulate investment in new lines of R & D. However, there is no exaggeration in stating that the product patent regime in pharmaceutical products, directly or indirectly, creates private monopolies

[5] Lionel Bently and Brad Sherman, Intellectual Property Law, Oxford University Press, Oxford, 2003
[6] LTC Harms, The Enforcement of Intellectual Property Rights: A Casebook, WIPO, Geneva, 2005

encouraging ever-greening of patents, resulting in patent abuse affecting the human rights of millions of patients in low income countries, facilitating giant multinational pharmaceutical companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high.

Coincidentally, for example, in the parliamentary debates on amending the patent law in 2005 to comply with the TRIPS requirements by shifting from the process patent regime to product patents in pharmaceuticals, etc., reference was made to the ' Novartis ' and the medicine ' Gleevec / Glivec ' and how Novartis overpriced the drug after EMR was granted.

India has played a very important role as the manufacturer and supplier of medicines to various parts of the world in the pre-TRIPS era, where poor humanity was desperately in need of drugs at cheap and affordable rates. Before the end of the TRIPs Agreement, India was the pioneer in the global supply of inexpensive antiviral drugs and other important medicines. This delivered 50% of the world's cheapest medicines to countries such as Papua New Guinea, Laos, Kenya, Asia, and so on. India has also taken the lead in facilitating access to and providing those most in need in developing countries with affordable necessary generic HIV medicines. Because AIDS-affected countries do not have adequate manufacturing capacity in the pharmaceutical sector, they depend on imports from major generic drugs producing countries like India to treat millions of their patients with HIV. The TRIPS Agreement, however, included major legislative changes allowing the patenting of a drug that had raised serious concerns about its public health effects. It also raised concerns about the impact on local production and supply of generic anti-retro viral agents of the medicines patent regime of TRIPS.[7]

From practice, India had understood the inverse relationship between product patents and the indigenous pharmaceutical industry and its effect on the supply of critical drugs at affordable prices. While India had a drug patent system, 85% of our medicinal requirements had to rely on imports. This situation was reversed when we moved to patent regime manufacturing, i.e. our own products met 85% of India's medicinal requirement. By 1970, after India's patent system prohibited the granting of product patents for pharmaceutical and chemical substances, the country's pharmaceutical industry reached high heights and became the major drug supplier. After studying the situation in and experience of other countries and recommending India to introduce process patent system, Justice Ayyangar said thus:

I have considered the matter with the utmost care and have reached the conclusion that the chemical and pharmaceutical industry of this country would be advanced and the tempo of research in that field would be promoted if the German system of permitting only process claims were adopted.

On 01.01.2005, India had to move from the process patent regime to the product patent regime in medicines, agricultural and chemical substances in order to comply with the TRIPS requirements. Nonetheless, numerous reforms have been implemented in the 2005 amendment to discourage drug patent misuse, including pre-grant challenges, revisions in section 3 extending the reach of non-patentable inventions and updating section 3(d). The most significant change in section 3(d) was specifically to avoid the ever-greening of pharmaceutical patents and to test attempts at repetitive patents.

[7] Narayan, Intellectual Property Law, Eastern Law House

IV. SECTTION 3 (D)- NON PATENTABLE INVENTIONS AND THE *NOVARTIS CASE*

Non patentable inventions are dealt with in section 3 of the Indian Patent Act. A close look at the Indian Patent Act as it stands today makes it clear that two distinctly separate concepts are "invention" and "patentability." This is a critical distinction at the heart of the Indian Patent Act. It is best to understand the duality of the two terms from the examples of' non-patentable inventions.' The subject matter must meet the twin tests of "invention" and "patentability" for the grant of a statutory patent in India, like any other jurisdiction. The' invention' function is fulfilled if it passes the three patentability prerequisites-novelty, innovative phase and industrial usefulness as discussed above. As the term is generally understood, something may be an "invention," and yet it may not qualify for the purposes of the Act as an "invention." It, however, may even qualify as an "invention" as specified by the Act and yet may be denied patent for other major considerations / public interest as stipulated in the Act.

The most controversial section among the non-patentable clauses is the section 3 (d). The section 3 (d) after 2005 amendment reads thus: “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”. The Explanation to section 3 (d) sates thus: 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.” It is important to take a note of section 3 (d) of the erstwhile Patent Act before 2005 amendment which read as: “The mere discovery of any new property or mere 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.”

As demonstrated, there is an inclusion of the opening words in the substantive provision in the revised section and the incorporation of clarification in the substantive provision. It includes the terms at the beginning of the clause "the pure discovery of a new form of a known substance that does not result in the enhancement of the existing efficacy of that substance or;" and deletes the term "actual" before "new use;" and also adds a clarification at the end of the provision.[8]

V. CONCLUSION

More than 8,000 people worldwide are expected to die every day due to non-accessibility to care and only about one in ten people in' low and middle income' countries in desperate need of HIV antiviral medication have access to approved medicines. To order to encourage creativity, patents are required. The patent system offers necessary opportunities for scientific investment and allows inventors to participate in new research and development areas, thereby encouraging more innovation. At the same time, important areas such as public health should be considered, and countries should use the flexibility of TRIPS to exclude / revoke patents in order to protect public health.

[8] Watal, Jayashree, Intellectual Property Rights in WTO & Developing Countries, Oxford University Press, New Delhi, 2001.

The court of Novartis was not opposed to patent law. The decision of Novartis is not contrary to the laws of patents. The court, when determining the case, considered only the public interest and public health. In many parts of the world, the right to health is a cause of concern. One-third of the world's population has no access to basic drugs, and among this one-third, most people live on the continent of Africa and Asia. Since price is one of the major accessibility factors, this decision was of great importance as it allowed many poor countries to access the patented drug at affordable prices.

The need for the hour is to create a balance between patents and patients — a balance between patent laws and concerns of public health, so that the medicines are available to ordinary people. Check and balances in the Patent system including TTRIPS flexibilities, exclusion from patentability, compulsory licensing etc. must be boldly evoked by countries to address public health issues.

Countries have to penalize ever greening activities by making necessary amendments to their patent laws. For example, by enforcing penalties under sections 26C and 26D of the Australian Patent Act, 1990, Australian patent law provides protections against ever greening. The Act also has a provision to pay the government damages if greening activities are ever proved. Likewise, Article 18.9.4 of the Free Trade Agreement between the Republic of Korea and the United States (KORUSFTA) was expressly designed to require the creation of an "anti-ever-greening" pharmaceutical patent supervisory agency.

Patent ever greening is contrary to the patent scheme and intent and is highly unethical. Patents should not lead to drugs being inaccessible and unaffordable. Developing and least-developing societies need to take Novartis as a case study to consider how the flexibilities of TRIPS can be used against illegal patent greening.

REFERENCES

[1] D. Bhowmik, K. P. S. Kumar, S. Paswan, and S. Srivastava, “Tomato-A Natural Medicine and Its Health Benefits,” Phytojournal, 2012.
[2] I. K. Arah, H. Amaglo, E. K. Kumah, and H. Ofori, “Preharvest and postharvest factors affecting the quality and shelf life of harvested tomatoes: A mini review,” International Journal of Agronomy. 2015.
[3] G. Zhu et al., “Rewiring of the Fruit Metabolome in Tomato Breeding,” Cell, 2018.
[4] P. Paduchuri, S. Gohokar, B. Thamke, and M. Subhas, “Transgenic Tomatoes – a Review,” Int. J. Adv. Biotechnol. Res., 2010.
[5] T. Hirai, G. Fukukawa, H. Kakuta, N. Fukuda, and H. Ezura, “Production of recombinant miraculin using transgenic tomatoes in a closed cultivation system,” J. Agric. Food Chem., 2010.
[6] W. Lim, R. Miller, J. Park, and S. Park, “Consumer Sensory Analysis of High Flavonoid Transgenic Tomatoes,” J. Food Sci., 2014.
[7] A. Gerszberg, K. Hnatuszko-Konka, T. Kowalczyk, and A. K. Kononowicz, “Tomato (Solanum lycopersicum L.) in the service of biotechnology,” Plant Cell, Tissue and Organ Culture. 2015.
[8] T. Lin et al., “Genomic analyses provide insights into the history of tomato breeding,” Nature Genetics. 2014.
[9] L. Liu, Z. Shao, M. Zhang, and Q. Wang, “Regulation of carotenoid metabolism in tomato,” Molecular Plant. 2015.
[10] C. Zhang, R. Wohlhueter, and H. Zhang, “Genetically modified foods: A critical review of their promise and problems,” Food Sci. Hum. Wellness, 2016.