Research Essentials

Patent Law and Intellectual Property in the Medical Field

Rashmi Aggarwal and Rajinder Kaur

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Patent Law and Intellectual Property in the Medical Field

The growing presence of technology has created significant changes within the healthcare industry. With the ubiquity of these technologies, there is now an increasing need for more advanced legal procedures.

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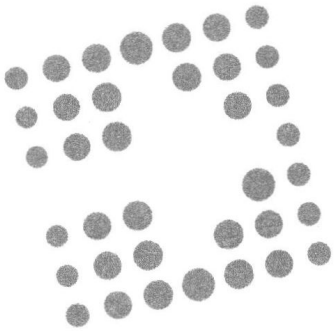

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Preface

The TRIPs agreement of the WTO envisaged a global IPR regime with major consensus on best practices and policy framework on all IPRs for the WTO members. India signed the TRIPS agreement in 1995 and committed to being TRIPs compliant by 2005. This led to notification of The Patents (Amendment) Act, 2005 which came into effect on April 3, 2005 fulfilling the TRIPs agreement. There was a direct implication on the medical patents regime in India. The rationale behind this amendment as emphasized by the then Government of India was that it will increase R&D in the country- the only way to survive in this competitive globalized economy to which India had opened up in mid 1990s. Indian pharma industry had been manufacturing high quality generic medicines at an affordable cost under the previous process patent regime. With effect from January 1, 2005, India began recognizing product patents, an important step towards complying with its TRIPS obligation. This had put an end to 'reverse engineering' practiced by the Indian companies paving the way for innovation and research in the pharma industry. It might not have severally changed the fate and face of the Indian pharma industry immediately but it was inevitable that in the times to come the number of new product launches had to be under the product patent provisions as against the process patents. Thereby, the domestic companies had to gain significant breakthroughs in their R&D efforts. At the same time the interest of the consumer, who in case of the pharma industry is a patient, needed medical care and access to medicines at most reasonable prices could not be diluted.

The patent protection is the statutory right granted under the national patent acts, to the patentee to exercise his absolute right on his invention and thereby it casts a duty on the part of the legislature to ensure that there are requisite laws to guarantee these protections. Though it's a monopoly right granted for a limited period of time, the right of exclusion of other stakeholders has to be carefully construed. Hence, any patent regime has to deal with following contentions:

1. Any patent protection leads to a limited monopoly in favor of the patentee which is justified on the ground that when the patentee is given exclusive right to ascertain this protection to ensure commercial viability of his invention. The commercial gains are primary benefits for the patentee and provides motivation to incentivize and encourage further R&D for technological and other advancements.
2. Patents guarantee a statutory right only for inventions and not prior art. Though the grant is national, investigation whether it is an invention or not is global. These are proprietary rights of an investor for a limited period but the knowledge is a public property, a common heritage of the people and hence can these inventions be declared as private properties of the inventors and exclusive right of use can be bestowed on them under the patent regime?

In India, this differentiation was adopted in The Patents Act, 1970. The architect of The Indian Patent Law of 1970, S Vedaraman, the then Director of the Indian Patent Office had summarized the spirit of the patent legislation as "We are not against patents. And we are prepared to pay decent license fees. But we in India cannot afford monopolies." From 1970 till 2005, India had a process for the pharma, agrochemicals and food industry and laid down that the patents shall not be granted for the claims or the products but for the manufacturing of these products. This provision was very well received by the Indian pharma industry and it rigorously indulged in 'reverse engineering'. Over a period of time the local pharma industry flourished so much that 85% of the pharma products were produced and distributed by these local manufacturers.

With the opening of Indian economy in early 1990's, the pharma multinationals felt threatened by this practice of their Indian counterparts. They did not find much merit in the grant of process patents for pharma inventions though the protection of inventions through products patents in their own countries was developed only in the last 30 years. For example, in Switzerland, the Swiss pharma industry fought for the enactment of a patent law at the end of the 19th century to imitate the foreign drugs, such as Aspirin. It was in 1978 after many deliberations that the product patent was introduced in Switzerland for pharma products. Such patents protect the interest of technology exporters, which shield them from low-cost competition. The erstwhile Indian Patents Act 1970, was perceived as a balanced legislation that helped the growth of the domestic pharma industry and also adequately covered the public interests. The Indian pharma industry produced high quality products of almost all therapeutic groups and that helped exports of generic pharma products to the developing and developed countries at competitive prices. The strong base of

the Indian pharma industry did not find any favor with the multinational companies. A group of these companies banded together, and worked relentlessly behind the scenes, first to work out what they called was an "ideal", "Global" patent regime, and then to "sell" it to the US administration and then to have it put on the WTO agenda and through the courtesy of this body have on the international trade to incorporate it in the TRIPS agreement in accordance with which all national Patents Acts of the member states of the WTO had to be amended. The thrust of their whole effort was to overturn the 1970 Act in India and similar legislation elsewhere in the world.

In India, the erstwhile Patents Act, 1970 provided the process patents under Section 5 which served to legalize "copying" of the drugs that were patented in developed countries as newly invented products but were unprotected in India. These Indian pharma companies were paying for licenses and royalties, hence that could access the newest molecules from all over the world and reformulate them for sale in the domestic market. Further, it provided for the general principles of working of the patentable inventions. The provision on these principles emphatically laid down the intention of the legislature to grant the patents to encourage inventions and to secure that the inventions are worked in India on a commercial scale. Thus, the inventions to be patentable had a commercial utility to it and further, the patentee ensured that the product is not kept to himself and that he should explore the marketing aspect of the patented process without any unreasonable delays. The law made it mandatory for the patentee to manufacture the process as only dealing in the imports of the process was not permitted under this provision. These trends lead to the share of the multinationals decline to 40% of the Indian market. The Patents Act, 1970 was amended three times in 1999, 2002 and finally in 2005 to bring it in line with the TRIPS agreement. In the amending process, some safeguard provisions had been incorporated. However, some provisions were beyond the TRIPS requirements and were called as TRIPs plus, the contentious of was Section 3(d). A critical evaluation of these amendments needs to be done in order to understand its impact on the Indian pharma industry.

Another provision which finds special mention here is on Compulsory License (CL) which permitted a third party to approach the Controller of patents, the official-in-charge of the grant of patents in the Patent office to grant a CL at any time after the expiration of three years from the date of the sealing of a patent. The pre-requisites for the grant of the CL were:

1. Reasonable requirements of public with respect to the patented invention have not been satisfied and there is a shortage of goods
2. Patented invention is not available to the public at a reasonable price

These two conditions though broadly covered the grounds on which the CL could be granted but a lot of other grounds could have been covered through this provision. A special ground in relation to the pharma industry where if there is a shortage of certain essential medicines and the patentee is manufacturing the patented medicine to the best of his ability but could not cater to the demands of the market. Or when the production cost is more than the profits which can be generated from the manufacturing of the drug than the Government can intervene and grant a CL to the generic company which can provide the same drug at a reasonable cost. The Controller could grant the CL to achieve certain purposes such as that the patented inventions worked on a commercial scale in India without undue delay and to the fullest extent that is reasonably practicable and that the CL should not be given against the interests of any persons for the time being working or developing an invention in India.

These provisions envisaged that the right given to any person through a patent protection should not be diluted by the grant of the patent protection if it is likely to prejudice the patentee rights. How did these rights get prejudiced was not clear from the reading of the provision. A more elaborate description of these interests was required so that the balancing between the better interests of the public by the grant of the CL to a third-party vis a vis infringement of the third party could be maintained.

The TRIPS agreement was an endeavor, using the WTO forum, to re-impose on the third world a regime of monopoly domination by the multinational companies from which the third world countries had been trying to escape, through the enactment of suitable legislation from their respective States. The TRIPS agreement did not represent some sort of an "ideal" or "optimum" regime. It represented nothing intrinsically sacrosanct but only an imposition reflecting, the unequal bargaining strengths of the participants in the Uruguay Round Negotiations at that time. TRIPS provided a three-stage frame for countries such as India which did not grant product patent rights in pharmaceuticals, when TRIPS came into force on 1 January, 1995:

1. Introduction of a facility ("mail box") from January 1, 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications will not be processed for the grant of a patent until the end of 2004. Exclusive Marketing Rights (EMRs) could be obtained for the application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.
2. Compliance, from January 1, 2000 with other obligations of TRIPS, namely, those related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof etc.

3. Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mail box are also required to be taken up for examination from January 1, 2005.

The important changes incorporated in The Patents (Amendment) Act, 2005 are:

1. Grant of patents for pharmaceutical, chemicals and food substances *per se* which were non-patentable vide Sections 3 and 5 of The Patents Act, 1970.
2. The grant of patents for the products and hence a shift from the process patent regime to the product patent regime.
3. Recognition of micro- organisms as a patentable subject matter.
4. Reversal of burden of proof in cases where infringement of a process for producing a novel compound where it prima facie appears that no other process could have been used.

The provisions on inventions which were patentable under the earlier act have not been amended except clause (d) of Section 3 of the principal Act. It first ruled out patenting of any discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance. This provision could also be interpreted in the light of the inventions *per se* where there has to be a technological improvement in the known property of an object for it to be entitled for the grant of patents. In the pharma sector if a medicine is invented and it is only an improvement of the earlier drug it shall not be subjected to the grant of the patents under this provision.

Further, this provision also covers the mere discovery of any new property or new use for a known substance or of the mere use of a known process or a machine or apparatus unless such known process results in a new product or employs at least one new reactant. The discoveries *per se* are not patentable and hence this provision is rather not required in such details. Did the exhaustive list of the different types of discoveries complicated the grant of pharma patents?

The explanation attached to the clause is just to clarify the different components of the pharma inventions which may involve 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. Based on case to case basis the various constituents of any medicine had to differ significantly in regard to efficacy for it to be granted a patent and mere improvements cannot be granted patents. Only non-obvious and significant changes in the composition of the pharmaceutical substances can be considered for the grant of patents. The final

decision on whether the substance is an invention and thereby should be granted a patent was subject to the discretionary understanding of the patent office. Should this provision be made objective and will it have a direct bearing on the patent files by the MNCs in India?

This provision further incorporates the term "new use" of already known property of the medicine. For example, if there is a medicine which can be injected and if one manipulates the composition, it can also be used as an oral medicine then this new use is not patentable. However, if the second medical indication of a known drug molecule passes the test than it is patentable. Consequently, if a discovery of a new form of a new 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 pharma companies incur a major expenditure on the discovery of a new use of a known substance which is now made non-patentable.

The language of the provision 'differs significantly in properties with regard to efficacy' is the final test of patentability as regards all inventions around a drug molecule. It seems that this explanation will keep a huge amount of R&D outside the scope of patentability, because the properties concerning efficacy will have an overriding effect over the standard tests of patentability when it comes to pharma inventions. The pharma companies will restrain themselves from indulging in R&D relating to better efficacy which may not be significant efficacious. As the patent protection is granted only for the latter there might not be improved versions of available medicines in the market any more. Either there will be new inventions or medicines which are significantly different from the available drugs.

The objective behind such an elaborate explanation in Section 3(d) is probably to check what the Indian generic drug makers alleges as ''ever greening''. "Ever greening" is a phrase in currency in relation to updating of a patented product and protecting it as new. It is when the patent owner attempts to extend the patents monopoly by seeking a new patent that updates the first one before its expiration. This is usually done by claiming things such as "inventive" method for administering the pharma company covered by the base patent. For the pharma products, this means an extended monopoly that excluded generic drugs from the market. The act thereby makes it clear to the domestic companies that the new use of previously patented entities will not qualify for patents. How far reaching have been the consequences of this provisions needs to be assessed as it has been more than a decade since India made patents to be TRIPs compliant and more.

The objective of present edited volume is to understand the Indian patent laws, impact of all three amendments on the Indian medicine industry and subsequently on the consumers, the real stakeholders. Further, can we question whether IP policy was means to an end or an end in itself? Should there be unilateral approach within the context of more innovation more IP or more IP and thereby more innovations

or should there by plurality of approaches? Can there be a thematic permeation to the IP regulations? There are many arms to these contentions. The book has been divided into 11 chapters.

Chapter 1, "Patents: An Overview and Legal Aspects," provides comprehensive understanding of Indian patents law and reviews the legal effects of patent rights. It reviews the main benefits, types and costs of the patent system, focusing on the role that patents play in providing incentives for innovation, in promoting the dissemination of knowledge, and in helping technology transfer and commercialization of new technology, problem of the optimal length and scope of patent protection, both for the case of a single innovation and for the richer case of cumulative innovations.

Chapters 2 and 3 provide a comparative between specific pricing policies of medicines as main contention against grant of patents for life saving medicines have been on the availability and affordability of medicines in least developed, developing and developed nations. The chapters cover various techniques pharmaceutical industry adopt to control price of patented products such as proliferation of me-too drugs, product reformulation, prolonging patent rights, biasing research and large promotional expenditures.

Chapter 4, "Impact of National and International Regulations on Indian Generic Drugs Industry," is an analysis. The chapter is a study on evolution of the IP laws in India with regard to pharma products and their impact on the pharma industry in India. It analyses the amendments to Indian Patents Act 1970 as a result of India's obligations towards the TRIPS agreement while balancing the need to safeguard the interests of its population, domestic industry, international laws and treaties.

Chapter 5, "Parallel Import in India: A Study," covers the concept of parallel importing when there the patented drugs are not either affordable or there is a shortage of goods in the market. As a fall out the national regulators allows for parallel importing of drugs without seeking permission of the patentee.

Chapter 6, "Exclusions on Patentability," provides detailed understanding on exclusion of patentability with reference to Diamond v. Chakrabarty where the U.S. Supreme court endorsed a controversial view holding that "anything under the sun made by man" is patentable, but the situation was rectified subsequently in Diamond v. Dier. The chapter will take up the study relating to the provisions of exclusions in patentability in international and national regimes while highlighting the emerging grey areas on the exclusions of patentability.

Chapters 7 and 8 are a study on the issue of patenting vis-a-vis stakeholder perspectives holding diverse views. On one hand the pharma companies demand for rigid patent protection on the context of R&D spending's and on the other hand the health activists and governments of developing nations want greater flexibility in the IP protection and shorter patent period protection. It explains the concept of CL, its use and provides illustrations on issuance and denial of CL in different countries.

In Chapter 9, traditional knowledge and IPR, both are supplementary and complementary to each other but the aim of traditional knowledge is to promote community interest, protect indigenous rights against bio piracy and bio prospecting, on the other hand IPR provides monopoly and profit. These chapters also cover the effects of Bonn guidelines and Biodiversity Act, 2002 and the issues related to traditional knowledge and how those issues cannot be handled by the existing IPR laws.

Chapter 10, "Colgate-Palmolive's Attempt of Patenting Toothpaste Formula," is a case study of Colgate-Palmolive, legal dispute on allegations of purloining of an archaic formula to be used for a mouthwash product by the company which was a prior art and traditional know-how in India.

Chapter 11, "Various Tools Available to Access Patent Information in India," is a comprehensive study on search engines to establish the credentials on whether the patent application can be granted a patent or not by the national patent offices. For the patent grant, technical information about the invention must be disclosed to the public in the patent application. This information is available from both free and fee-based sources across globe. This chapter is a study on different databases and tools available in India for the patent search.

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