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RESEARCH ARTICLE

Patent: A Tool For Providing Protection To Innovative Research Ideas

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Abstract:

A patent is an exclusive right granted by the government to the original inventor or researcher of an invention, it is recognized internationally by the trade related intellectual property rights agreement (TRIPS) governed by the WTO (world trade organization).IPR is legal right which is granted to a person for creation of the mind. In the present article, a brief historical background of intellectual property rights in relation to the Indian pharmaceutical sector has been summarized because role of Intellectual Property Rights (IPR) is very significant in pharmaceutical industries. Patenting invention is one parameter that enhances the strength of a country economically. The purpose of patent is to encourage inventions by promoting protection and utilization innovative research ideas. The concept of compulsory licensing is briefly discussed according to the Indian pharmaceutical market. Compulsory license is a permission granted by the government to a non patentee to make a patented product.

Keywords: Patents, Trade related intellectual property rights, Indian pharmaceutical sector, compulsory licensing.

Introduction

A Patent is an exclusive monopoly granted by a government to an inventor over his invention for limited period of time. It is a kind of intellectual property right (IPR), which allows rights (including exclusive manufacturing and marketing rights) pertaining to an object (product) and/or a means (process), with a view to reward the invention. Patents are statutorily designed real life legal instruments aimed at protecting inventions. Inventions, in modern times, are the outcome of well-planned research and development. Patents act as economic incentives to inventors who put in intellectual labor to develop new and useful inventions. Patents foster research and development by providing limited term exclusivity to patentees to commercially make use of the inventions they own. Patents are granted by national governments in consideration for disclosing to the public the scientific and technological information subsisting in the inventions by the inventors/or the subsequent owners of the inventions. Published patent specifications are therefore, important scientific documents containing extremely valuable scientific information[1, 2]

Patentable Inventions

Invention means a new product or process involving inventive step and capable of industrial application. Not all inventions are patentable. For an invention to be patentable, it must be new, useful and non-obvious. Invention means a new product or process involving inventive step and capable of industrial application. Inventive step is defined as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or

both and that makes the invention not obvious to the person skilled in the art. The national laws of a number of countries prescribe limitations on the patentability of inventions. As for example, the Indian law declares that inventions which are frivolous or which claim anything obviously contrary to well established natural laws are not patentable. Inventions, the commercial exploitation of which could be contrary to public order or morality or which cause serious prejudice to human, animal or plant life or health or to the environment are also declared as non-patentable[3].

Patent Specification

The process of patenting begins with the execution of an idea by an inventor. Typically an idea is executed by preparing a technical disclosure statement that enables a person ordinarily skilled in the art to reduce the invention into practice. The technical disclosure is then converted into a patent specification. This is an extremely sophisticated process that is governed by well-established conventions in patent law and practice. The process typically involves conducting prior art searches to distinguish the current invention from prior art and developing a patent disclosure that demonstrates the best mode of working the invention. The patent specification comprises a title, the technical field, cross-reference to related patents (if relevant), the background of the invention, the description of the related art, the summary of the invention, the brief description of the drawing figures (if any), the detailed description of the preferred embodiments, claims and abstract [3,4].

HISTORY OF INDIAN PATENT SYSTEM[5]

A) 1856:

The Act VI of 1856 on protection of inventions based on the British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.

B) 1859:

The Act modified as Act XV; patent monopolies called exclusive privileges (making. Selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification).

C) 1872:

The Patents & Designs Protection Act.

D) 1883:

The Protection of Inventions Act.

E) 1888:

Consolidated as the Inventions & Designs Act.

F) 1911:

The Indian Patents & Designs Act.

G) 1970:

The Patents Act (Act 39 of 1970) came into force on 20th April 1970.

H) 1999:

On March 26, 1999 Patents (Amendment) Act, (1999) came into force from 01-01-1995.

I) 2002:

The Patents (Amendment) Act 2002 came into force from 20th May 2003.

J) 2005:

The Patents (Amendment) Act 2005 came into force

PATENT PROCEDURE [6, 7]

Patent Forms

Form 1- Application for grant of a patent.
Form 1A- Application corresponding to an international application for grant of a patent.
Form 2- Provisional/ complete specification.
Form 3- Statement and undertaking under Sec- 8.
Form 4- Request for extension of time.
Form 5- Declaration as to inventor-ship.
Form 9- Request for publication.
Form18- Request for examination of application for patent.

Application form for patents:

The application form should contain the following necessary details: Name, addressee and nationality of the applicant, Title of the invention, State if it is filed with complete or provisional application, the proof of assignment if any, A statement certifying that the applicant is in possession of the invention and is the true and first inventor, The date and signature of the inventor by a patent specification

Filing a Patent Application in India

Filing a patent application in India is required some important documents, which are important for granting a patent in India.

a- Application form in duplicate (Form 1 or 1A)
b- Provisional or complete specification in duplicate
c- Abstract of the invention in duplicate
d- Drawing in duplicate (if need)
e- Priority document (if priority date is claimed) in convention application
f- Declaration of inventor ship
g- Power of attorney (if field through patent agent)
h- Fee (to be paid in cash/by cheque/by demand draft)

Filing and Prosecuting Patent Applications:

Most countries have national laws providing for patent administration systems. These national laws not only prescribe the substantive principles concerning the patentability of inventions but also the procedure for securing patents for inventions and maintaining such patents after the grant. Once an application for a patent is filed, the national patent office in most countries will publish the application (there are some exceptions to this). Typically an application for patent will be examined for formal and substantive compliance by the national patent offices. This examination may precede prior searches and in such cases the national patent office may issue a search report. This will be followed by the establishment of an Examination Report. It is the

obligation of the applicant for patent to remedy the objections by the Examiner of Patents and there will be certain time limits attached with these processes. Once the applicant complies with the national patent office requirements, the patent will be granted and issued. It is the patentee's responsibility to maintain an issued patent by paying the annuities until the patent expires after its 20 years' term (the term of patent may not be 20 years in all countries).

Procedure for grant of a patent:

Initially, a patent examiner examines the patent applications and then communicates the objections, if any, to the applicant via the first examination report. The applicant then has a grace period of 15 months to answer the objections and comply with the requirements. If the applicant does not comply with the objection, the application is abandoned. If the applicants comply with, the objections, then the patent office sends a notice of acceptance to the applicant that the claims have been accepted for publication in the official gazette. Claims are then published in the gazette of India and the specification is opened to the public. The public can oppose the grant of the patent within four months from the date of publication or five months with an extension of one month.[8]

CHANGES IN PATENT REGIME IN INDIA

Patent Amendments in India after TRIPS:

TRIPS provides 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. But Exclusive Marketing Rights (EMRs) can be obtained for that 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 and so on.

3. Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mailbox are also required to be taken up for examination from January 1, 2005.[5]

Compliance with the TRIPS requirements has taken substantial time in India. This reflects the significant opposition to TRIPS in India. An Ordinance was actually introduced a day before TRIPS came into effect. But the Ordinance lapsed because it could not be followed up with the necessary legislation within the stipulated time required. Then the government introduced a Bill and it was passed in the Lok-Sabha (the Lower house of India's Parliament). But in the Rajya- Sabha (the Upper house), where the opposition was in a majority, the Bill was stalled – the Bill was referred to a Parliamentary Select Committee and the report could not be submitted by the time the Parliament was dissolved in May 1996. USA and later the European Commission (EC) filed a dispute against India at the WTO alleging that India had not complied with the provisions of Articles 70.8 and 70.9 of TRIPS. The Panel set up by the Dispute Settlement Body (DSB) of the WTO ruled that India had not complied with its obligations. India appealed against this ruling, but the Appellate Body of the WTO rejected the appeal and asked India to comply with the requirements by April 1999. Again a Bill was introduced, and this time it was passed in the Rajya Sabha on 22 December 1998, but the Bill could not come up for consideration in the Lok Sabha. Ultimately an Ordinance was promulgated followed by an Act passed in March 1999. The Patents (Amendment) Act 1999 amended the Patents Act, 1970 with retrospective effect from 1 January 1995 to implement mailbox facilities and EMRs as mentioned in (1) above.

But it has taken much less time than what it did to introduce the Patents Act, 1970. The task of changing the British Patents and Designs Act, 1911 was started immediately after India's independence in 1947. Several bills were presented to the parliament. But it was not before another two decades that the new patents act could be enacted.

Another Bill was introduced in the Rajya Sabha in December 1999 to bring about the other changes in the patent regime as mentioned under (2) above. This Bill too faced similar hurdles and could not be passed immediately. The Bill had to be referred to a joint parliamentary committee. This committee consulted a large number of people including, lawyers, economists, industry representatives, NGOs and others. Several objections were raised. Some of these were incorporated and the committee submitted a revised Bill in December 2001 (Joint Committee 2001). This Bill with a few changes was approved by the Parliament in May 2002. The amended Act (The Patents (Amendment) Act, 2002) came into force on May 20, 2003. The Patents (Amendment) Act, 2002 made 64 amendments to the Patents Act, 1970 relating to terms of patents (20 years), exceptions to exclusive rights, compulsory licensing and so on.

A third Amendment was necessary by the end of 2004 to replace the EMR system and to introduce product patent protection as mentioned under (3) above. A bill (The Patents (Amendment) Bill, 2003) was introduced in the

parliament in December 2003. Before this bill could be passed, Lok Sabha was dissolved. After the elections, the new government, which came into power in May 2004, referred the issue of the Third Amendment to a Group of Ministers (GoM). Many public interest groups and others demanded that the recommendations of the GoM should be made public and a debate be held before finalizing the amendments. But this was not done. In fact even without discussing it in the parliament, full-fledged product patent regime has been introduced in India from 1 January 2005 through a presidential decree (the Patents (Amendment) Ordinance, 2004) issued on December 26, 2004.[8,9]

FLEXIBILITIES UNDER TRIPS

It is anticipated that with the introduction of full product patent protection in pharmaceuticals from 1 January, 2005, as the generic companies are prevented from introducing new drugs, the lack of competition will result in high prices. Supply of low cost new drugs to the Indian market and to other countries will be threatened. But TRIPS provides for some flexibilities to member countries of WTO to take action to tackle such negative consequences of product patent protection.

Within the scope of TRIPS, the following are the main flexibilities, which developing countries can use:

1. Provide exemptions from grant of patents in certain cases
2. Provide exceptions to product patent rights in certain cases
3. Limit data protection

1. Exemptions from grant of patents:

Under Article 27(1) of TRIPS, patents will have to be provided for inventions, which are "new, involve an inventive step and are capable of industrial application" The agreement however does not define these terms. This provides some flexibility. It has been suggested that a developing country can interpret these terms so as to restrict the number of patents. Chapter II (Sections 3 to 5) of the Patents Act, 1970 deals with "inventions not patentable." It was hoped that the third amendment would provide the qualification that product patents will be granted only for new drugs, which represent significant therapeutic advances. It has been the demand of not only the generic pharmaceutical industry, but also of Indian scientists, lawyers and others that patents may not be granted for "a new molecular modification or a salt or ester or a derivative or a formulation or dosage form of a known new chemical entity having the same or similar pharmaceutical activity" or new uses or new combinations of existing NCEs. One of the arguments in favor of product patent protection in pharmaceuticals is that the development of new drugs is a costly business and hence there must be enough financial incentive to continue to do so. But as the NIHCM (2002) study shows, most of the new drugs are unnecessary combinations of existing drugs or simple modifications of existing drugs, which represent practically no therapeutic advance.[10, 11]

2. Exceptions to exclusive rights:

Patents basically confer on the patentee the right to prevent others from using the invention. But such rights are not absolute. All patent laws usually provide some qualifications to such exclusive rights. Article 30 of TRIPS permits member countries to "provide limited exceptions to the exclusive rights conferred by a patent.

The following three are the most significant and common exceptions, which the national laws in many countries provided when TRIPS came into effect:

A) Early working.
B) Parallel imports.
C) Research and experimental use.

A) Early working:

The "early working" provision is popularly referred to as the "Bolar" provision or exception. The Bolar provision is very important for generic entry. It permits generic entry soon after the patents expire and hence allows the consumers to benefit from competition and lower prices without delay. In the absence of it, generic companies will have to wait till the patents actually expire before they can start the tests necessary for getting regulatory approval. It is known as Bolar provision after the court case involving Roche, an MNC and Bolar Pharmaceuticals, a generic company. So Bolar provisions can be used to introduce generics immediately after the expiry of patents.

B) Parallel imports:

Under Article 28 of TRIPS, the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing from other countries. This is however subject to Article 6 on "exhaustion." What it basically means is that the patent holder in a country cannot legally stop imports of patented products offered for sale in another country.

Under the original 1970 Act, importing was not mentioned as an exclusive right. This has been amended (in Section 48) to conform to TRIPS. But unlike Article 28 of TRIPS, Section 48 of India's amended patents Act provides no qualification about exhaustion of patent rights. Instead another section (107A(b)) has been inserted which says, "importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product shall not be considered as an infringement of patent rights." This does permit parallel imports but only in some cases. As the Indian Drug Manufacturers Association (IDMA) has pointed out, the phrase "duly authorized by the patentee" may cause delay and difficulty. In accordance with the spirit of Article 28 of TRIPS, any import from any legitimate source even if not specifically authorized

should be permitted[12.]

c) Research and experimental use:

Section 47 of the Patents Act, 1970, which has not been deleted in the recent amendments, provides other exceptions. The patented product/process may be made or used by any person for the "purpose merely of experiment or research including the imparting of instructions to pupils." It is also possible to exempt acts of experimentation even if made with commercial purposes.

If the indigenous sector is asked once in a while to develop a process, it is possible that they may not be able to do so. The opportunity of using the patented product for R&D purposes will enable the indigenous firms to be ready with efficient processes and use these whenever they are permitted to do so. Article 66.2 obliges the developed countries to provide incentives to developing countries to promote technology transfer[13]

3. Limiting data protection:

To get marketing approval for a new drug developed, innovator companies are required to submit test and clinical data relating to safety and efficacy to national health authorities. The current practice is that when generic companies apply for approval of their drug, they are not required to conduct their own studies and submit independent data. They can rely on the safety and efficacy data submitted by the innovator company and get marketing approval for their products. But if the law of a country provides for data exclusivity, i.e., grants exclusive rights to the innovator company to prevent subsequent applicants from using the data submitted, then generic companies cannot use such data till the data exclusivity period ends.

Data exclusivity provisions have implications for generic entry and hence competition and prices. A patent is taken immediately after a new drug (new chemical entity) is developed. But usually it takes several years of clinical trials and other testing and drug development before a drug is approved for marketing. Thus a drug discovered and patented in 1995 may actually be approved for marketing in 2005. In developing countries, it may be introduced even later, for example in 2010. With a 20-year patent term under TRIPS, the monopoly patent rights are supposed to expire in 2015 and generic companies can enter the market. But if the developing country provides for data exclusivity for 10 years, then generic companies cannot use the test data before 2020 because generic companies typically do not have the resources to conduct such time consuming and costly studies. As a result data exclusivity effectively extends the monopoly beyond the patent term.[14, 15]

India has been able to use an important TRIPS flexibility with positive implications for generic competition and the amended Act. In the process many negative aspects prices. But India has been under tremendous pressure from MNCs and the US government to introduce data exclusivity provisions. Government officials admit that it is not a TRIPS obligation but feel that a re-consideration by India may be necessary. In the USTR 2004 report, India as been targeted as a "priority watch list" and points out that "…the United States is encouraged by the Indian Government's recent statements concerning implementation of data exclusivity regulations …"[15.]

COMPULSORY LICENSING[16]

As different studies and reports have highlighted, in a product patent regime, a proper compulsory licensing system is of vital importance to deal with the negative implications of product patent protection on prices. If generic companies are given licenses to produce a patented drug on payment of royalty, then competition among manufacturers would drive down prices, but the royalty paid to the innovators would continue to provide funds and the incentive for R&D.

Patents Act, 1970 had a clear strategy – to eliminate the monopoly of the MNCs and remove the bottlenecks in the previous regime that prevented the indigenous firms from producing patented drugs. And it was done through a very simple process of abolishing product patent protection in drugs. The Act of 1970 also had provisions for compulsory licensing for pharmaceutical processes. In fact under Section 87 of the 1970 Act, any process patent related to pharmaceuticals were to be endorsed with the words "Licenses of right" within three years of the sealing of the patent. In such cases, anyone could ask for a license from the patent owner to use the patented process on mutually agreed terms. But a compulsory license was redundant in the previous regime. Being free to produce the patented drugs, the indigenous firms could develop their own processes and they indeed did so, as we have mentioned above. But in the product patent regime being introduced in India, the indigenous firms will not be able to produce a patented drug even if they develop the processes of manufacturing it, unless they get a compulsory license. Hence it is of fundamental importance to have a simple and easy to administer compulsory licensing system.

But this has not been done. The basic problem with the amended Act is that it lacks any positive strategy. It appears that adequate attention has not been devoted to design the law to take advantage of the flexibilities, which TRIPS provides. The entire amendment has been carried out very mechanically. It starts with the relevant text of the Patents Act, 1970 and then makes some changes to make it TRIPS compliant. This has been done by deleting some clauses of the 1970 Act (for example abolition of special license of right compulsory licensing provisions relating to pharmaceutical processes) and lifting some clauses from TRIPS and inserting these in importance in promoting competition while ensuring that

have remained in the amended Act, which could have been tackled without violating TRIPS.

In the amended Act, an application for a compulsory license can be made under two sets of circumstances: under Section 84, three years after the sealing of the patent and under Section 92, anytime after the sealing of the patent with respect to a patent notified by the government as eligible for a compulsory license. The amended Act has elaborate provisions on compulsory licensing in Chapter XVI (Sections 82 to 94). The general principles note that patents are granted to encourage inventions and to make the benefit of patented invention available at "reasonably affordable prices to the public," to secure that these are worked in India, and not to enable patentees to enjoy monopoly power by importing. That the patent right is not abused by the patentee and the patentee does not "resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology" (Section 83). Act also specifies the "general purposes" to be followed while granting compulsory licenses, for example that "the patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable" An application for a compulsory license can be made under Section 84 on the following grounds: that the "reasonable requirements of the public" have not been satisfied, or that the product is not available at a "reasonably affordable price", or that the patented invention is "not worked in the territory of India". Thus under the Indian law, if a patentee does not exploit locally the patented inventions, then compulsory licenses can be asked for.

RECAPITULATION:

Under TRIPS, it is mandatory for all member countries of WTO to provide patent protection for all products including pharmaceuticals. But the protection of the rights of the patentees is not the sole concern of TRIPS. TRIPS provide flexibility for governments to strike a balance between the private rights of patentees and the socio-economic needs and objectives of its people.

The costs of high prices resulting from product patent protection can be tackled by:

(i) Resorting to parallel imports or granting compulsory licenses during the patent term.

(ii) Ensuring that the entry of generics is not delayed after the expiry of patents.

The recent amendments to India's patent law provide for parallel imports and hence the country can shop around and import cheaper alternatives, if available. But considering the status that the generic companies in India have achieved, what is of greater importance in India is a proper compulsory licensing system. In a product patent regime, a proper compulsory licensing system is of vital patentees get compensation through royalties. But India has not been able to take full advantage of the compulsory licensing provisions. Even in cases of special provisions relating to national emergency, extreme urgency or public non-commercial use, adequate care has not been taken to put in place a proper structure to prevent delay due to litigation. India as a low cost producer of drugs has particular significance from the point of view of supplies to countries with no manufacturing capacities. Care has not been taken in the patent amendments to facilitate such exports [6, 13.]

In the absence of compulsory licensing, generic companies can enter the market only after the expiry of the patents. But the entry of generics depends on patent and other legislation. India has incorporated the Bolar provision. This will permit the generic producers to use the patents even before the expiry to get regulatory permission and hence to enter the market as soon as the patent expires. India has also not yet provided data exclusivity. Hence lack of access to test data may not prevent generic entry after the expiry of patents.

But multiple patents can be taken to effectively extend the patent term. While deciding on the inventions eligible for patents, the terms, "new", "inventive" can be defined to grant patents only for new drugs which represent significant therapeutic advances. Modifications of existing chemical entities, which do not involve clinical improvements, can be excluded. This would restrict the number of patents and prevent the delay of generic entry. Such qualifications have not been provided in the patent amendments carried out in India.

If the bias in the Patents Act, 1970, which did not provide product patent protection in pharmaceuticals, was in favor of the non-patentees, the bias in the amended Act is clearly in favor of the patentees. No lime limit has been specified for processing of compulsory licensing applications and a compulsory license can be used only after the appeals against the grant of such a license by the Controller of Patents are turned down following a detailed procedure. But in the case of applications for product patents, time limit has been specified and patents can be granted even before it is convincingly settled that it can be granted. Unlike in the case of compulsory licenses, full-scale opposition proceedings can start only after the grant of patents[13, 16]

CONCLUSION

It is too soon to draw any strong conclusions about what the effects will be of India's upcoming introduction of product patents for pharmaceuticals. For the 70% or so of the population who currently does not have access to pharmaceuticals, the introduction of patent protection, and any price effects that may follow, are irrelevant. The

drugs currently on the market, just under ten percent are on patent in Europe. Extrapolating this percentage into the future, which may itself be questionable, means that even if product patents result in significantly higher prices, much of the pharmaceutical market will not be affected. Price control may also be ineffective in keeping down prices, since patent protection in combination with both the transfer-price loophole and a possible threat to not supply give firms non-negligible power in bargaining with the government over the price of patented drugs.
Indian firms are moving into the world generics market and although the introduction of product patents will cause them to lose their first-mover advantage, their low manufacturing costs will continue to give them an advantage in competing for this market. The bulk of production for the domestic market is drugs that are not on-patent. As a result of these two features, the introduction of product patents should not have a strong adverse affect on employment in the industry or on the contribution of the pharmaceutical sector to the balance of payments.

The positive contribution of intellectual property comes in its dynamic effect on the creation and diffusion of knowledge. Considering first the diffusion of information, it appears that Indian firms are well able to access and information disclosed in patent specifications filed elsewhere. Since most important pharmaceutical innovations will be patented internationally, there is likely to be little or no additional benefit to be gained by Indians from specifications being filed domestically. In the case of diffusion of products into the market, granting protection may speed diffusion, for the traditional reason that having a monopoly position makes the process of adapting a product, getting marketing approval and introducing it to consumers profitable.

Finally, there are several issues regarding the effect of product patents on discovery research R&D being done in India. Although strong intellectual property rights are important to MNCs in deciding where to locate R&D facilities, given the centralized nature of R&D and fact that costs are not the paramount concern there does not seem to be any compelling reason for them to locate in India even after product patents are available. Further, a number of MNCs are already increasing their use of local subsidiaries to do development work. Although stronger intellectual property rights may make the Indian environment more appealing to MNCs as a location for R&D, it is unlikely that product patents will make a dramatic difference to their choices. There is more reason to think that the upcoming introduction of product patents will make a difference to the amount and type of R&D being done by Indian firms.

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