

Patent Amendments in India in the Wake of TRIPS

By Srividhya Ragavan¹

I. Introduction

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 Committee² 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)³ and became obligated to comply with the Trade Related Intellectual Property Systems (TRIPS).⁴ 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 paper examines, on a subject matter basis, the changes to the Indian patent system brought about by TRIPS and India's reaction to the same.

II. Exclusive Marketing Rights

Section 5 of the Indian Patent Act of 1970 (hereinafter, 'IPA') 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 policy⁵ 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.⁶ 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 mailbox⁷ 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 notified⁸ 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.

The Indian sentiment over the introduction of EMRs also accounted for the lapsing of the bill. Indian Drug manufacturers believed EMRs would lead to the destruction of the local drug industry and that it was more restrictive than even the product patent regime. They argued that foreign drug companies would get the right for exclusive marketing in India before going through an examination in India. Indian drug manufacturers also felt that EMRs did not address domestic production, thereby leaving the ground open for foreign multinationals to take over the market.⁹ However, the biggest impediment to the implementation of the EMR legislation was the fear that the cost of medicines would increase substantially¹⁰ and that Indian drug companies would be driven out of business.

Notably, only 7 out of more than 250 drugs in the WHO list of essential drugs are on patent. Therefore about 90% of the drugs would have been off patent in any case and would be available to the public without any patent restrictions. Moreover, market forces determine the prices of new products. The prices of therapeutic equivalents and generic drugs remain unchanged. The Deputy Controller of Drugs¹¹ in India also noted that globally around 15 to 20 drugs enter the market every year and only a few of them are commercial successes. At the same time, each year patents continue to expire for earlier products. In any case, none of the drugs that have a patent anywhere in the world can be patented in India by virtue of Section 13 (2) of the IPA, which provides for a universal search. Most of the drugs required by the common man are produced indigenously and not abroad.

In India, the Government administers drug prices through the Drug Prices Control Order so the Deputy Controller of Drugs offered assurances that the Government could still intervene and control the prices if required. (However, the power of the Government to control the prices will substantially decrease after the product patent regime comes into play. In any case, such a control would violate Art. 31 of TRIPS.) Professor A V Ganesan also pointed out that¹² around 650 patented drugs were introduced in the world market in the past 15 years (from 1983 to 1998) of which 72 were introduced into the Indian market under the existing dispensation between 1986 and 1998. In the last five years, i.e. 1994 to 1998 alone, 39 new drugs were introduced in the Indian market. There has generally been a gap of three to five years, if not more, between the introduction of a new patented drug in the world market and its subsequent introduction in the In-

dian market. It can therefore be surmised that the Indian market may, on an average, see 5 or 6 new patented drug introductions each year for the foreseeable future. This means that people in India will die of diseases for 20 long years although a cure is available and yet unavailable - a tragedy their luckier American counterpart will not have to face. Such is the bastardized value of life of some people!

The US has estimated an annual loss of 450 billion dollars due to 'piracy' in India.¹³ It is unclear how the drug industry in the US plans to offset this loss after the introduction of the product patent in India if Indian industry will continue to have the benefit of introducing drugs that are off patent. In any case, if health care is the issue, patent law is possibly not the best method of trying to tackle the issue of drug price control. Maybe India should look at the Health Care laws as an alternate way to tackle this issue.

More importantly, EMRs were simply meant as transition protection, and because it takes typically 8-10 years for a drug to move from the patent application stage to the market, although this situation may not continue if the "2000 by 2000" objective is achieved by the drug industry¹⁴, it is unlikely for a new patented drug to seek an EMR in India before 2003. Articles 70(8) and 70(9) apply only to new drugs patented on applications made after January 1, 1995. Therefore, the EMR provision would not have led to an increase in new patented drugs in the Indian market nor would it have been a route for the introduction of known product or products that were already in the public domain in India.¹⁵ As an after thought, India would have been better off just implementing the EMR provisions on time. Instead, it ended up in a dispute on an inconsequential issue that only lead to the loss of credibility for the country. As for product patents, they are not due till 2005 by which time India will have ample time to restore its mechanisms.

A. The Mail Box Dispute:

Amidst all of this, India did not fulfill its obligation to have a transitional system within the stipulated time period. Therefore, the United States asked for a consultation¹⁶ with India, which ultimately failed. The U.S. then requested the Dispute Settlement Body¹⁷ ('DSB') of the WTO to examine whether India had defaulted in its TRIPS obligation. India argued that the applications for chemical and biological patents were being filed in the patent office which in itself constituted an effective means as required by TRIPS. Moreover, India said that its patent legislation had been supplemented by administrative notifications that had the force of law. Notwithstanding the above, India argued that as a developing country it was entitled to delay the process under Article

65 (2) for a period of 4 years. The U.S. argued that the mere fact India felt the need for an ordinance at the outset indicated that there was a need for a formal legislation.

The Panel¹⁸ ruled that India was in default of its obligations because the administrative notifications could not be considered as in compliance with the requirements in TRIPS. The Panel also held that India was obligated under 70(9) to have a transitional system in place immediately and not after five years. This ruling was upheld¹⁹ by the appellate body.²⁰ After the decision of the appellate tribunal of the WTO, India was forced to amend the IPA to avoid facing trade sanctions. Hence both the BJP and Congress party (which were at that time the opposition and the ruling parties respectively) were forced to put the much-delayed legislation in place. The Patent First Amendment Act was thus passed in December 1999.

B. 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).²¹ 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.

C. 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,²² Argentina, China,²³ Japan,²⁴ Korea²⁵ and Canada²⁶ 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.

A subject-by-subject discussion of each area sought to be amended by the second amendment is provided below.

1. Patentable Inventions:

The Second Amendment Bill amends the definition of 'invention' in Section 2(j). Under the IPA, an 'invention,'²⁷ 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 1982²⁸, 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";²⁹
- 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.³⁰

On the other hand, the definition³¹ 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.³² 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.³³

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 sub-section 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.³⁴

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.³⁵

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. 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.³⁶ 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"³⁷ 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,³⁸ 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,³⁹ Argentina,⁴⁰ 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 mechanism⁴¹ 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,⁴² 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 raise to it ceases to exist.

6. Right to import & parallel 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 license holder. 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.⁴³

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.⁴⁴ 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.

7. "Bolar" Provisions

The United States permits testing to establish the bio equivalency of drugs before the expiration of the term of the patent.⁴⁵ 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 1999.⁴⁶ 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.

III. Conclusion

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 casualties, which will be detrimental to India in the long run.⁴⁷

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² The report of this committee is considered to be the back bone of the Indian Patent law that was enacted in the year 1970.

³ Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, LEGAL INSTRUMENTS - RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M 181 (1994) [hereinafter WTO Agreement].

⁴ Agreement on Trade - Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS - RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M 81 (1994) [hereinafter TRIPS Agreement].

⁵ See STATEMENTS OF OBJECTS AND PURPOSE, PATENTS BILL, 1967 (Act No. 39 of 1970)

⁶ This provision was amended to fulfill the requirements of TRIPS Article 27(1). The Patent Amendment Act, 1999 now provides for exclusive marketing rights for these categories of substances till the grant of product patent in the year 2005.

⁷ A facility that enables the filing of patent applications for chemicals, food and drugs till the time the product patent regime is in place.

⁸ GOVERNMENT OF INDIA, NOTIFICATION No IP/N/1/IND/1

⁹ Postings of National Campaign Committee for Drug Policy, owner-e-drug@usa.healthnet.org, to <http://www.healthnet.org> (1999) (copy on file with the Author)

¹⁰ Corporate Law Group, *Indian Patent Act - A perspective against the backdrop of TRIPS*, available at <http://www.iprlawindia.org>

¹¹ Mr M Venkateshwaralu, Deputy Drug Controller, Government of India, *Address at the 50th Indian Pharmaceutical Congress and 17th Asian Congress of Pharmaceutical Sciences*, (Jan, 1999) (transcript available at <http://www.rediff.com>)

¹² A.V.Ganeshan, *The implication of Patent Amendment Ordinance, 1999*, INDIAN COUNCIL FOR INTERNATIONAL ECONOMIC RELATIONS, (February, 1999) (Copy on file with author)

¹³ *Intellectual Property Rights in India*, available at <http://www.indiaonestop.com>

¹⁴ One of the concerns raised was if the pharmaceutical companies were able to realize their plan of 2000 by 2000, that is reducing the interval of "laboratory to market" to 2000 days by the year 2000, then more new patented medicines may enter the market than is assumed in Mr. Ganesan's paper. If this happens, their effect will be seen in India only after 2003. Mr Ganesan explained that their effect on EMR will be insignificant and also added that "not a single new chemical entity (NCE) has so far come into the world market based on a product patent application filed on or after January 1, 1995. He also observed that in judging the magnitude of the patent and problems related to EMR, we should not go by the number of patent applications filed. This is because only a miniscule percentage of the product patent applications ultimately result in marketable products. In other words, the world sees about 40 new drugs (NCEs) every year, although the product patent applications filed for pharmaceutical products in the world run into several hundred thousands every year. Mr. Ganesan emphasized, and the Drug Controller of India concurred, that the Drug Controller has the authority to follow independent procedures, including field trials, before giving approval to market a patented drug in India. Furthermore, the Patent Office can also reject a patent application if the product does not meet the 'novelty' criteria. This would effectively disallow patenting of drugs already in the "public domain", particularly indigenous medicines. *See generally*, note 142.

¹⁵ *Supra* note 100

¹⁶ On July 2, 1996 under Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes read with Article 64, the US asked for a consultation which failed on July 27, 1996

¹⁷ On November 7, 1996 a panel was requested by the US which the Panel agreed to take up on November 20, 1996.

¹⁸ GATT Dispute Panel Report on U.S. Complaint concerning Indian Patent Protection for Pharmaceutical and Agricultural Chemical Products, (September 1997) available at <http://www.wto.org>.

¹⁹ Aggrieved by the decision of the Panel, India raised three main issues at the appellate level. The first concerned the proper interpretation of the word "means" in Article 70(8) of the TRIPS Agreement. The second was whether there was a requirement under Article 70(8) to provide for exclusive marketing rights from the date of entry into force of the Agreement. The Appellate Body

agreed with the Panel, and was of the view that India is obliged, by Article 70(8)(a), to provide a legal mechanism for the filing of mailbox applications that provides a sound legal basis to preserve both the novelty of the inventions and the priority of the applications as of the relevant filing and priority dates and held that "administrative instructions" did not constitute a sound legal basis. With regard to Article 70(9), the Appellate Body agreed with the Panel that India should have had a mechanism in place, to provide for the grant of exclusive marketing rights effective

as from the date of entry into force of the WTO Agreement.

²⁰ GATT Dispute Appellate Body Report on U S Complaint concerning Indian Patent Protection for Pharmaceutical and Agricultural Chemical Products, (October, 1997) at <http://www.wto.org>.

²¹ *See*, 35 U.S.C 102 which will apply in such cases.

²² Both Brazil and Argentina belong to the third world and therefore are going through a similar phase like India.

²³ To see how and China attracted foreign investments in spite of having the same disadvantages like India.

²⁴ Japan was able to negotiate for a good transfer of technology agreement before they changed their laws.

²⁵ The Korean benchmark for patents was made as late as 1980. Korea in 1982 entered into an Agreement with the US whereby patent protection would be provided for pharmaceuticals and defaulted on that Agreement. *See generally*, Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry*, THE INTERNATIONAL LAWYER, Vol 30 No 4, 835 at 863

²⁶ To survey the functioning of the Canadian generic drug industry.

²⁷ Sec 2(j) of the Patents Act, 1970

²⁸ Bishwanath Prasad Radhy Shyam v. Hindustan Meta Industries, A.I.R. 1982 SCC 144.

²⁹ *See* 35 U.S.C 101, 102 and 103 for a comparison with the U S Standards of the same concept.

³⁰ *See generally*, Thomas Brandt v. Controller of Patents and Designs, A.I.R. 1989 Delhi 249; Raj Prakash v. Mangath Ram Chowdry, A.I.R. 1978 Delhi 1, Ram Narain v. Ambassador Industries Ltd, New Delhi, para 17, A.I.R. 1976 Delhi 87, Gillette Industries Ltd v. Yeshwant Brothers, A.I.R. 1938 Bom 347.

³¹ "invention" means a new product or process involving an inventive step and capable of industrial application; "inventive step" means a feature that makes the invention not obvious to a person skilled in the art;

³² DR N S GOPALAKRISHNAN, THE PATENT SECOND AMENDMENT BILL - AN ANALYSIS, (A submission made to the Select Parliamentary Committee

in India for the review of the Patent Act, 1970), (copy on file with the author).

³³ Section 25 (1)(e) of the Patent Act, 1970 which details the opposition procedure.

³⁴ *See* Article 6g of Argentina's Patent Law which has a similar provision. Brazil in its latest Amendment to the Patent Act has also introduced a very similar Section.

³⁵ Clause 21 and 24 respectively of the Patent Second Amendment Bill, 1999.

³⁶ Section 84 of the Patents Act, 1970. Section 85 adds that the controller will look into the nature of the invention, the ability of the applicant to work the invention and the capacity of the applicant to undertake the risk of capital etc., before taking a decision.

³⁷ On the ground that the reasonable requirement of the public has not been satisfied and the price of the substance is not reasonable.

³⁸ Clause 35 of the Patent Second Amendment Bill, 1999 amends Section 90 of the IPA.

³⁹ This law was changed in 1993 to tune in with TRIPS

⁴⁰ Article 44 of Argentina's patent law, authorizes the national patent office to establish "limited exceptions to the conferred rights" in sectors of vital interest to the socio economic and technological development of the country.

⁴¹ Section 90 (bb) of the Patent Second Amendment Bill, 1999

⁴² Chapter XIX of the Patent Second Amendment Bill, 1999

⁴³ *See*, WMS Gaming Inc. v. U S Crt of Appeals for Federal Circuit, 184 F.3d 1339, *also see*, Atlantic Thermoplastics v. Faytex Corp, 970 F.2d 834. The former cases treat willful infringement differently where the infringement is literal and where it is by the doctrine of equivalents. The latter case treats issues relating to validity and infringement differently in a process by product claim.

⁴⁴ This is very similar to the expressions of Prof Correa of Brazil. *See generally*, CARLOS CORREA, INTELLECTUAL PROPERTY, THE WTO AND DEVELOPING COUNTRIES : THE TRIPS AGREEMENT AND POLICY OPTIONS, 80-84 (Third World Network, 2000)

⁴⁵ This is done to facilitate the generic drug market and is done in exchange for extending the patent term of the drug for a period of an additional five years under the US Drug Price Competition and Patent Term Restoration Act, 1984.

⁴⁶ Section 107A: - "...any act of making or using a patented invention within three years before the expiry of the term of the patent by any person for the purpose of development and submission of information to any regulatory authority responsible for grant of marketing approval for the product of invention"

⁴⁷ *See generally*, G S Srividhya, *Patent disputes- Professional Competence has the edge*, HINDU BUSINESS LINE, July 12, 2000 at 6.