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EVERGREENING: A DECEPTIVE DEVICE IN PATENT RIGHTS

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ABSTRACT: ***Patents are the exclusive right of rewarding the first and true inventors of new inventions. An innovation must be original, requiring an innovative phase and an industrial application, in order to be patentable. In principle, patents exist to help the propagation of creative information. The patent system offers the requisite incentives for scientific investment and enables inventors to participate in new lines of research and development, thus encouraging more innovation. It is considered an exclusive right and not a monopoly, because there are built-in controls and balances in the patent system to avoid patent misuse, such as compulsory licenses, authorized use, etc. The recent trend in the patent system, however, shows that there is a tendency to increase patent rights, especially in the pharmaceutical sector, by making trivial changes and modifications. In general, drug firms are ever-greening, tweaking existing molecules to demonstrate creativity by filing fresh patent applications. Patent ever-greening is a term used to mark procedures that have arisen in some jurisdictions in which a small alteration to an existing product is made and believed to be a new innovation. The present paper addresses patents with a specific focus on patent greening at all times. A study will also be made of the seminal judicial decision in Novartis A G v. Union of India.***

KEYWORDS: ***Patent, Ever greening, Novartis, Pharmaceuticals.***

INTRODUCTION

Intellectual property (IP) refers to knowledge and information which can be commercially incorporated into tangible objects and exploited. The word used to describe independent rights, such as patents, trademarks, copyrights, industrial designs, geographical indications, sensitive details and layout designs, is collective. The existence, extent, quality and length of each right varies from property to property. IP protection is an encouragement to human creativity; to human creativity; it provides the requisite impetus for new R&D; it acts as an instrument for cultural, social, economic and technical growth. The key justifications for intellectual property rights (IPRs) are:

Patents are one of the powerful types of IPR. New inventors to be compensated are patented by countries. Patent law recognizes the exclusive right of a patent proprietor to benefit directly from his invention. A patent is an exclusive right given by a country to the owner of an invention for the development, use, and manufacture and selling of an invention, provided that the invention complies with certain conditions.1

To receive a patent, there are different legislative requirements that must be met. An exclusive privilege to honour the real and first inventors of new inventions is patent as a right. An invention must fall within the scope of the patentable subject-matter in order to apply for patent protection,

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

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and must satisfy the three statutory criteria of novelty, creative phase and industrial application. This implies that, in order to be patentable, the invention must be novel, non-obvious, requiring an innovative phase, and also have an industrial application. As long as the patent applicant was the first to invent the alleged invention, the criterion for novelty is usually fulfilled.

The criteria for industrial design means that the product must be useful to the industry and must fulfil a minimum human need. The creative step (non-obviousness) criterion excludes patentability if the contradictions between the claimed invention and the relevant prior art is such that, at the time of the invention, the claimed invention would have been evident to a person with common knowledge of the art to which the subject-matter relates.2

Innovation may be a product or procedure, and all technological areas are protected by its scope. In order to gain protection, the inventor must announce the invention as well as describe the method of performing it. The patent grants the patent proprietor the right, among other things, to exclude anyone from making, using or selling the invention.3

Countries may exclude from patentability certain inventions for the protection of public order or morality, or for the protection of human, animal or plant life or health, or for the avoidance of serious environmental harm, because such exclusion is not solely due to the fact that exploitation is prohibited by the municipal laws of those countries.

The aim of patent law is to encourage scientific innovation, new inventions and industry development. The patent system is based on the rational presumption that the public will reap extra benefits as the government takes more measures to promote the production, promotion and distribution of new inventions.4

The underlying argument is that when people devise new innovations, produce and sell new goods incorporating these inventions, and reveal knowledge to the public about their inventions, society profits, so that others might learn and advance from these inventions. Substantial investment in expertise, energy and capital is always needed to create something new. The technology that has been unveiled helps to encourage more imagination and innovative ideas. The economic benefit of patent data is that it presents the industry with information technology and can be used for commercial purposes. When there is no insurance, there might be a substantial opportunity to take a free ride on someone else's investment. As the inventor may not be able to recover the investment, this free-riding opportunity decreases the motivation to create something new.

Patents are also intended to correct industry defects. Market failure leads to sub-optimal investment rates in technical activities and occurs because companies that can use an innovation will still have a competitive advantage over businesses that innovate and suffer these costs despite incurring research and development costs. There will be no motivation to innovate as a result. With a temporary monopoly upon its intellectual property that they have created, patents reward

[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.

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innovators. The patent holder is expected to reveal scientific information that emphasizes creativity to the public in order to facilitate the dissemination of knowledge.

Therefore, patent gives inventor property rights to new inventions. The patent is considered and is the most economically possible form of IPR among all forms of IPRs, having a direct impact on the scientific and technological development of a country and having a major impact on the public health policy of a nation. Innovation per se may not be patentable, even though it clears the triple patentability test, as the discussions above demonstrate. The invention must not be excluded from patentability, i.e. the patent must not be the subject of a non-patentable invention in the country concerned.

Under Article 27, clauses 2 and 3, the TRIPS Agreement provides its Member States with ample flexibility to exempt such inventions from patentability, inter alia, for the protection of public order or morality or for the protection of human, animal or plant life or health. Furthermore, each person has the right to exclude from patentability such inventions for any of these appropriate purposes. In India, section 3 of the Indian Patent Act has been amended to allow for non-patentable inventions. Inventions that are not patentable but nonetheless meet the prerequisites of the patent are enlisted.5

DISCUSSION

Understanding the term Patent Evergreening

Patent perpetual greening is a violation and abuse of the patent system. It's the everlasting continuation of a patent. It denotes the practice of pharmaceutical companies seeking additional patents on minor variations of the original drug-new release forms, new dosages, new combinations or variations, or new forms, switching 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 characterize processes that have evolved in certain jurisdictions in which a minor change is made to just an existing product and claimed as a fresh innovation. The coverage/protection provided by the alleged new innovation is then used to extend the patent proprietor's monopoly rights over the drug, therefore preventing competition. Usually, just before their patents expire, these changes are made to blockbuster products. Ever-greening is possible in many countries, such as Australia and the US, as their legal standard for patent security is very weak. Different methods of drug delivery are already known for decades (such as dosage form, for example) (such as extended release, for example).6

Evergreening has many detrimental consequences. Ever-greening extends the market's licensing agreements span. This allows the generic supplier to wait indefinitely for all patents to expire and delays the opening of the generic market. It has a negative effect on public health and plays a negative role in shutting down value of domestic generic drugs, providing lower sections of society with access to essential prescription or life-saving medicines at reasonable rates. For example, in

[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

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India, the patented drug 'Gleevec' costs Rs. 4,115/-per tablet. At Rs. 30/-per pill, Resonance and the Indian generic drug company are selling their synthetic medicines in India.

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 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. Although the annual cost of Gleevec is Rs.15,00,000/-19 in India, its generic versions cost just Rs.10,000/-per year. The price drops to 95 percent when patents for a commonly used drug expire. Allowing patents directly or indirectly to enable new use of pharmaceuticals facilitates ever-greening in developing nations.

Coincidentally, for example, the 'Novartis' and thus the 'Gleevec/Glivec' medication and how Novartis overpriced the drug after EMR was granted were referred to in the parliamentary debates on trying to amend the patent law in 2005 to comply with the TRIPS provisions by moving from both the process patent system to product patents in pharmaceuticals, etc.

In the pre-TRIPS period, when poor humanity was desperately in need of drugs at cheap and affordable prices, India played a very important role as both the producer and supplier of medicines to various parts of the world. India was the leader in the global supply of affordable antiviral drugs and other essential medicines prior to the end of the TRIPs Agreement. This has provided countries like Papua New Guinea, Laos, Kenya, Asia, and so on with 50 percent of the world's cheapest drugs. India has also taken the lead in promoting the access to and availability of affordable generic HIV medicines for the less well off in developing countries. Since AIDS-affected countries do not have sufficient pharmaceutical manufacturing capacity, imports from major generic drug producing countries such as India depend on them to treat millions of their HIV patients. However, the TRIPS Agreement contained significant legislative amendments authorising the patenting of a drug which had raised considerable questions about its effects on public health. It also raised questions about the effect of the TRIPS drug patent system on the local development and availability of generic anti-retroviral agents on the local production of medicinal drugs.7

India understood from experience the inverse relationship between product patents and the indigenous pharmaceutical industry and their effect on the availability of essential drugs at reasonable prices. Although India had a scheme for drug patents, 85% of our medicinal requirements had to be dependent on imports. As we switched to patent regime development, i.e. our own products met 85 percent of India's medicinal requirement, this condition was reversed. By 1970, after the granting of product patents for pharmaceutical and chemical substances was banned by India's patent system, the pharmaceutical industry in the country reached high altitudes and became the largest supplier of drugs. Justice Ayyangar, after observing the situation and

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

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experience of other countries and suggesting the implementation of the method patent system in India, said:

"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, in order to comply with TRIPS specifications, India had to switch from the method patent regime to the product patent regime for medicinal products, agricultural and chemical substances. Nonetheless, the 2005 provision to prevent the abuse of drug patents introduced several changes, including pre-grant challenges, amendments in section 3 expanding the scope of non-patentable inventions and updating section 3. (d). Specifically, the other most important reform in section 3(d) was to prevent the ever-greening of pharmaceutical patents and to test repeated patent applications.

An analysis of section 3 (d)- non patentable inventions and the Novartis case

In section 3 of the Indian Patent Act, non-patentable inventions are discussed. "A closer inspection at the Indian Patent Act as it currently exists makes it apparent that "invention" and "patentability" are two distinctly different terms. At the heart of the Indian Patent Act, this is a vital distinction. From the examples of 'non-patentable inventions, it is interesting to understand the duality of that same two terms.' The subject matter must, like every other jurisdiction, satisfy the twin tests of "invention" and "patentability" for the award of a statutory patent in India. If it passes the three prerequisites for patentability-novelty, creative phase and industrial usefulness as discussed above, the 'invention' role is fulfilled. As the word is commonly known, anything may be a "invention," and yet it may not qualify as a "invention." for the purposes of the Act. However, it may also qualify as a "invention" as defined by the Act and yet, as stipulated in the Act, may be denied patent for a few other significant considerations / public interest.

Section 3 is the most contentious section of the non-patentable clauses (d). After the 2005 amendment, Section 3(d) reads as follows: 'Merely the discovery of a new type of a known substance which does not increase the known effectiveness of that substance or merely the discovery of any new property or new use for a known substance or merely the use of a known process, system or apparatus, whether such a known process results in the discovery of a new product or at least one new use.'

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. Therefore, the reason for section 3(d) states: for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, isomer mixtures, complexes, combinations and other

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derivatives of the known substance shall be considered to be the same substance, unless their efficacy properties vary significantly.8

The inclusion of that same opening terms mostly in substantive provision in the updated section and indeed the incorporation of explanation in the substantive provision are, as has been seen, included. It contains the words at the beginning of the clause 'pure emergence of a new use of a known drug which may not give rise to or boost the current effectiveness of that substance;' and deletes the word 'real' prior to 'new use;' as well as providing clarity at the end of both the provision.

CONCLUSION

More than 8,000 people worldwide are estimated to die every day due to inaccessibility to treatment and only around one in ten people who have access to licensed medicines in 'low and middle income' countries in dire need of HIV antiviral medication. Patents are necessary in order to promote innovation. The patent system provides the requisite opportunities for technological investment and encourages inventors to take part in new fields of research and development, promoting further innovation. At the same time, attention should be given to essential areas such as public health, and countries should make use of TRIPS' versatility to exclude/revoke patents in order to ensure the health.

The Novartis court was not opposed to the law on patents. Novartis' decision is not contrary to the laws regulating patents. The prosecution must prove only each public interest and public health when assessing the case. The right to health is a cause of concern in many parts of the globe. One-third of the world's population does not have access to basic medicines, and one-third of them live mainly on the continents of Africa and Asia. This decision seems to be of great importance as price is one of the key accessibility factors, as it permitted many poor countries to consume the patented drug at reasonable prices.

The need for the hour is to achieve balance between patents and patients, a balance between patent laws and public health issues, so that ordinary people can access the medications. Patent framework checks and balances, including TTRIPS versatility, exclusion from patentability, quantitative restrictions, etc., must be audaciously appealed to by countries to tackle public health By making required changes to their patent laws, countries have to penalize greening practices at all times. For example, Australian patent rule permits safeguards against evergreening by imposing penalties under sections 26C and 26D of the Australian Patent Act, 1990. If greening operations are ever confirmed, the Act also has a clause to compensate the government damages. Similarly, Article 18.9.4 of the Korea-U.S. Free Trade Agreement (KORUSFTA) was specifically designed to require the establishment of an anti-greening pharmaceutical patent supervisory agency.

Patent greening is extremely immoral and is contrary to that same patent system and purpose. Patents do not contribute to the inaccessibility and unaffordability of medications. In order to understand how the versatility of TRIPS can be used against unlawful patent greening, developing and least-developing societies need to take Novartis also as case study.

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