

Chapter-5

A review of Amendments in Indian Patent Act
in complying TRIPs and its implications

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5.1 INTRODUCTION TO THE INDIAN PATENT ACT

Intellectual property has assumed a completely new dimension in India after the turmeric, neem and the basmathi disputes. The debates over the imposition of Special 301 not only added to the realization of the need for strong intellectual property laws but also increased the resistance to change. Ironically, Special 301 was at one time perceived as the most draconian piece of law dumped on the Indians, until the WTO came and took over that image. Yet, these changes served as eye openers to the importance of intellectual property rights and set the stage for legislation in this area of law. The story of patents in India dates back to the first Indian patent law which was enacted in 1856 and modeled on the same lines as the British Patent Act of 1852. A proper institution and authority for the administration of patents, however, was not established until the appointment of the Controller of Industrial Patents and Designs by the Indian Patents and Designs Act in 1911.

This act introduced rights over industrial designs and portions of the act governed the laws relating to industrial designs until as late as 2000, when the Indian Designs Act of 1999 was enacted. In 1959 the Government of India appointed the Justice Rajagopala - Ayyangar Committee to suggest revisions to the patent law. In 1965, based on this report,

a bill was introduced, but this bill lapsed in 1965 and again in 1966. This bill was re-introduced in 1967 and eventually passed as the Indian Patent Act of 1970.

The rules based on this act were passed in 1971 and the act along with the rules came into force in 1972. This legislation prevailed in the country undisturbed despite the passage of Super and Special 301 and threats from the US. The conclusion of the Uruguay Round in 1994 paved the way for more change in this area of law. More importantly, India joined the World Trade Organization (WTO) and became obligated to comply with the Trade Related Intellectual Property Systems (TRIPS). Although the obligations under TRIPS related to all the areas of intellectual properties identified by TRIPS, it was the obligations related to patents that required the most changes as far as India was concerned.

With this as a background, this is an attempt to analyse, on a subject matter basis, the changes to the Indian patent system brought about by TRIPS and India's reaction to the same.

5.2 THE INDIAN PATENT ACT 1970

The Patent Bill was first introduced in Parliament in 1967, but the Patent Act, 1970 came into force only in 1972. The Indian Patent Act 1970 which is in operation in our country does not allow product patents on medicines, agricultural products and atomic energy. This is the most suitable patent act for the developing world. Here, process patents are allowed for 5-7 years. Mainly with the help of the Indian Patent Act 1970 India is today

self-sufficient in the production of basic drugs covering various groups of drugs. Indian scientists developed new processes for 107 drugs. Indian companies are now among the world leaders in the production of bulk drugs from basic stages. At present, the prices of drugs in India are comparatively cheaper than many other countries. As per UNIDO, India is identified to produce its own drug needs with its own technology and manpower indigenously.

After 1970, many new drug firms were established by Indian businessmen. At present, around 23 thousand small, big, and medium factories are producing drugs in India.

Attempts to change the Indian Patent Act 1970 are a part of this globalisation programs. The imposition of an unequal trade treaty like the World Trade Organisation (WTO) is a step towards globalisation in favour of the MNCs of rich nations. With its help, the market of the developing nations is forced open for the developed countries. Most of the developing countries were forced to sign the WTO agreement without realizing its implication: as a result, the developed countries are the gainers. Already, at the dictates of the IMF, World Bank and WTO, the Government of India is slackening all checks and controls to invite the MNCs in all industries including the pharmaceutical industry. FERA and MRTP Acts have been amended. Customs duties and corporate taxes have been lowered. Relief, concessions and facilities have been extended to the MNCs as to Indian companies.

All these, already, had an adverse impact on the indigenous drug industry. As per the requirement of WTO guidelines for the product patent regime, the availability of new drugs in our country may be delayed depending on the desire of the patent holders. As per the guidelines, a product patent is granted for 20 years and a process patent for another 20 years. At present, newer drugs are made available in our country within a 4-6 years period. Prices of drugs will go up by 5 to 10 times as it is evident from the prices of drugs in India and other countries like Pakistan, U.K. and U.S.A. where product patents are in force. Ranitidine is sold by Glaxo in India at Rs. 7.20. The same product is sold by the same company in Pakistan at Rs. 65 and in the U.S.A. at Rs. 545. Similarly, the anti-viral drug Aciclovir costs Rs. 33.75 in India while the same drug is sold in Pakistan at Rs. 363. There are many such examples. The drug prices in the U.S.A., U.K. and other developed countries have gone up so high that the health care expenditure in those countries is predominantly funded by insurance companies at a very high premium. In those countries people cannot think of treatment without insurance coverage. Product patent regime will definitely hamper India's drugs exports as countries will be forced to purchase from patent holders only.

5.3 PATENT FIRST AMENDMENT ACT OF 1999

This amendment introduced Chapter IVA dealing with exclusive marketing rights. The amendments under Section 24A(1) mandate that the Controller to refer every application seeking an EMR to an examiner to see whether it is an invention for which a patent can be granted under Section 3 and 4 (and not under Section 5 which previously excluded drugs etc). Unless the Controller is satisfied that the claimed substance will not qualify

for a patent under Section 3 of the Act, (in which case he can reject the application), he may proceed to grant an EMR. Section 24A(2), read with Rule 33G, allows the Controller to conduct tests and report it within 90 days thereby avoiding delays. The critical aspect is the issue of subjectivity vested in Controller to determine whether it is an invention falling within Section 3 and 4, which will be the decisive factor for granting the EMR. However, this cannot be avoided since the office mechanism is not well equipped to accommodate a more expansive process. Section 24B(1)(b) authorizes the grant of an EMR for five years for inventions made in India on or after January 1, 1995 and for which a claim for process patent has been made, and granted. This provision has been criticized as being discriminatory on the basis of place of invention and contrary to the national treatment provision of TRIPS. However, the discrimination here is actually not on the basis of place of invention but on the grant of a process patent. The Act provides for this discrimination because in India there will only be process patent applications (as the product patent regime is not in place yet) and this can be disadvantageous to the applicant.

In the case of substances that can be used as medicines or drugs, Section 24B(2) provides that prior publication or use, before the filing of the claim for patent by the applicant either in India or in a convention country, will not constitute EMR infringement. However, it implies that such prior use excludes use by the third persons. It also does not specify whether such use by a third person (or even by the person himself), will bar the patentability of the invention (as in the United States). If it does bar patentability, then a person who clearly has an unpatentable invention is getting an EMR for five years. If it

does not bar patentability, then it will violate Section 13 that bars patentability if the document has been published earlier in India or abroad. To qualify as a prior user, commercial use by the third party should be mandatory. Rule 33F of the draft rules states that documents relating to specifications and trial or use referred to in Section 24B(2) shall include public documents, public trials or use, and interestingly, specifies that it shall not include personal documents or secret trials or use. Thus implying that such a secret use by a person who later applies for a patent can constitute EMR infringement.

5.4 LEGISLATIVE ACTION FOR SECOND AMENDMENT

Other than the EMR, India had two more milestones to cross along the TRIPS barrier to introduce other changes to the IPA by January 1, 2000 and to introduce product patents by January 1, 2005. The Patent Second Amendment Bill of 1999 was introduced in the Upper House on December 20, 1999 to cross the first milestone (and avoiding running into the DSB in Geneva) and to amend the IPA to make changes that were required immediately. The bill, however, was not passed by the Rajya Sabha and was referred to the Select Parliamentary Committee. The committee examined the bill and decided that they needed to understand the issues further before they could send their report. The committee therefore decided to tour various countries which include Brazil, Argentina, China, Japan, Korea and Canada to imbibe best practices before incorporating their suggestions and submitting the report. It is unfortunate that the Select Parliamentary Committee, after coming all the way to Canada, did not choose to visit the U.S. to study its patent system. If nothing else, the committee could have passed itself off as being

smarter and could have helped ease the tension. The elaborate tour of the world can now be interpreted as one more effort by India just to be stubborn and irrational when dealing with WTO issues. In any case, India has already defaulted on the deadline that was set at January 1, 2000. This tour by the Parliamentary committee will further delay the submission of the report by another few months and it could be the next monsoon session (June to August) of the Parliament before this bill is tabled again. This is an inordinate delay and can potentially lead to another consultation and dispute at the WTO.

Major area subject to discussion sought to be amended by the second amendment is provided below.

5.4.1 Patentable Inventions

The Second Amendment Bill amends the definition of 'invention' in Section 2(j). Under the IPA, an 'invention,' has to be a "new and useful" art, process, method or manner of manufacture, machine, apparatus or other article or substances produced by manufacture. The courts, however, had already defined the terms "new" and "useful". The Supreme Court, in 1982 , summarized the requirements of a patentable invention as follows:

- 1) It has to qualify under the test for "new" and "useful", which is to say "utility" and "novelty";

2) It must be “the inventor’s own invention as opposed to a mere verification of what was already known before the date of the patent”; and

3) An inquiry into whether a particular process of manufacture involves novelty and an inventive step to qualify as an invention is a mixed question of law and fact dependant upon the circumstances of each case. On the other hand, the definition introduced in the second amendment requires that an invention should have an “inventive step” and is “capable of industrial application” which are synonymous with “non obvious” and “useful”, respectively. Professor Gopalakrishnan opined that this current statutory definition does not in any way alter the requirements under the old definition. The criterion of non-obviousness was a part of the pre-grant opposition envisaged under Sec 25(1)(e) of the IPA. However, the new definition will force a different treatment of “inventive step” for the test of patentability and for the opposition procedure.

5.4.2 Exclusions from patentability

The Bill amends the existing Section 3 which provided a list of exclusions from the definition of invention to be in line with TRIPS. The new definition excludes, in subsection 3, inventions whose “primary or intended use or commercial exploitation” is contrary to law and morality. The exclusions regarding primary and intended use, however, may also be contrary to Art. 27(2) of TRIPS which limits exclusions from patentability to “inventions,... the commercial exploitation of which is necessary to protect ordre public or morality”. Moreover, the proviso to Art 27(2) envisions that

“such exclusion is not made merely because the exploitation is prohibited by their law”. Therefore, TRIPS not only envisions the Indian legislation, but also that such an exclusion is in line with the international trend of patentability. Therefore it is not clear whether the exclusion envisioned in the bill mentioned above will be acceptable.

The bill also amends the previous clause (i) to exclude medicinal, surgical, curative, prophylactic, diagnostic, therapeutic treatments for humans, plant and animals. TRIPS, however, does not envision such an exclusion for plants. It also does not exclude medicinal and surgical methods. The exclusions in India extend to treatment of diseases, (acceptable under TRIPS), or to increase their economic value or that of their products. However, the arguments for including plants and the exclusions for economic gain may be justified under the grounds of ordre public, more so, since there is the Plant Variety Protection Act of 1999 in India. India also excludes the patenting of computer software and business methods patents specifically and biotech patents by implication. It is yet unclear whether that will be acceptable under TRIPS. It is notable that Argentina and Brazil have carved out similar exceptions to their definitions of patentability.

5.4.3. Term and Date

Article 33 of TRIPS specifies a 20-year patent term from the date of filing of the application. Section 53(1)(b) of the IPA limited patent protection to 14 years from the date of filing of the complete specification under Section 45 (except in the case of a process patent where it is five years from the date of sealing the patent).

The proposed bill amended the 14-year term to 20 years beginning from the date of the filing of the application.

5.4.4. Application Requirements

Section 8(d) of the proposed bill amends Section 10 of the IPA (relating to the specification) and requires “an abstract of the technical information” of the patents. However, there is neither a definition of the term “abstract” nor is there any criterion for the kind of technical information that is required. Regardless of much the IPA is amended to suit TRIPS, unless the law and the rules relating to claims and specifications including drafting, interpretation, etc. are harmonized or, at least clarified, the grant of a patent will always rest on very subjective factors. Section 8 also requires identification of the source and origin of the biological material in the specification. Although such a requirement is not envisioned under TRIPS, it does not specifically prohibit Members from seeking the source and origin of biological material. This provision will go a long way in avoiding the turmeric and neem type disputes for India. The best solution is to possibly include it, not as a requirement of the application, but as falling within the criterion of anticipation and obviousness within the Patent Rules.

5.5.5. Compulsory Licensing

Chapter XVI of the IPA provides for compulsory licensing - as a necessary safeguard for protecting the public interest. Three years after a patent is sealed, any “interested party” can allege that the invention is not reasonably available to the public and can request the

grant of a compulsory license. The bill removes Section 86 to 88 of the IPA which previously provided the right to the Central Government to seek a "license of right" over patents not worked for three years in India. The bill also amends Section 90 which deemed that reasonable requirements of the public are not satisfied if the invention is not manufactured in India or the patentee refuses to grant a license, thereby removing a presumption that requirements of the public are satisfied based on local manufacture. The criterion to be considered by the Controller to grant a compulsory license under Section 85 has also been amended to include a national emergency, etc. (and local manufacture is not one such criterion). Interestingly, under Section 84, a specific inclusion has been made enabling third parties to seek for a compulsory license on the ground that the invention is not manufactured in India. Similarly, in Section 89, the bill introduces non-working in India as a specific criterion for the revocation of the patent. Section 90(c), which provides non-working in India under certain circumstances as a ground for imposing a compulsory license, has not been revoked. This is envisioned as a balancing mechanism, but there is a likelihood of it being interpreted as violating the right of the patent holder to import as established under Art. 27 and Art. 28 of TRIPS. Article 27.1 of TRIPS provides that patent rights shall be enjoyed "without discrimination as to the place of invention, field of technology and whether the products are imported or locally produced." The Indian Government opines that its provision is in line with Article 31 of TRIPS that allows for the use of the patents within certain terms and conditions. It is also interesting to note that several countries including the Honduras, Argentina, Brazil (which has several types of compulsory licenses, including for lack of local working, national emergency, dependent patents, public interest and

abuse of the rights) and China have incorporated provision relating to compulsory licensing. The Indian Government also pointed out that there have been no instances of misuse of the provisions relating to compulsory licensing in India since 1970. The foreign multinationals, however, are skeptical that once the product patent regime comes into place the Government could potentially misuse the same. It would be prudent to wait and watch the Government's use of the provision before assuming the worst. After all, more than 80% of the patents owned in India are owned by foreign multinationals. It is a fact that local manufacturing in India, where labor and raw materials are cheap, will go a long way in reducing cost of the product.

The bill also introduced a checking mechanism that requires an applicant for a compulsory license to prove that she approached the patentee with reasonable terms for a license. Similarly, where the patent holder imposes a condition for a grant back, prevention of challenges to the validity of the patent is deemed to be against public interest. This is a very welcome provision and is absolutely required considering that the bargaining power of an individual or company, compared with a patent holder, is always less. The bill provides for an appeal before an Appellate Board, on decisions of the Controller, including a grant of a compulsory license. Section 95A, as introduced in the bill, also provides for revocation of the compulsory by the Controller himself if the circumstances that gave rise to it ceases to exist.

5.4.6. Right to import & parallel import

Import The IPA did not vest on the patentee or a license holder the right to import a patented product into India, thus favoring local manufacturing. After the second amendment almost all of the restrictions on the need for local manufacturing had been removed. Hence there was a need to ensure the accessibility of products in all ranges of cost for the Indian consumers. Therefore, the bill introduces Section 107A(b) which states that importation of a patented product from a duly authorized license holder will not amount to infringement. This favors parallel importation of the patented product from a licensee in another country. Section 48 of the bill vests the right to import only in the patent holder. Section 107(A)(b) discusses only infringement and is subject to the product being validly patented and from a licenseholder. This section treats the issue of infringement differently from the issue of vesting the right of importation. The right to import is only given to the patent holder as envisioned under TRIPS. However, importing a patented product from either the patentee or from a valid license holder will amount to infringement. This provision is valid under TRIPS and there are several examples of such treatment for various issues in patent law even in the American jurisprudence. Such imports can also be justified on the doctrine of exhaustion. This doctrine specifies that the patent holder does not have any control over a buyer or a licensee once the product has been placed on the market. However, the concept of exhaustion is also based on an implied license and therefore suggests that a buyer can remanufacture the goods and import them into the same market for lesser cost. This argument would completely defeat the object of TRIPS and to some extent patents themselves. Hence Section 107(A)(b) was included with the specific objective of

defining the contours of such imports and also retaining the spirit of TRIPS. This is a very laudatory move it will restrict spurious parallel imports into the country, will balance the effect of taking away the need for local production and will also be in line with TRIPS.

5.4. 7 Bolar Provisions

The United States permits testing to establish the bio equivalency of drugs before the expiration of the term of the patent. On the other hand, stock piling before the expiration of the term of the patent is prohibited. A similar provision is sought to be introduced under Section 107A of the Second Amendment Bill of 1999. Where there are acts that are not directly related to production, but are still damaging to the patent owner, an injunction can be obtained under the Civil Procedure Code.

5.5 EXCLUSIVE MARKETING RIGHTS

Section 5 of the Indian Patent Act of 1970 provides that patents will be granted to claims for processes or methods of manufacture (and not for the substances) for inventions relating to food, medicine and chemical processes. The policy behind this was to enable a developing country like India to benefit from inventions from other countries by ensuring the availability of the same products at cheaper prices produced by a different process. Such access was required because inventions in drugs and food were life saving in nature and India is a country with 50 million people living below poverty line who otherwise could not

afford them. This is especially true in the case of drugs patented abroad, which have a much higher cost. Article 27 of TRIPS, however, provides that members are obligated to provide patent protection for any invention, whether products or processes, in all fields of technology without discrimination based on the place of invention or production or field of technology. Article 65 gives India until 2005 to establish its product patent regime. Furthermore, Art. 70 (8), read with Art. 65 (2) and (4) of TRIPS, obligates developing countries to provide for a mailbox mechanism for depositing applications and an exclusive marketing regime right (hereinafter, EMR) for such inventions during the interim period. The mailbox provision mandates that such a facility should be available during the interim five years (until 2005) or until the time the product patent was introduced. The applicant is entitled to an exclusive marketing right over the product provided that a patent application has been filed and a patent granted for that product in another member state and marketing approval has been obtained in such other member". India was required to fulfill this obligation by January 1, 1995.

In order to fulfill the TRIPS obligations, the President of India on December 31, 1994, promulgated the Patents (Amendment) Ordinance to amend the Patent Act of 1970 and provide for an EMR. The Ordinance became effective on January 1, 1995 and India notified the Council for TRIPS as required under Article 63(2) of TRIPS. However, the Ordinance lapsed on March 26, 1995 since legislation of this kind ceases to apply at the expiration of six weeks from the re-assembly of Parliament. The Patents (Amendment) Bill of 1995, which was intended to give permanent legislative effect to the provisions of the Ordinance, was passed by the Lok Sabha in March 1995, but unfortunately lapsed in

the Rajya Sabha. Therefore the Patents (Amendment) Bill lapsed with the dissolution of the 10th Lok Sabha on that date in November 1995.

5.6 PATENTS (AMENDMENT) ACT 2002

An amendment to the Patents Act, 1970, namely, the Patents (Amendment) Act, 2002 has been notified in the Gazette of India on 25.6.2002.

This Act makes the Indian patent law not only TRIPs compliant but also incorporates safeguards for protection of public interest, national security, biodiversity, traditional knowledge, etc. The opportunity has also been utilised to harmonise the patent granting procedures with international practices and to make the system user friendly.

Some of the important changes made are as follows :

- a) The definition of the term “invention” has been modified in consonance with international practices and consistent with TRIPs Agreement.

- b) Section 3 of the present Act has been modified to include exclusions permitted by TRIPs Agreement and also subject matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable inventions and also to specifically exclude the inventions which in effect are traditional knowledge.

- c) The rights of patentee have been aligned as per Article 28 of the TRIPS Agreement.
- d) A provision for reversal of burden of proof in case of infringement, suit on process patent, in accordance with Article 34 of the TRIPS Agreement, has been added.
- e) Uniform term of patent protection of 20 years for all categories of invention as per Article 33 of the TRIPS Agreement has been prescribed.
- f) The provisions relating to compulsory licensing have been modified to suit the public interest requirements and also to comply with TRIPS Agreement
- g) A provision has been incorporated for enabling parallel import of patented products at lowest international prices.
- h) To ensure smooth transition of a product from the monopoly status created by the patent to the public domain, a provision has been incorporated for obtaining marketing approval from the appropriate regulatory authorities before the expiration of the patent term.
- i) Several provisions have been incorporated for protecting bio-diversities and traditional knowledge.

j) The provisions relating to national security has been strengthened.

k) A provision has been incorporated for hearing of appeals which at present, lie before High Court, by the Intellectual Property Appellate Board, for speedy disposal of such appeals

l) Several provisions have been incorporated with a view to simplifying and rationalising the procedures.

5.7 NEW INDIAN PATENT (AMENDMENT) ACT 2005

On 23 March 2005 the Patent (Amendment) Bill 2005 was passed by the Rajya Sabha (Upper House). There has been very little public debate around the Bill to determine the effects of the amendments that have been made.

Several amendments have been made to the Ordinance (the new Patent Bill 2005). However, many of these fail to address the serious concerns of the issues relating to access to medicines.

From the text that has been made available, the following provides a critique of the key issues of the new law which were voted on and the potential impact:

5.7.1 Expansion of the Scope of Patentability

TRIPS does not define the basic criteria of patents viz. novelty, inventive step and industrial application. Further, the only obligation under TRIPS Agreement is to protect pharmaceutical products. As a result implementing countries have the option to limit the patent protection only to a new chemical entity. However, according to latest reports data shows that there are 8926 applications pending for examination in the mailbox in India, the vast majority by U.S and E.U multinational pharmaceutical companies.

However, only 274 new chemical entities received marketing approvals from the US FDA between 1995-2003. This is a clear indication that many of the applications in the mailbox are patenting of products with frivolous or marginal changes and, therefore, fall outside of the requirement of protection required for patents by TRIPS.

The clauses in the Bill to limit the scope of patentability are extremely ambiguous and full of technical loopholes which allow for “evergreening”. Ideally the law should clearly limit patent protection to “new chemical entities”.

Some of the key issues relating to the scope of patentability are given below.

5.7.2 Inventive Step

The Bill provides the following definition of what is required of a patent application to meet the inventive step criteria:

”a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both that makes the invention not obvious to a person skilled in the art”.

The above provision arguably broadens the existing provision to the benefit of patent holders and is ambiguous to the extent that it allows for two criteria for meeting an inventive step. As it stands, to meet an inventive step criteria the patentee will either have to show that the invention includes a “technical advance” or has economic significance, or both.

The provision should have required the applicant to comply with both requirements for an inventive step, namely “existing knowledge and having economic significance” and delete the term “or both”. Otherwise, the requirement of technical advance is compromised and diluted by the fact that a patent could be simply granted on economic significance alone. Economic significance alone, cannot determine the inventive step of a patentable invention.

5.7.3 Interpretation of the word - Pharmaceutical substance

The amendment currently describes “Pharmaceutical substance” as “any new entity involving one or more inventive steps”.

As it stands, the provision is too broad as it allows all types of pharmaceutical substances. The term “chemical” ought to have been inserted so as to read “any new chemical entity”.

5.7.4 Inventions not patentable

Section 3(d) has been amended to read:

“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 the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant”.

The use of the phrase “which does not result in the enhancement of the known efficacy” is ambiguous, too broad and potentially allows for new forms of existing substances to become patented. For example, “result in enhancement of efficacy” could be a minor amendment to an existing invention to in order to get around the provision as it stands.

In addition, the new Act retains the word “mere” which potentially causes ambiguities within the provision.

Also, the explanation supporting the above provision provides:

”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 “unless they differ significantly in properties with regard to efficacy” is not necessary and offers an entry point in favour of the patentee, thus leading to excessive litigation. For example, certain properties are never known or are clear at the time of application in the claim so one would not know how they differ, thus leaving any recourse to opposition.

The definition of pharmaceutical substance is not linked to the provisions relation to the exclusion for patents and, therefore, stands alone. Furthermore, the inventive step requirement has been severely diluted. As a result, section 3(d) allows “evergreening”.

5.7.5 Immunity to ongoing generic production:

The Bill permits generic manufacturers to continue producing generic version of new drugs which are in the mailbox. However, this only applies where the generic producer has made a significant investment provided they were producing and marketing the

generic version prior to 1 January 2005. However, the generic companies are required to pay the patent holder a reasonable royalty.

The question of “significant investment” poses a threat of potential infringement suits as the generic producer would have to clearly show that it has made what would be considered a significant investment in producing and marketing the generic drugs. With respect to the reasonable royalty¹ it creates the problem of excessive demands from the patent holder and litigation. The reasonable royalty rate should have been fixed at a particular percentage, the norm being 4%. For example in that in South Africa, Glaxo Smith Kline demanded a royalty of 25 % before the courts intervened.

5.7.6 Pre-grant Opposition

The amendment has restored the ability for any member of the public to oppose patent applications before its grant. The grounds for bringing an opposition remain as before and provide recourse to challenging frivolous and legally invalid patents.

However, the effectiveness of the opposition process depends upon the access to information on the mailbox applications. The Patent Office in 2005 has issued a notification in its official journal that inventions either filed or claiming priority on 30 July 2003 have been deemed to have been published. However, there no actual physical publications available. This lack of publication takes away the possibility of accessing information relating to the patent application and the ability to oppose the same.

5.7.7 Publication

The Bill amends Section 11A of the Patents Act which prescribes the initial publication requirement. After the publication the applicant shall have the rights as if patent for the invention had been granted on the date of publication of the application. However, no infringement proceeding is permissible until the grant of patent. This means that one can get the privilege of patent from the date of publication i.e. even before filing the request for the examination of application. Lastly the Bill refers to the publication of an application, but fails to make the publication of the complete specification available to the public.

5.7.8 Compulsory Licensing

The effective and efficient issuance of compulsory licenses is imperative to curb the abuse of patent rights by the patentee. The amendment has only made cosmetic changes to quicken the process of dealing with an application for a compulsory license in section 84(6) to the extent that where the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period, the Controller can now interpret "reasonable period" to mean a period not ordinarily exceeding 6 months.

However, the amendment does not remove the existing requirement that only after three years after the grant of a patent, (unless there is a national emergency, which has never been used) can a person make an application to the Controller for the grant of a compulsory license. Therefore, in total the request for a compulsory license does not have to be considered for at least 3 years and 6 months from the date of the grant of the patent. Furthermore, one also has to take into the account that the Bill fails to provide a timeline within which the Controller must deal with compulsory license application once made. Therefore, this could lead to a further delay before any license can be issued as it is well known that MNC pharmaceuticals often refuse to deal with requests for compulsory licenses or demand high royalties.

With respect to exporting drugs to a country which makes a request for a generic drug, the amendment no longer requires the importing country to issue a compulsory license. However, one question that arises is whether the procedure for the grant of the compulsory license for the domestic market (under section 84(6) discussed above) will also be the same for compulsory licenses for export. It is quite possible to argue the procedure both ways, therefore, potentially delaying urgent new drugs that a developing or least developing country may require.

The Act further fails to provide the safeguard available within Article 44 of TRIPS, which effectively allows Member States to limit remedies to remuneration that would be available to the patent holder where third parties are authorized by the Government,

without the authorization of the right holder, to use the patented good rather than issue an injunction.

5.7.9 Discretionary powers of the patent office

The Ordinance took away the limitations imposed by the Act, and made it discretionary of the Patent Office by virtue of the Rules. As a result, the patent office can now tamper with the various time lines by amending the Rules as and when they choose.

Under the amended ordinance, 7 types of time limits will be determined by the office through the Rules and not by the statute. The excessive and unbridled delegation to the Patent Office is further increased by the following provision: "The central government may, if it is satisfied that circumstances exist, which render it practically not possible to comply with such condition of previous publication, dispenses with such compliance". As a result, the public will not be given an opportunity to offer its comments to the Rules before it being amended.

5.7.10 Quick Examination

As per the Ordinance the time frame for making the examination report is left to the Rules. The new Rules provide a period 1-month for the examination report to be issued following the application. This period was previously 18 months period.

This is likely to create immense pressure on the Indian Patent Office as there will not be enough examiners to deal thoroughly with the flood of applications which is likely to occur, thus resulting in improperly examined and legally invalid patents. Indeed, as the U.S Federal Trade Commission report mentioned in its 2003 report “the increasing rate of 10% of patent applications each year is causing examiners only having 8 to 25 hours to read, understand, search for prior art and evaluate the patentability of the applications”. The Indian Patent Office does not have the infrastructure for research, access to information and capacity to face the challenge that the new Act will bring.

5.8 IMPLICATIONS OF AMENDMENTS

The Indian Patent Act has been in need of change for several years now. It is important for a country like India, with a huge market and potential for international trade, not to neglect its legal system particularly in an area like patents, which are the cornerstones for development. However, all the amendments made are inadequate unless the patent system, especially the patent office and patent enforcement, is improved. Otherwise this entire patent legislation will become a paper tiger with minimal enforcement and continued WTO disputes, leading nowhere both for India and for the countries that seek to trade with India. The changes that will be effected on account of TRIPS are not, as such, bad for India. However, such change should come with the realization of the importance and the need for a similar system for India.

The continued WTO reproach and the thrust by the pharmaceutical companies, giving little respect for Indian sentiment, will be a mutually destructive exercise. In many ways the behavior of the Joint Parliamentary Committee (JPC) is in itself a reflection of such a sentiment. A better approach with more mutual appreciation would have resulted in the JPC visiting the USA, which then could have resulted in a system more similar to what the pharmaceutical companies are seeking to achieve. Instead, this whole debate has sent them to countries not really known for their patent systems, paving the way for a less meaningful approach. In many ways such demands breed distrust and certainly distaste. Although the recent amendments are laudatory, it is important for India to improve many areas, including training to judges for patents, improving the Patent Rules and improvise the Sections and Rules relating to claims, to improvise the Patent office and to centralize the functions of the patent office. The first step, however, lies in understanding the correlation between trade, development and intellectual property.

Today the market potential in India has attracted a new wave of investment by foreign multinationals and the talent generated in India is recognized across the world, making the need to merge with the rest of the world even more imminent. Unless the legal and trade issues are in place, India will be left far behind. Trade today implies that Indian companies and lawyers meet their foreign counterparts in national and international forums. Unless the country devotes time to develop its system, the lack professional depth and efficiency will be the causalities, which will be detrimental to India in the long run.

Although The Patents (second Amendment) 2002, takes a step closer TRIPS compliance, it has received a mixed reception among both multi-national patent owners and local Indian pharmaceutical industry. This amendment provides stronger protection to patent holders that currently exists.

There are also many possibilities that the amended legislation could have utilized in respect of those provisions where the TRIPS has not harmonized as yet the patent law space. Many European nations have used the space and are using it till date. Patents for pharmaceutical products deserved in India such provisions in particular.

This act also contains controversial provisions, particularly relating to compulsory licensing, it does make clear the intention of the government to strengthen its patent laws and to achieve TRIPS compliance. India realizes that in the absence of stronger laws, it will not be able to attract research funds, technology transfer, and foreign investment, or, in the long run, sustain local development.

In continuance of the ordinance The Parliament of India recently has approved the third Patents (Amendment) Bill 2005 with the Rajya Sabha passing it on March 23, 2005. Earlier, the Lok Sabha passed the Bill after the Government incorporated several amendments.

India has introduced a new product patents regime, covering drugs, foods and chemicals. This is in compliance with the Trade-Related Intellectual Property Rights (TRIPs)

agreement of the World Trade Organisation (WTO). India has an enviable record of fully adhering to its international obligations. Moreover, strong patent laws are expected to encourage foreign investment in research and development projects and consequently benefit the Indian economy.

With patent protection, India could be ideal centre for activities of research and development and clinical studies. The contract research organisations of domestic and global are viewing as the hotbed for clinical research. The proficiency in English and skilled manpower, and availability of huge patient volunteers with this new amendment is going set phase for unprecedented opportunities for domestic manufacturers.

Domestic manufacturers along with MNCs may also find it profitable to discover novel drugs for diseases of developing countries. The diseases like Malaria, Tuberculosis need to be addressed urgently. There seems to be stimulation in activities in this neglected field of diseases.

The amendment made in the Act promises to safeguard the interest of the nation by amendments like the Act does not applicable to molecules marketed by Indian companies prior to 2005. Provisions regarding the exclusive marketing rights included in the Act have removed the doubts from manufacturers minds who are willing to develop technologies that would bring the cost of the recently patented drug to a developing country. Still the unanswered question is whether the drug can be made available to the

poor countries at an affordable price after the environment created by this series of amendments or not.

Some of the amendments to the Patents Act required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have just been adopted by Parliament. Among the many issues dealt with by the amendments, one of the most debated questions has been their impact in the health sector and more specifically on access to medicines. The debates are unlikely to subside with the adoption of the Bill. On the one hand, the amendments have already been attacked for not going far enough to allow compliance with the TRIPS Agreement. On the other hand, the amendments are fundamentally changing the 1970 Patents Act and are likely to negatively affect people's access to medicines.

To understand how significant the adopted amendments are concerning access to medicines, it is necessary to look back at the regime adopted in 1970. The law adopted then drastically restricted the rights of holders of medical patents to foster the availability of cheaper medicines. The patents legislation together with other measures such as price control have had significant positive impacts: Medicine prices have, for instance, decreased significantly since the 1960s compared internationally. Further, there is now a vibrant local generic pharmaceutical industry. In addition, some local companies have developed sufficient expertise to produce their own new medicines.

The TRIPS Agreement has imposed the wide-ranging changes that have just been adopted. The controversial nature of these amendments explains in fact why the Government was initially reluctant to accept TRIPS in the WTO context and why Parliament initially refused to adopt the first Patent Amendment Bill in 1995. The changes imposed by TRIPS on India include increasing the duration of all patents to 20 years, broadening the scope of patentability and the introduction by 2005 of product patents on medicines. These legislative modifications will eventually lead to higher medicine prices in India.

While the TRIPS Agreement lays down a number of precise standards and rules, it also includes a number of exceptions and qualifications. Over the years, the exceptions and qualifications have been largely ignored or sidestepped in most developing countries. Following increasing controversies concerning the impact of TRIPS in the health sector, the last WTO ministerial conference addressed the issue of health and adopted a Declaration on the TRIPS Agreement and Public Health (Doha Declaration). The Doha Declaration does not modify TRIPS but restates that member States are allowed to fully use the exceptions provided in the treaty to foster public health goals. In other words the Declaration gives countries like India further authority to fully use the exceptions and qualifications provided in TRIPS. The amendments just adopted by Parliament must be read in the context of the recently adopted Doha Declaration.

On the one hand, it generally follows quite closely the requirements of the TRIPS Agreement. The amendments thus generally alter the balance between the interests of

patent holders and the interests of society at large in favour of the former. The duration of patents in the health sector is, for instance, dramatically increased from seven to 20 years. The amendments also strike out an important provision of the Act seeking to oblige patent holders to manufacture their inventions in India.

On the other hand, the new Patents Act uses some of the exceptions and qualifications included in TRIPS to foster public health goals. It uses, for instance, the health-related exceptions in Sec. 3 of the Act which determines which inventions are not patentable. Some of the most interesting and most controversial new provisions are found in the chapter on compulsory licensing. While TRIPS generally imposes a stricter compulsory licensing regime than what was provided under the Patents Act, 1970, the amendments strive to make use of some of the possibilities opened by the Doha Declaration. The section of the compulsory licensing chapter (Sec. 83) which sets out the general principles applicable to compulsory licensing is particularly noteworthy. It specifically mentions that patents granted should not 'impede protection of public health' and should not prohibit the Central Government from taking measures to protect public health. Further, it recalls that patents should be granted to make the benefits of the patented invention available at reasonably affordable prices to the public.

On the whole, the framework for compulsory licensing set out in Sec. 83 is quite progressive from the point of view of access to health. However, the most noteworthy feature of the principles set out is that they only inform the specific chapter on compulsory licensing. The Doha Declaration generally recognises member States' right to

take measures to protect public health. This is not limited to compulsory licenses but applies generally to patenting in the health sector. In other words, there is no reason why the principles enunciated at Sec. 83 should only apply at the level of the implementation of patents. It is noteworthy that while the amended Patents Act does not make innovative use of the leeway provided by the Doha Declaration beyond Sec. 83, some members of the Joint Parliamentary Committee on the Patents Bill did propose an exception to the uniform 20-year rule for medical patents. The fact that these progressive principles do not inform the whole Patents Act are indicative of the increasingly regressive nature of the debates concerning patents in the health sector. Indeed, while ten years ago the issue of patentability in the health sector was a subject of intense discussion, the amended Patents Act shifts the debate to the single issue of compulsory licensing, and thereby indirectly creates a situation where it will become extremely difficult to discuss broader issues in the future.

On the whole, the amended Patents Act is noteworthy for dismantling most of the specificities of the 1970 Act. The 1970 Act constituted a carefully crafted response to specific socio-economic challenges that has served India well over the past three decades. It is therefore surprising that the removal of exceptions meant to foster better access to medicines has happened without any revision of the underlying policy. In fact, the socio-economic needs are more or less the same as before as universal access to medicines has not been achieved. Further, while India's intellectual property obligations have changed with the TRIPS Agreement, its obligations in the field of the human right to health have not changed in recent decades. A significant shift in the orientation of the patent policy in

the field of health without careful consideration of the implications for the right to health is thus surprising. There is still scope for debate in the next few years since product patents on medicines do not have to be introduced before 2005. This may give a chance for a further broad-based debate on the advantages and shortcomings of strengthening the patents system in the health sector.

In summary, there are several amendments where introduced and series of changes have been brought into effect by the Indian government from the year 1995 to 2005 in order to make the Indian patent act or Indian IPR regime became the TRIPS compliant. However, these changes have been successful in changing the face of the pharmaceutical industry. How the Indian pharmaceutical business have been impacted by these changes is been studied in the next chapter.

Chapter six contains in depth study of impact of intellectual property regime on pharmaceutical business. It also provides the findings of the study with respect to industry professionals and whether they consider IP as an important strategic element or not. Further, it provides the study of the objective set forth in the Chapter-1 in relation to study the extent to which strategy formulation has been impacted by the changes in the IPR regime.