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RESEARCH ARTICLE

PRODUCT PATENTS AND ITS IPLICATIONS ON INDIAN PHARMACEUTICAL INNOVATION

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Abstract

This paper considers the role of Intellectual Property Rights in the development of new pharmaceuticals. A number of research have found patents are significantly more important to pharmaceutical firms in appropriating the benefits from innovation compared with other high tech industries, because the cost of drug innovation are very high while the costs of imitation are relatively low. The paper highlights the innovative process of product patents in drugs and pharmaceuticals. It also focuses on the pre and post TRIPs impact on pharmaceutical patent innovation.

INTRODUCTION

Intellectual property rights (IPR) have become important in the face of changing trade environment which is characterized by the following features namely global competition, high innovation risks, short product cycle, need for rapid changes in technology, high investments in research and development (R&D), production and marketing and need for highly skilled human resources. Geographical barriers to trade among nations are collapsing due to globalization, a system of multilateral trade and a new emerging economic order. It is therefore quite obvious that the complexities of global trade would be on the increase as more and more variables are introduced leading to uncertainties.

Many products and technologies are simultaneously marketed and utilized in many countries. With the opening up of trade in goods and services intellectual property rights (IPR) have become more susceptible to infringement leading to inadequate return to the creators of knowledge. Developers of such products and technologies would like to ensure R&D costs and other costs associated with introduction of new products in the market are recovered and enough profits are generated for investing in R&D to keep up the R&D efforts.

One expects that a large number of IP rights would be generated and protected all over the world including India in all areas of science and technology, software and business methods. Public Private Partnerships (PPPs) are seen to have a significant role in bringing in much needed investments as well as efficiencies in utilization and management of The World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) set global minimum standards for the protection of intellectual property, substantially increasing and expanding intellectual property rights, and generated clear gains for the pharmaceutical industry and the developed world. India too showed signs of resistance to quick enforcement of International Intellectual Property Right (IPR) protection laws as demanded by the developed countries.

The intellectual property (IP) system, and in particular the patent system, can play a pivotal role in relation to health-related development objectives as an incentive for innovation in the pharmaceutical field and as a policy

tool to facilitate technology diffusion and access to essential drugs. Conversely, poorly structured IP systems, with an inappropriate balance between innovation and access, can hamper the ability of governments to deliver one of their primary development objectives, safeguarding the health of their populations.

Indian Pharmaceutical Industry:

The Indian pharmaceutical industry currently tops the chart amongst India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian pharmaceutical industry is estimated to be worth $ 6 billion, growing at about 10 percent annually. It ranks very high amongst all the third world countries, in terms of technology, quality and the vast range of medicines that are manufactured. It ranges from simple headache pills to sophisticated antibiotics and complex cardiac compounds; almost every type of medicine is now made in the Indian pharmaceutical industry.

India is already among the top six producers of pharmaceuticals of the world. The Government of India has announced a host of measures to create a facilitating environment for the Indian pharmaceutical industry. India is home to 10,500 manufacturing units and over 3,000 pharma companies. India exports all forms of pharmaceuticals from APIs to formulations, both in modern medicine and traditional Indian medicines. Globally India ranks among the top exporters of formulations by volumes. India's generics exports have been growing at a rate of nearly 24 per cent annually over the last four years. India's pharma exports stood at US$ 14.7 billion in 2012-13, registering a growth rate of 11 per cent. India plans to increase its total exports to US$ 25 billion by 2016.[1]

Since independence, efforts of Indian Pharmaceutical Industry (IPI) have mostly been directed towards the development of alternative cost effective manufacturing processes for molecules already invented and patented in other countries. Very little was invested in R&D and no effects were made for development of new molecules/products. Over the last few decades, this contracted patent regime in India, recognizing only process patent, has had a negative impact on the development of professional expertise in the new chemical entity development as potential therapeutic agent. This in turn also gave lesser exposure to conducting advanced clinical trials and drafting patents and patent related litigation in the areas of new chemical entities, genetic engineering, combinational chemistry, natural products, agro-chemicals and agricultural products.

Post Trips - Pharmaceutical Industry;

The innovations in a knowledge intensive sector are essentially a dynamic process. India’s stance at WTO has undergone a sea change. India being a founder member of WTO, acceded to the TRIPS agreement, and the product patent regime was reintroduced in India. The patent system is a social policy tool that aims to stimulate innovation. Internationally, patent protection is governed by the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS does not establish a uniform international law, but sets out minimum standards of patent protection that must be met by all WTO members. The significance of the new IP regime on pharmaceutical industry in India, the amendment to the Patents Act, 1970, in fulfilment of the obligation to comply with TRIPS. The Indian pharmaceutical industry, which had little technological capabilities to manufacture modern drugs locally in the 1950s, has emerged technologically as the most dynamic manufacturing segment in the Indian economy in the 1990s. It achieved a significant scale and level of technological capability for manufacturing modern drugs indigenously and cost efficiently to emerge as a major developing country competitor in the world market. Only after the emergence of TRIPS, Indian pharmaceutical industry woke up to the challenges of new intellectual property regime. The Indian pharmaceutical industry became part of the knowledge industry consequent to TRIPS. India has had a unique position among the countries in the developing world for it has a strong generic pharmaceutical industry, which has been able to provide medicines at prices that were among the lowest in the world. Much of the credit for this development goes to the Patents Act that India enacted in 1970.

Earlier, India’s patent policy protecting the interest of public more than that of the monopoly rights. After the TRIPS, India was in the difficult situation of protecting people’s interest on the one hand and fulfilling the WTO’s agreement of TRIPs on the other hand. Now the social cost of granting patent would obviously entail in monopoly. As a result, there will be a rise in price, accompanied by lower supply of quantity. So in the short run, it is true that consumer welfare will fall. Hence short run costs will have an adverse impact on society. TRIPS implementation in India and other manufacturing countries will effectively cut the lifeline of affordable drugs unless safeguard measures are implemented to prevent this. One danger in compulsory licensing is that it will discourage further the commercial R & D necessary to new drugs to fight global epidemics. The monopoly power in the short run would encourage more innovation and greater enthusiasm in research and development which would be beneficial in the long run. Patent is one of the IPRs which gives the inventor sole right to

produce his property or license it to other producers. But misuse of this right is not desirable and it is not expected that patent holders would get into anti competitive ways such as ever-greening of patents, patent pooling etc.

Product patents and its implications on Indian pharmaceutical innovation:

The protection of the patents is an essential feature of the pharmaceutical industry. Since the innovation of pharmaceuticals is a high-risk and high-cost business and imitation, on the contrary, is a low risk and low cost business, it is universally accepted principle that protection against imitation must be provided in order for the innovation to exist. It is often argued that if no protection is provided against imitation, the high cost of R&D would discourage companies from investing money in innovation, with the consequence that certain medicines would never be able to reach the market. Thus, the function of a pharmaceutical patent is to provide a sufficient degree of protection to ensure that the new drugs are developed, however, without making it difficult for the competitors to enter the market.

The Supreme Court of India has recently held with respect to the application of Section 3(d) of the Patents Act, 1970 that mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance is not an invention and thus not patentable. In this case, the appeal case filed by Novartis against the rejection of patent for its anti-cancer drug sold under brand name "Gleevac" was rejected by the Hon'ble Supreme Court. The judgment of the Supreme Court of India, therefore, left the door open for the true and genuine inventions but at the same time, aimed to check an attempt at repetitive patenting or extension of the patent term on spurious grounds.

Another important tool for addressing the problem of abuse of patents in the pharmaceutical industry is issue of the compulsory license by the Government without the consent of the patentee. The Indian Patent Act has provisions regarding issue of the compulsory license to a third party. Generally, the grounds on which a compulsory license can be requested by an interested person after the expiry of three years of granting of the patent are: (a) reasonable requirements of the public have not been satisfied; (b) patented invention is not available to the public at a reasonably affordable price and (c) the invention has not worked in the territory of India. The compulsory license is a legal instrument designed to force the intellectual property owners to license out their statutorily granted right to the interested third parties, capable of manufacturing the patented product, at a cheaper prices. The main objective behind the compulsory licensing is that the Government ensures that the public in general are not denied drugs due to their pricing being too high. In March 2012, the Indian Patens Office had granted its first compulsory license, for the manufacture and sale of Bayer's patented drug Nexavar to Natco Pharma Limited.[2]

New Invention:

The Patents Act, 1970 defines the term "new invention" as any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art. It appears that the intent behind this provision is to define a 'novelty' standard - which, along with 'non- obviousness' (or inventive step) and 'utility' (industrial applicability), are the three prerequisites for patentability.[3]

Section 2 (j) defines an invention as a new product or process involving an inventive step and capable of industrial application.[4] Since "new" is already a part of the term 'invention' introducing a term such as 'new invention' to define a novelty standard is circular and makes for careless drafting. A clearer way of doing this would have been to define the term 'new' as found in the term 'invention'.

The 'new invention' definition suffers from yet another infirmity. While it appears to endorse an absolute 'novelty' ground, the Act still retains a relative 'novelty' ground in Section 25. It stipulates that a patent application can be opposed on the ground that the invention was publicly known or used in India before the priority date of that claim. To this extent, the ground for opposition is based on relative 'novelty', i.e. the invention should be known or used in India, whether or not it is so known or used in any other part of the world. The new definition under the 2005 Act however provides for absolute novelty in order to qualify as a 'new invention', the said invention should not have been anticipated by publication in any document or used in the country or elsewhere in the world.[5]

Consider an application for patent X in India, where the said invention had already been used in China at some earlier point in time. It would appear that such application could be refused by the patent office on the ground that the invention had been used in China and is not therefore a 'new invention'. However, at the stage of opposition, a third party cannot take up this ground under Section 25, since the invention had never been publicly used in India before the priority date of the claim. This difference in standard seems odd, because an interested third party is more likely to be aware of a foreign use of the invention in question than an Indian patent examiner.

Inventive Step:

A new Section 2(1)(ja) substituted the existing definition of 'inventive step' to mean:

"a feature of an invention that involves technical advances as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".[6]

This amendment attempts to redefine a cardinal principle of patent law. The legislative intent behind this amendment is to make the threshold of inventive step required for an invention to be patentable higher than the existing standard. If so, for an invention to be patentable, it must involve an inventive step and this is a feature of the claimed invention that involves technical advances compared to the existing knowledge or having economic significance or both. Further, the new definition retains the original language of the law that inventive step is a feature of the invention that makes it not obvious to a person of ordinary skill in the relevant art.

'Inventive step' was originally defined in the Patents Act to mean 'a feature that makes the invention not obvious to a person skilled in the art'. An explanatory note to Article 27 (1) of the TRIPS Agreement states that 'inventive step' is synonymous with 'non-obviousness'. There exists a plethora of judicial pronouncements on what constitute 'non-obviousness' as a criterion of patentability[7]. Further, many national patent offices have practice guidelines explaining the fundamental propositions concerning what is not obvious to a 'person of ordinary skill' in a given technological art – so as to make an invention patentable[8]. The revised language of law does not reflect the distilled stock of knowledge on what constitutes 'inventive step'. The wording *'technical advances as compared to existing knowledge'* has the potential to dilute the very basis of obviousness/novelty requirements. If an invention is not adequately distinct over the prior art – it is not patentable. As such, arguably, no additional safeguard is achieved by adding expressions that make the whole definition vague.

The second phrase is '*economic significance*'. As per the new definition, an invention to be non-obvious must have '*economic significance*' or '*technical advances as compared to existing knowledge' or both.* The use of 'or' makes the presence of both the aspects–'economic significance' or 'technical advances as compared to existing knowledge' non-mandatory, but desirable. 'Technical advances as compared to existing knowledge' is the quintessence of the jurisprudential tenet that 'an invention to be patentable must be distinctive over the closest prior art'. It is this that makes an invention non-obvious to a person of skill in the relevant art. If so, the language used in the new definition leaves room for dilution of the condensed principles on 'what constitutes inventive step'.

The other important expression occurring in the new Section 2(1)(ja) is *'economic significance'*. The aspect of economic significance is very well covered under another cardinal patentability requirement, namely, 'usefulness'. If so, the inclusion of the expression *'economic significance'* in the definition of 'inventive step' may further dilute this cardinal criterion of patentability. Arguably, this can make the legal position TRIPS non-compliant. However, a lot would depend upon the interpretation of the new definition by the patent office and thereafter by the judiciary.

New Definition for 'New Inventions':

The Act retains the old definition of 'invention' in Section 2(1)(j), but adds a definition on 'new invention'[9]. 'New invention' means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

The key question in this context is whether the aforesaid definition of 'new invention' would act as a limitation on the definition of 'invention' under Section 2(1)(j). And if it is, does this amendment conform to Article 27 of the TRIPS Agreement. 'Novelty' of an invention is typically ascertained by testing if the invention has been anticipated by prior publication, or prior public working or prior public knowledge. There are ways to ascertain this as well – of course with some levels of inherent limitations in carrying out prior art searches. But, redefining the 'novelty' requirement in the manner provided in the Act purportedly makes it an absolute requirement. The absolute

novelty requirement, as against relative novelty, thus applies to all the aforesaid aspects, i.e., prior publication, prior public knowledge and/or prior working.

The newly introduced definition of 'new invention' can be interpreted to act as a check on Section 25(d), (e) and Section 64(e) and (f) of the Patents Act, 1970 (as amended). These provisions deal with the use of anticipation by prior public knowledge or prior public use in India as grounds for opposing or revoking a patent application or patent as the case may be. While the novelty requirement as provided in Section 2(1)(j) conforms to Article 27 (1) of the TRIPS Agreement, the definition of new invention read with the definition of invention as above, has taken the legal provision away from TRIPS. The amendment, however, may avoid granting of frivolous patents for low-threshold inventions.

Originally 'patent' was defined to mean 'a patent granted under the Act'[10], the amended redefined definition of 'patent' means a 'patent for any invention granted under this Act'. When attempting to understand the legislative intent behind this amendment, the first question that arises is–whether there can be a patent for anything other than an invention. The legislative intent seems to further qualify the definition to ensure that a patent can be granted only for an 'invention' as provided under the Act, meaning thereby that the combined reading of the provisions of the Patents Act, 1970 will have an overriding effect in ascertaining the validity of a patent even after its grant.

New Use' Claims:

The Ordinance amended Section 3(d) to ensure that what is not patentable is only mere new use. If a second medical indication or therapeutic use of a known drug molecule passes the test that it is not a mere new use – as per the Ordinance, it would have been patentable. The Patents Amendment Act, 2005, changed this position. Instead, it contains a rather too long explanation on the exemption to patentability under Section 3(d). According to this Section what is not patentable is:

(a) 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;
(b) The mere discovery of any new property or new use for a known substance; and
(c) The mere use of a known process, machine or apparatus–unless such process results in a new product or employs at least one new reactant.

Consequently, if a discovery of a new form of a known drug molecule results in an enhancement of its known efficacy, it is patentable. Similarly, the mere discovery of a new use of a known substance is not patentable. The amended Section 3(d) when read in conjunction with Section 3(i) would ensure that all methods of use inventions are un patentable. A joint reading of the amended Section 3(d) and Section 3(i) keeps a major portion of pharmaceutical R&D outside the scope of patents. On the other hand, the amendment will restrict patent holders from making undue commercial benefit by developing a portfolio of patents around drug molecules. Typically, innovators of drug molecules use patent prosecution strategies (including filing divisional applications, continuation applications and continuation-in-part applications) for patent term extension. The patent term extension strategies often stem from continued research and development on new use of the drug. If a drug that is originally therapeutically indicated in the treatment of disease condition 'X', if later on clinically proved to be useful for the treatment of disease condition 'Y', the new use claims coupled with methods of treatment claims will enable the innovator-patentee to keep all the competitors off from the market space. The amended Section 3(d) has taken this into consideration to the advantage of the generic pharmaceutical industry. However, what is kept off from the patentability is Swiss-type[11] new use claims[12].

The Act further provides an explanation to Section 3(d) that *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. The phrase *'differ significantly in properties with regard to efficacy'* is the final test of patentability as regards all inventions around a drug molecule. While the law would attach a higher level of obligation on the patent applicant to pass this test, a lot would depend upon the invention claimed and also the way in which the specification in general and the claims in particular are drafted.

Mail Box Mechanism:

There has been a widespread concern that India is going to witness a flurry of litigations once pharmaceutical product patents come into force. The new proviso to Section 11 (A) brought in by the Amendment (which was not present in the Ordinance) ensures that a patent obtained through the 'Mail Box'[13] route cannot be used to initiate infringement action against a generic manufacturer who has made significant investment for producing and marketing the patented product prior to 1 January 2005. Most Indian pharmaceutical companies had stopped their product development activities on molecules, which are either directly or indirectly covered by patent applications pending in the 'Mail Box'.

On the other hand, a knowledge-based pharmaceutical company that spends substantial amount of time and money in developing a new molecule or an invention around a new molecule will not be able to make commercial use of the invention in India. After routing an application for patent through the 'Mail Box' all that a patentee can ask for is 'reasonable' royalty from an Indian company who would continue to commercially exploit the claimed invention. As such, this provision has the potential of nullifying the very purpose of the transitional protection provided in the TRIPS Agreement.

Pre-Grant and Post-Grant Opposition:

All grounds available for post-grant opposition have been made available to pre-grant opposition as well. The Act thus envisages two oppositions, first when the patent application is published, and second when a patent is granted. The post-grant opposition has to be initiated by an 'interested person'[14]. But any person can institute pre-grant opposition with the same ground as that of the post –grant opposition. The law allows a pre-grant opponent the right to be heard, whereas there is no provision in the Act enabling the Applicant to counter the pre-grant opposition.

It is pertinent to highlight that the Rules mandate that a pre-grant opponent has to file 'a statement supported by evidence'. That makes the pre-grant opposition a legal proceeding involving a process of adducing evidence. In a proceeding when an opponent is allowed to adduce evidence against a patent applicant and if the patent applicant is given no chance to counter the evidence, it may not conform to the principles of administrative law and justice.

The grounds to seek compulsory licences have been expanded. The newly inserted Section 92A(1) of the Act extended the scope of issuance of compulsory licenses for manufacture and export of patented pharmaceutical products to countries having insufficient manufacturing capacity in the pharmaceutical sector, if that country has by notification allowed such importation.

Conclusion

Patent as an institution of private property was by and large alien to India. The predominantly public funded research and development in the post independent India kept the patents law somewhere at the periphery of the economic system. Coupled to this was the exclusion of product patents for 'food, drug, and medicines' in the scheme of the patents law. This lead to a widespread misconception that product patent is not available in India in any field of technology. The national debate on TRIPS compliance, however, marked a new beginning for India's thus far premature patent system. Thus, a positive outcome of the recent public debate on patents and TRIPS compliance is that it resulted in substantial increase in the public awareness on patents in the country.

The need for innovation cannot be over emphasised in a sector as critical as the pharmaceutical sector which is directly relatable to human health and life. Research and Development relating to new drugs, therefore, is required to be adequately incentivised and inventions must be protected allowing patentees to recover huge investments made in such activities and earn reasonable returns.

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1. "GENERIC PHARMACEUTICALS" -- Note by the Delegation of India .
2. [Patents Act, 1970, Sec 2(1)(l), amended by Patents (Amendment) Act, 2005.]
3. The patent act 1970.
4. Patents Act, 1970, Sec 25, *as amended by* Patents (Amendment) Act, 2005.)
5. Patents Act, 1970, § 2(1)(ja), *as amended by* Patents (Amendment) Act, 2005.
6. Benmax v Austin Motor Co Ltd (70 RPC 284); Beecham Group Ltd's Appln. (1980RPC 261); Biswanah Prasad Radhey Sham v Hindustan Metal Industries (1979) 2 SCC 511 at 519; Martin &Biro Swan Ltd v Millwood Ltd 1956 RPC 125, pg 139

7. See the Manual of Patent Practice, UK Patent Office; the Manual of Patent Examining Procedure, the United States Patent & Trade Marks Office; the Guidelines for Examination, the European Patent Office.
8. (Section 2(1)(l) of the Patents Act, 1970 (as amended)
9. (Section 2(1)(m) of the Patents Act, 1970)
10. New Use claims are first granted by the Swiss Patent Office, hence are known as Swiss-type claims
11. Swiss-type claim means - **list of special types of claims** that may be found in a patent or patent application. For explanations about independent and dependent claims and about the different categories of claims, i.e. product or apparatus claims (claims referring to a physical entity), and process, method or use claims (claims referring to an activity).
12. A "mailbox" is created to receive and store the applications.
13. Section 2(1)(t) of the Patent Act, 1970.