EVERGREENING OF PATENT

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Introduction

Patent is a monopoly right given for a limited period to an inventor who has made a new, useful and non-obvious invention of some product or process. Patent is essentially a statutory right. Patent has emerged as an important form of intellectual property right in recent times. In India product as well as process patents are granted for a term of 20 years. After the expiry of 20 years the patented invention falls in public domain.

For the grant of patent it is essential to show that it has novelty, utility and non-obviousness. Further minor improvements in the patented invention do not entitle a patentee to claim a fresh patent. In *Bishwanath Prasad v. H.M. Industries*[1] the Supreme Court observed that the fundamental principle of patent law is to grant a patent only for an invention which must be new and useful. The thrust is on novelty and utility. It is essential for the validity of a patent that it must be the inventor's own discovery as opposed to a mere verification of what was already known before the date of the invention. The invention must be more than a mere workshop improvement.

Concept of Evergreening of Patent

In the field of pharmaceutical patents, evergreening of patent has become a contentious issue. The pharmaceutical companies attempt to extend the monopoly right beyond the period of 20 years. When the term of patent is about to end the pharmaceutical companies make inconsequential variations to the existing patented drugs. In recent times evergreening of patent is largely resorted to due to generic versions of patented drugs. A generic drug is a drug which is produced and distributed without patent protection. The generic drug may still have a patent on the formulation but not on the active ingredient. A generic must contain the same active ingredients as the original formulation. According to the U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand name counterpart with

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1 A.I.R. 1982 S.C. 1444.

respect to pharmacokinetic and pharmacodynamic properties. By extension, therefore, generics are considered identical in dose, strength, route of administration, safety, efficacy, and intended use.

It has been in practice since the passage of the Waxman-Hatch legislation (Drug Price Competition and Patent Term Restoration Act) in 1984, in which the pioneer drug can receive an extension term equal to one-half the time of the investigational new drug (IND) period, running from the start of the human clinical trial to the time till the new drug application (NDA) is submitted.

Evergreening strategies usually followed by the pharmaceutical industries involve:

1. Redundant extensions and creations of 'next generation drugs' which result in superfluous variation to a product and then patenting it as a new application.
2. Prescription to over-the-counter (OTC) switch.
3. Exclusive partnerships with cream of generic drug players in the market prior to drug patent expiry thus significantly enhancing the brand value and interim earning royalties on the product.
4. Defensive pricing strategies practice wherein the innovator companies decrease the price of the product in line with the generic players for healthy competition.
5. Establishment of subsidiary units by respective innovator companies in generic domain before the advent of rival generic players.[2]

In most cases, generic products are available once the patent protections afforded to the original developer have expired. When generic products become available, the market competition often leads to substantially lower prices for both the original brand name product and the generic forms. The time it takes a generic drug to appear on the market varies from country to country.

Large pharmaceutical companies often spend millions of dollars protecting their patents from generic competition. Apart from litigation, companies use other methods such as reformulation or licensing a subsidiary (or another company) to sell generics under the original patent.

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[2] *Drug Patent Evergreening: An Overview available at* http://blog.mmsholdings.com/blog/bid/86991/ (last visited Aug. 24, 2014).

According to Indian Patent Act, 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 results in a new product or employs at least one reactant is not patentable.[3]

For the purpose of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, and mixture of isomers, complexes, combinations and other derivatives of known substances shall be considered to be same substance, unless they differ significantly in properties with regard to efficacy.

Judicial View on Evergreening of Patent

The High Courts as well as the Supreme Court of India have dealt with the contentious issue of evergreening of patents in few cases till now.

In *E Hoffmann La Roche Ltd. v. Cipla Ltd.*[4] Roche filed a patent application for Tarceva a drug derived from Erlotnib for treatment of lung cancer in 1996. The Drug Controller General of India gave approval to Roche for marketing Tarceva in India in 2005. The Cipla brought it's generic version by the name Erlocip in 2008. The once a day tablet cost of Roche is about Rs.4800, while Cipla's generic version costs about Rs.1600.

Roche filed infringement suit in Delhi High Court in 2008 to restrain Cipla from selling the generic version of Erlotnib. But Delhi High Court refused to grant temporary injunction and allowed Cipla to market it's generic version of lung cancer treatment drug Erlocip, a copy of Plaintiff's patented drug Tarceva in public interest. Therefore the principle laid down is that public interest will be given priority over patent right.

In *Novartis A.G. v. Union of India*[5] the Supreme Court rejected a patent application made by the drug manufacturer, Novartis A.G. ('Novartis') in relation to its cancer cure drug Glivec. This decision is a significant development in India's patent regime.

The Novartis filed the application for grant of patent for Imanitinib Mesylate in beta crystalline form which is used for treatment of leukemia at the Chennai Patent office in 1998. Novartis claimed that

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3 § 3 (d).
4 (2012) 52 P.T.C. 1 (Del.) decided by Justice Manmohan Singh.
5 (2013) 6 S.C.C. 1.

the invented product, beta crystalline form of Imanitinib Mesylate is an invented product as it has more beneficial flow properties, better thermodynamic stability and lower hygroscopicity than the alpha crystal form of Imanitinib Mesylate.

On 25 January 2006, the Assistant Controller of Patents and Designs passed an order rejecting the patent claim filed by Novartis on the grounds that the invention claimed by Novartis was obvious, anticipated and that the grant of patent on the drug is not permitted under Section 3(d) of the Patents Act, 1970. It was observed by the Controller that the appellant's invention was anticipated by prior publication of Zimmermann patent, it was obvious to a person skilled in the art, the patentability of the alleged invention is disallowed by Section 3(d) of the Act and July 18, 1997, the Swiss priority date was wrongly claimed as the priority date for the application in India and hence the alleged invention was also anticipated by the specification made in the application submitted in Switzerland.

Against this order, Novartis filed an appeal in the Madras High Court, which was later transferred to the Intellectual Property Appellate Board (IPAB). The appeal was rejected by the IPAB on 26 June 2009. Aggrieved by the rejection of grant of patent on the drug, Novartis approached the Supreme Court. The Supreme Court in its judgment dated 1 April 2013 upheld the rejection of Novartis' patent claim on the drug.

The main issue before the Supreme Court bench of Hon'ble Mr. Justice Aftab Alam and Justice Ranjana Desai in *Novartis* case was whether the drug stands the test of patentability as specified in Section 3(d) of the Patents Act. It provides that an invention which is in effect a 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 is not patentable.

Section 3(d) of the Patents Act was inserted by way of 2005 amendment to make India's intellectual property regime compliant with the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). The basis for including such provisions in the Patents Act was to avoid 'evergreening', a term given to the practice of extending the patent life of a drug by making incremental and minor changes to an existing drug.

The Supreme Court held that, the term 'efficacy' in Section 3(d) meant "the ability to produce a desired or intended result". Therefore, the test of efficacy in the context of Section 3(d) would depend upon the result, the function or the utility that the product under consideration is desired or intended to produce. Consequently, the court concluded that in the case of a medicine that claims to cure a disease, the test of efficacy could only be 'therapeutic efficacy', i.e., the capacity of the drug for beneficial change.

The court further held that a mere change of form with properties inherent to that form would not qualify as an enhancement of the efficacy of a known substance.

Mr. Anand Grover, the learned Counsel for Cancer Patients Aid Association contended that in pharmaceutical field drug action is explained by Pharmacokinetics (effect of the body on the drug) and Pharmacodynamics (effect of the drug on the body).[6]

Learned counsel for the appellant Mr. Gopal Subramanium contended that Section 3(d) is *ex majore cautela* (i.e., out of abundant caution).[7] The primary purpose of Section 3(d) as is evident from the legislative history is to prevent evergreening and yet to encourage incremental innovations. On concerns about public health issues and Doha Declaration he submitted that these concerns are addressed in the Act, in provisions relating to compulsory licensing, revocation of patents[8], and the multiple stages for opposition to the grant of patent[9].

Considering these contentions of the counsels the Supreme Court concluded that the physiological properties of the drug, i.e., more beneficial flow properties, better thermodynamic stability and lower hygroscopicity do not result in enhancement of 'therapeutic efficacy'. Further, on Novartis's claim that increase in bioavailability results in enhancement of therapeutic efficacy from the known substance, the Supreme Court held that the same will need to be collaborated with necessary data and research in each case and as Novartis did not submit any material to demonstrate this, the drug fails to satisfy the test laid down in Section 3(d) of the Patent Act.

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6 *See* Raizada Somit & Manoj Kumar V. Hiremath, *Pharmaceutical Patenting in the Context of Novartis A.G. v. UOI*, *in* EVERGREENING OF PATENTS 363-372, 370 (Prof. A. Lakshminath & Dr. Ajay Kumar eds., Satyam Law International, 1st ed. 2014).

7 *See* GOPALKRISHNAN N.S. & T.G. AGITHA, PRINCIPLES OF INTELLECTUAL PROPERTY 75 (Eastern Book Co., 2nd ed. 2013).

8 The Patents Act, 1970 §§ 63, 64, 65.

9 The Patents Act, 1970 § 25.

However the *Novartis* judgment does not impact the patentability of incremental chemical and pharmaceutical substances as it is apprehended by some experts. The Supreme Court has clearly stated that Section 3(d) does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances, leaving the question of patentability of such substances to be determined on a case-to-case basis. Therefore, in interpreting cases under Section 3(d), courts in India will now look into the ability of the product to materially improve upon an existing result.

The judgment in *Novartis* case has largely been welcomed as it has given precedence to accessibility of life saving drugs at affordable cost over monopoly right of patentee. The Supreme Court has clarified that it must not be construed as a ban on patent protection to all incremental inventions of chemical and pharmaceutical substances. However the judgment has not been received well by the pharmaceutical industry. It is to be seen that how much foreign investment will be impacted with this decision in pharmaceutical sector. But the judgment is aimed at protecting the genuine innovators.

The Indian law has been aptly interpreted by the apex court in tune with international standards, i.e., protection of an innovative new product as opposed to a minor change to the product.

Conclusion

The apex court's decision sets a precedent that evergreening of patent will not be easy in India like in many other countries. Earlier by introducing minor or insignificant changes in patented drugs, the patentee companies used to renew the patent granted. This will not be possible now. The Supreme Court's judgment has also brought a relief for patients who depend on life saving drugs. It will help in maintaining price of essential drugs within the reach of the people.