CHAPTER – II

LEGISLATION – SALIENT FEATURE

Patent Legislation In India – 1970 : An Overview

Every study of patents will ultimately focus on the national legislation. In India, the Indian Patent Act, 1970 as modified in 1999, 2002 and finally in 2005 is the governing patent legislation. Before understanding the 1970 Act, it is important to appreciate that patents protect inventions that are:

1. novel,
2. non-obvious/ with an inventive step and
3. useful.

The first issue normally in patents is the subject matter that can be protected by patents. These subjects are termed as ‘patentable’ subject matter. Patentable subject matter is normally established by statute. If the subject matter of the inventions is patentable, then the requirement for patentability is that the invention has to be new. If the inventions is precisely same (therefore inventions that are not exactly the same but are different even in some minor aspects can still be novel and hence patentable) as the earlier work in the field, it said to lack novelty and therefore will not be patentable.

However, even if the invention is novel, if the invention is something that a person skilled in that art (that is scientists working in the same area) finds it obvious, then it will be denied a patent.
When an invention is sought to be patented, the patent application describes the invention by the use of claims and specification. In gist, the specification details the problem the technical problem that the invention solved. The claims are the concise definitions of various aspects of the invention. Claim serve as the primary source of proprietary rights. It is claims that will distinguish one invention from the other. Claim drafting is a rather very technical subject. This job is normally called patent prosecution. In the US, patent prosecutors should mandatorily have a doctoral degree in SCIENCE along with a LAW degree. Also, a PhD holder in chemistry can ONLY draft a chemical patent. To draft a biotech patent, one should get a PhD in biotech and so on. This is to ensure that the patent drafter has a very good understanding of the invention enough to appreciate the scientific nitty gritties. The law degree of the scientist enables him to draft like a lawyer. In fact in order to be patent prosecutor in the US, one has to clear two bar exams. One is the state bar exam. This tests the law and gives the person eligibility to practice any law related subjects. The test is conducted by the bar council. However, those who aspire to work as patent prosecutors have to additionally pass the Patent Bar. This Bar is conducted by the Institute of Engineers. It does NOT test law – it tests the candidates basics in that area of science in which the candidate wants to prosecute patent applications. It is not merely the caliber of inventions that gains American so many patents. It is the degree of sophistication in claim drafting that gives them the ability to bring out very minor differences that ensures America is flooded with invention. For example, in America there are several existing patents for caps to cover the top of the bottle. Though all these are ultimately nothing but bottle covers, each specifies a novelty that the other covers lack. For example, one cover assures no spillage. The other assures a moth flow of water into the mouth through a small nozzle. The third assures easy close without having to keep winding the cover. Another interesting patent is for the bottom surface of tumblers. One claims that it enables the glass tumbler to be placed firmly on smooth surface. The other claims that the surface is thick enough to prevent breakage. The third assures quicker heating in microwave.

These are not peculiar or unusual inventions in the US. All these lay man terms of less breakage, faster heating etc are defined technically by
claim drafting. In the area of patent law, it is claim drafting that is the most technical and difficult area to learn and accumulate.

**Patent Act, 1970:**

**Patentable invention:** Under the Patents Act, 1970 (hereinafter, the Act) any ‘new and useful invention,’ qualifies for a patent under section 2(j). Section 2 (j) details that an invention has to be a *new product or process involving an inventive step and capable of industrial application*; and includes a new and useful improvement over any of them. Thus in India any ‘new and useful’ invention is a patentable subject matter. The term invention has been defined by the court in *Raj Parkash v. Mangat Ram Chowdhary*, AIR 1978 Delhi 1. The court held that,

“Invention is to find out or discover something not found or discovered by any one before and it is not necessary that the invention should be anything complicated and the essential thing is that the inventor was the first one to adopt it and the principle therefore is that every simple invention that is claimed, so long as it is something novel or new, would be an invention and the claims and the specifications have to be read in that light and a new invention may consist of a new combination of all integers so as to produce a new or important result or may consist of altogether new integers and the claim for anticipation by the defendant has to be either by prior user or by prior publication”.

The Act under section 3 defines what cannot amount to an invention. These are:

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature;
(d) the mere discovery of a new form of a substance which does not result in the enhancement of a known efficacy of that substance or the mere discovery of a new property or new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation: For the purpose of this clause, 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.

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

(g) Omitted.

(h) a method of agriculture or horticulture;

(i) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(j) plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(k) a mathematical or business method or a computer program per se or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;
(n) a presentation of information;
(o) topography of integrated circuits;
(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties or traditionally known component or components.

Notably, ‘inventions,’ the primary use or intended use of which would be contrary to law or morality or injurious to public health’ are excluded from patentability to facilitate compulsory license. The ‘law or morality’ phrase in section 3 is used to restrict biotech patents. Exclusion of a ‘mere discovery of scientific principle or formation of an abstract theory’ denies protection to software related material. Clause (g) of section 3 excludes ‘a method of agriculture or horticulture’ thereby excluding protection to plant varieties. Notably, protection of plant varieties by some form of intellectual property is mandatory under TRIPS. India has enacted the Protection of Plant Varieties & Farmers Rights Act in 2001 to protect IP relating to Plants as per TRIPS provision.

**New and Useful:** The Act does not define the terms ‘new’ and ‘useful’. But these terms have been given meaning by the decisions of the court in India. The terms ‘new’ and ‘useful’ are comparative to universal requirements of novelty and utility. The court have also read the concept of non-obviousness into these terms in India. The supreme court in the case of M/s. Bishwanath Prasad Radhey Shyam v. M/s. Hindustan Metal Industries, reported in (1979) 2 SCC 511: (AIR 1982 SC 1444). In this decision, the Supreme Court propounded the test of inventive step.

By this the court held that,
“to be patentable the improvement or the combination must produce a new result or a new article or a better or of old than before. The combination article of known integers may be combined that by their working interrelation to produce a new process or improved result. Mere collection of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent. ... even in adopting the old contrivance to new purpose[s] there must be difficulties to be overcome requiring what is called invention, or there may be some ingenuity in the mode of making the adoption”.

The Supreme Court also held that whether an alleged invention involves novelty and an inventive step is a mixed question of law and fact.

**Obviousness:** The term obviousness is also not defined specifically in the Act. This term merely refers to the fact that if the invention is obvious then it is not patentable. Therefore any invention has to pass the test non-obviousness in order to be patentable. This test becomes more crucial in the case of new improvements or even combinations. In India though there is no test of non-obviousness for patentability, a patent granted by the patent office can be opposed on the ground of obviousness. Every patent application can be opposed on the grounds of anticipation by prior publication (that is someone else has already published this invention before and hence it is not a new invention), prior use, lack of utility, obviousness and lack of inventive step.

The courts have also in the case of Press Metal Corporation Ltd v. Noshir Shorabji, AIR 1983 Bom 144, intertwined the requirement of non-obviousness within new and useful. The court held that,

“New and useful method or manner of ‘manufacture’ need not necessarily be any product i.e. it need not necessarily be a new article; it may be any physical phenomenon in which the effect, be it creation or merely alteration may be observed. In considering whether the claim as made by the inventor is an invention, it will have to be considered whether the subject matter is not obvious. Obviousness is to be judged by the standard of a man skilled in the art concerned.”

**Process Patents:** A patent may be granted for a product, or a process. In the case of a product, the patent is in the end product. In the case of a
process the patent does not lie in the end product but only in the process of production.\textsuperscript{7}

**Reasons for India to exclude the Product Patents in certain categories of invention under the 1970 ACT.**

In 1950, foreign multinationals made the entire drug supply in India.\textsuperscript{8} Foreign multinationals controlled more than 90\% of the Indian pharmaceutical industry and hence determined supply and availability of drugs.\textsuperscript{9} Drugs were manufactured outside India and imported for a higher cost. The cost of drugs in India was amongst the highest in the world.\textsuperscript{10} The drug prices were so high that in 1961, the U.S Senate committee headed by Senator Estes Kefauver observed that India ranks among the highest priced nations in the world for drugs.\textsuperscript{11}

Around the same period the government of India made the first five-year plan to carve India’s development path. Statistics reveal that income from industries was as low as a mere 6.6\% of the total national income. A mere 8\% of the total labor force was working in industrial establishment.\textsuperscript{12} Epidemic diseases accounted for 5.1\% of the total mortality.\textsuperscript{13} The first five-year plan recorded that\textsuperscript{14} India was then the largest reservoir of epidemic diseases. Poverty was also at its peak in India. Around 50\% of India’s population were living under poverty\textsuperscript{15} and were unable to afford the cost


\textsuperscript{9} Banerji, at 78

\textsuperscript{10} Id.

\textsuperscript{11} Id.


\textsuperscript{13} Id.

\textsuperscript{14} First five year plan

of drugs. Consequentially, life expectancy was very low and mortality rate due to diseases was very high. The central government under the Drugs Act of 1940 imported required drugs since India had no local production of bulk drugs.16

Unable to control the expenditure on drugs the government of India took two significant steps to remedy the situation. First, the government signed an agreement with UNICEF to set up a factory for manufacturing of penicillin and other antibiotics.17 This resulted in the establishment of Hindustan Antibiotic Limited in 1954 to manufacture drugs at a cheaper rate for the public. Next, the government appointed Justice Rajagopala - Ayyangar Committee18 in 195719 to recommend revisions to the patent law to suit industrial needs. The object of the committee was to ensure India developed a locally sustainable pharmaceutical market. The committee submitted its report in 1959.20

The report submitted that the patent legislation needed a clear directive. In recommending changes, the Ayyangar committee was bound by the provisions of the Indian Constitution. Article 21 of the Constitution guarantees right to life, which includes the right to good health. The preamble of the Constitution requires policies to balance ‘social and economic’ rights. Hence public health concerns need to be weighed with business interests in

18 The report of this committee is considered to be the back-bone of the Indian Patent law that was enacted in the year 1970.
19 Between this period and 1950 (in 1950 the Dr Chand report was incorporated), a new Bill based on the UK Patents Act of 1949 was introduced and lapsed in India.
20 V R Krishna Iyer, GATT, TRIPS and Patent Law, The Hindu, September 11, 2000 at 5 where the wide admiration for the Rajagopala Ayyangar report has been recorded in the words of Justice Krishna Iyer, a renowned Judge in India known to fight for the cause of the downtrodden: “....A well-debated, development-oriented and patriotically processed statute of 1970, with a progressive perspective and successful sequel, passed after a thorough study (based on the Justice Rajagopala Ayyangar Commission report) proved a tremendous national triumph for the consumer and the manufacturer alike. This finest and most just parliamentary achievement.......”
amending the patent legislation. The Ayyangar report argued that a patent policy vesting unrestrained monopoly would deny a vast section of India’s population from access to medicines. The report concluded that a policy with unfettered monopoly rights would violate the preamble of the Indian Constitution. The report studied the patent systems of U.K, Germany and the U.S and pointed that Germany’s weakened patent protection encouraged the growth of chemical industry. Hence the report recommended a compulsory licensing system21 and process patenting of drugs. The Act based on the Ayyangar report and the rules came into force in 1972.22 (Model I has additional details on the issue).

Since health care was a major concern, the Drug Price Control Order was also passed in 1970.23 The order gave control over the prices of drugs to the government thus complimenting the compulsory license provisions in the Indian patent legislation.24

The patent policy of 1970 dramatically changed this condition.25 In 30 years, the Indian pharmaceutical industry is valued at USD 70 billion compared to a mere USD 2.1 million before 1970. Currently 24000 pharmaceutical companies are licensed in India. Of the 465 bulk drugs used in India, approximately 425 are manufactured within the country. Indian industry has emerged as a world leader in the production of several bulk drugs.26 Indian industry has emerged as a leader for the production of bulk

21 Id.
23 The Drug Policy was established in the year 1978.
24 After the Drug Price Control Order was passed, the government of India placed most drugs under price control.
25 Id.
26 see Martin Adelman & Sonia Baldia, Prospects and Limits of the Patent Provisions in the TRIPS Agreement : The Case of India, 29 Vand. J. Transnat’l L. 507 (1996) arguing that strong intellectual property protection will be in India’s interest given its infrastructure in pharmaceutical production. In contrast, J.H. Reichman uses the same data to argue that free-riding is a way for a developing economy to accumulate the skills and capital necessary to become innovative, but see J.H. Reichman, Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate, 29 Vand. J. Transnat’l L. 363 (1996).
drugs like sulphonamethoxazole and ethambutol. Indian production accounts for nearly 50% of the world production. Several companies like Ranbaxy, Dr. Reddy’s and Cipla have the potential to become billion dollar companies within the next few years. Other than developing indigenous pharmaceuticals, India has grown as a major player in the international generic drugs market. The U.S during the Anthrax scare considered importing cheap generic drugs from India.27 India emerged as a reliable exporter of the generic AIDS drugs in the South African AIDS crisis.28

Most importantly, the patent policy of 1970 has catered to the needs of the Indian poor. Drug prices in India are one of the cheapest in the world today and are affordable to the population. On an average, drugs manufactured in India are more than a 100% cheaper than the same drugs in U.S.29 For example, the price of antibacterial drug Norfloxacin at USD 6 cents (Rs 33.61) in India compares to USD 12.26 (Rs 613.77) in America. The anti-inflammatory drug Piroxicam costs less than USD 5 cents in India (Rs 14.04) as against the American price of USD 11.50 (Rs 592).30 AZT (azidovudine) a drug retailed in the U.S for USD 5.8231 is sold in India in capsule form for USD 1.42 per 300 mg. The government of India has

27 see Manu Joseph, Indian Cipro copies don’t pay off, Wired News, (Nov 8, 2001) at http://www.wired.com/news/medtech/0,1286,48153,00.html, detailing the cost of cipro was Rs. 27 (60 cents) per tablet eight years ago in India. The cost of cipro currently is Rs. 150 (4 cents). Indian drug-makers export the generic version of Cipro to Russia, Brazil, southeast Asia and the Middle East at highly competitive prices.

28 see Michael Waldholz and Rachel Zimmerman, Bristol Myers offers to sell two AIDS Drugs in Africa below cost, The Wall Street Journal, March 15, 2001 at B1 explaining that although Bristol Meyers lowered their prices by 55%, it was still higher than the price of Indian drug companies. see also Robert Block, Cipla tries to skirt South Africa AIDS-drug battle, The Wall Street Journal, March 9, 2001, at B6.

29 see David Scondras, A visit to India – Drug prices, Research and Global access, Being Alive, (May, 1999) at http://www.beingalive.org/news0599/0599_visittoindia.html, arguing that drug prices in India are between a 1000 to 4000 percent cheaper than the prices in the U.S.

30 Id.

31 Hytrin, a sophisticated anti-hypertensive, is sold in India for 7 cents a tablet. A month’s supply of the drug costs about USD 4.20. This is the final price after adding a 200% profit as allowed under the drug price control order. In the U.S, (Boston) the same drug from the same company costs USD 44.48.
achieved the Constitutional mandate of social and economic balance by setting a maximum sale price while still leaving a reasonable profit.

The Indian government assures availability of patented drugs in the market by retaining the power to compulsory license. Interestingly the Indian government has never used the compulsory licensing provision since the enactment of the patent legislation.

The economic brunt of the 1970 patent policy has not escaped India. Multinational companies, once major players, became reluctant to sell in India. By 1997, multinationals accounted for less than 30 percent of bulks and 20 percent of locally produced formulations. Most multinationals complied with the minimum requirements necessary to maintain presence in the Indian market (such as producing simple formulations from imported bulks), while awaiting stronger patent protection. The government responded by steadily reducing price control on drugs. In 1970 most drugs were under price control, by 1984 this was reduced to 347 drugs, and to 163 drugs in 1987. In 1994 only 73 drugs remained under price control.

In spite of such aggressive development of the indigenous pharmaceutical industry, only a mere 30% of India population has secured access to modern medication.

Examination of the policies of developed nations on patenting new methods of producing a known product treated in developed nations.

Novel and non-obvious process of making known products are patentable in developed nations (particularly the U.S and Europe) by the

34 see supra note 108 – 112 and accompanying text.
use of process by product claims. In *Atlantic Thermoplastics* Co. v. Faytex Corp., the plaintiff owned a patent containing process and product-by-process claims for a shock absorbing shoe innersole made from an elastomeric material and polyurethane foam. The issue related to innersoles with elastomeric heel inserts distributed by the defendant. Defendant bought the product from two separate manufacturers using separate manufacturing process. The plaintiff’s suit was against the defendant for infringing the patented process and therefore related to both the manufacturing process. The Federal Circuit held that the process of one manufacturer infringed the patent, as it contained all the claim limitations. The second manufacturer used a different process to achieve albeit an indistinguishable product, thus, no infringement of product-by-process claim. The Federal Circuit overruled *Scripps Clinic* by holding that a product claimed by a product-by-process description is only infringed when the allegedly infringing product is produced via the same process described in the claim. In effect this judgment allows the patenting of a different processes of producing a known product.

This is the equivalent of the process patents of developing countries. Section 5 of the Indian Patent Act, 1970 states that, ‘… no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or process shall be patentable’ (in the case of chemical process, substances that are intended to be used as or capable of being used as food, drug or medicine). Interestingly, the *Atlantic Thermoplastics* case related to a chemical process. Developed nations protect the product using the claimed process. Developing countries merely protect the process alone. Currently, both systems facilitate the same result and encourage novel methods of producing known products. The U.S does not believe in process patent but facilitates the same result by the use of a process by product

38 *Atlantic*, 970 F. 2d at 838.
claim. A careful study of Judge Rich in his overly harsh dissent criticizing the Federal Circuit for refusing to rehear Atlantic Thermoplastics case en banc reflects this argument. 40

TRIPS patent policy requires developing countries to only award product patents. Novel processes will not be patentable in developing countries since these countries do not use process by product claims. Consequentially, inventions patentable in developed nations by use of process by product claim will fall outside TRIPS compliant patent legislation of developing nations. Some generic drugs patentable in developed nation using process by product claim will be unprotected in developing nations. The lesson from this is the need to improve claim drafting techniques.

Compulsory licenses and working of patents: The Ayyangar committee recommendations to balance economic and social justice resulted in provisions on compulsory license and local manufacturing of patents. Compulsory licenses enable the government to intervene if the patents are not worked for the benefit of the people. Local manufacturing requirement necessitates local manufacturing of the patented products to ensure that the patented inventions are worked on a commercial scale in India to the fullest extent reasonably practicable. 41

Compulsory license is granted under Section 84 of the Act. Any interested third party can seek a compulsory license after three years of grant of patent on the grounds that either the patent has not been worked in such a manner as to satisfy the reasonable requirement of the public or that the patented invention is not available at a reasonable price. The controller of patents can compulsorily licenses the patent taking into account several factors including the nature of the invention and the ability of the applicant to work the invention to the advantage of the public.

39 974 F. 2d 1279 (1992)
40 see Atlantic, 974 F. 2d, where Judge Rich quotes a statement (made by Roger A Brooks, the Assistant Vice President to the Pharmaceutical Manufacturers Association. The statement was made on May 14 (1992) meeting of AIPLA (Bulletin), April-June 1992 p. 475) discussing the cost of research and development and that, ‘…innovative R & D is not going to be encouraged by the rule just laid down by the Atlantic Panel’.
PATENT LEGISLATION – SALIENT FEATURES

Alternatively, under section 86, the central government has the right to make an application requesting the controller to endorse a patent with the ‘license of right’. Licenses of right are granted on the same grounds for which compulsory licenses are granted. Under section 86 (2), the controller can issue an order to endorse the patent with a ‘license of right’ if the controller is satisfied with the arguments of the central government. Section 87 deems that a license of right is endorsed after three years from the date of sealing the patent for inventions in food, medicine, drug and chemical processes (that is, inventions entitled to process patents under section 5). A patent subjected to either a compulsory license or a license of right is open under section 88 for any person interested in working the patent to acquire a manufacturing license even if the patentee is not interested. The concept of licenses of right is alien to TRIPS. TRIPS provides for compulsory license under article 31 subject to certain terms and conditions.

Satisfying the reasonable requirement of the public is a precondition to avoid compulsory licensing of the patent. Section 90 of the Act deems that the reasonable requirement of the public is not satisfied unless the invention is worked in India. The reasonable requirement of the public is also prejudiced under section 90, if by reason of the refusal of the patentee to grant a license, the establishment or development of commercial activities in India is prejudiced. Non-working the patent in India, or manufacturing abroad and importing into India can be construed as violating section 90. Article 27(1) of TRIPS deems importation as amounting to working the patents. This section stipulates 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.” TRIPS does not distinguish an importer from a local producer and vests the same rights on both.

Term: Section 53(1) of the Act vests process patents in food, drug and medicines for a term of five years from the date of sealing or seven years from the date of filing a complete specification, whichever is shorter. However, since the license of right is deemed on inventions relating food, drug and medicines after 3 years, exclusive protection is effectively provided only for

42 Section 90 (a) (iv) Patent Act, 1970
three years. Patents protection for other inventions are available for a period of fourteen years as against the twenty years prescribed in TRIPS.43

**Burden of proof:** No provision in the Indian patent act clearly vests the burden of proof on either party. However, the Nagpur high court established in 1953 in the Bombay Agarwal v. Ramchand Diwan Chand44 that the ‘onus of proving infringement lies upon the plaintiff. The plaintiff not only has to prove the patent in his favor but also that the patent is being infringed by using a process patented by the plaintiff’. This contravenes article 34 of TRIPS. Article 34 vests the burden of proof on the defendant. This article applies if a new product is obtained by the patented process, or if an identical product is made and the patent owner is unable to determine the process used.

**Patent Amendment Act, 1999**

Article 27 of TRIPS provides that members are obliged 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.

During this time, India could not afford to violate TRIPS and face trade sanctions impacting Indian exports. The U.S. was extending preferential

---

43 TRIPS, art 33.
44 e.g., 1953 A.I.R. (Nag.) 154
P. G. Diploma in Patents Law

PATENT LEGISLATION – SALIENT FEATURES

tariff treatment under the GATT Generalized System of Preferences (GSP). The U.S. revoked duty-free treatment under the GSP for India’s exports of pharmaceuticals, citing India’s poor protection of U.S. patented drugs resulting in a levy of $ 60 million thus reducing Indian exports. On the other hand, Congress (I) was aware that local economic conditions would impede amendments to the Patents Act, 1970. In fact, Congress (I) understood that patent amendments would directly affect the party’s popularity amongst people. Hence, the party was forced to take an ambiguous position in fear of special 301 on one side and local politics on the other.

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.

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 manufactures also felt that EMRs did not address domestic production, thereby leaving the ground open for foreign multinationals to take over the market. However, the biggest impediment to the implementation of the EMR legislation was the fear that the cost of medicines would increase substantially. It was also feared that the Indian drug companies would be driven out of business.

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 consultation 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. This consultation failed on July 27, 1996. The U.S. then requested the Dispute Settlement Body (‘DSB’) of the WTO to examine whether India had defaulted in its TRIPS obligation. On November 7, 1996 a panel was requested by the US which the Panel agreed to take up on November 20, 1996.

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 Panel ruled that India was in default of its obligations because the administrative notifications could not be considered as a 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.

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. However, the appellate body upheld the
ruling of the Panel and India lost the appeal. After the decision of the appellate tribunal of the WTO, India was forced to amend the Patent Act 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.

**Patent First Amendment Act of 1999:**

This amendment introduced Chapter IVA dealing with exclusive marketing rights. The amendments under Section 24A(1) mandated 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 the Controller to determine whether it is an invention falling within Section 3 and 4. This will be the decisive factor for granting the EMR and it 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. This implies that such prior use excludes use
by the third persons. The section 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 patentability is not barred, then a person who clearly has an unpatentable invention is getting an EMR for five years. If patentability is barred, then it violates section 13. Section 13 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. Interestingly Rule 33F specifically excludes personal documents or secret trials or use. In doing so, this Rule implies that such a secret use by a person who later applies for a patent can constitute EMR infringement.

**Patent First Amendment Rules, 1999:**

The Patent Rules of 1972 provide the details of patent procedures. The first amendment to the patent act in tune with the international obligations resulted in the amending of the patent rules. Though the general procedure remain the same, this amendment incorporated several amendments in tune with the Patent Co-operation Treaty, 1970 (hereinafter, PCT). India became a signatory to this treaty in the year 1998. This treaty does not make any difference to the substantive patent law. It merely facilitates the procedure of patenting. Before the pct, even patent applicant had to apply for patents in each country where he proposes to market the invention. Other than the cost of making several applications in several countries using different currencies, the biggest hassle also was handling the procedural aspects and requirements in various legal system. Therefore the PCT was evolved with a view to reduce the burden on the inventors. PCT contemplates the making of a single application to get seek patent protection in several countries. Every country that is a signatory to the PCT therefore is bound to establish mechanism that enables the host country’s citizen’s to apply for patents in other countries. At the same time, the host country should also facilitate citizens of the PCT member countries to apply in their country. This application processes has been facilitated by the Patent (First) Amendment Rules. However, is it important to understand a few terms and procedural
requirements before the PCT requirements can be understood. Therefore the entire issue of application within India, application for an EMR and PCT application is discussed in the next chapter. The next chapter will deal with procedures for patent application. The last chapter will deal with issues related to patent search.

Patent Second Amendment Bill

Legislative action for Second Amendment:

Other than the EMR, India had one more milestones to cross the TRIPS barrier. This is 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). This bill sought to amend the Patent Act to make changes that were required immediately. 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 seeks to amend the definition of ‘invention’ in Section 2(j). 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. This new definition will perhaps force a different treatment of “inventive step” for the test of patentability and for the opposition procedure.

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”. That is the exclusions in TRIPS can only be made if it affects the ordre public. The proviso to Art 27(2) envisions that “such exclusion is not made merely because the exploitation
is prohibited by their law”. TRIPS envisions the exclusions in the Indian legislation are in line with the international trend of patentability. However, in view of the recent WTO meeting at Doha, (developing countries got concessions in this meeting), these exclusions will not be construed too strictly. India also excludes the patenting of computer software and business methods patents specifically and biotech patents by implication.

3. Term and Date: The proposed bill amended the 14-year term to 20 years beginning from the date of the filing of the application in tune with Article 33 of TRIPS. The term begins from the date of filing of sealing the patent.

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 how 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 Patent Act 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 raise to it ceases to exist.

1. Right to import & parallel import: The IPA did not vest on the patentee or the 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 the importation of a patented product from a duly authorized license holder will not amount to infringement. Thus it opens the market more for foreign companies.

India debated on whether to include this provision specifically or whether there was a concept of exhaustion – that is, the patent holder does not have any control over a buyer or a licensee once the product has been out in the market. However, the exhaustion concept is also based on an implied license and therefore suggests that a buyer can remanufacture the goods and import it into the same market for lesser cost. This argument would completely beat the object of TRIPS and to some extent patents itself. The Indian Government considered the argument of “exhaustion” applies and allowing cheaper parallel imports. However, the 1999 Bill includes Section 107A(b) detailing that importation of a patented product form a “person duly authorized by the patent holder” license holder will not amount to infringement.

45 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)
PATENT LEGISLATION – SALIENT FEATURES

G. “Bolar” Provision:

The United States permits testing to establish the bio equivalency of drugs the expiration of the term of the patent. One the other hand, stock piling before the expiry of the term of the patent is prohibited. A similar provision is sought to be introduced under Section 107A of the second Amendment Bill, 1999. The multinational companies have sought the inclusion of the following:

a) inclusion of the data exclusivity provision detailed under article 39.3 of TRIPS Is essential meant for data protection relating to trade secrets and therefore does NOT obligate any country to provide such a protection under the patent laws.

b) a right to obtain an injunction for acts not directly linked to production. It is notable that in India, under the Civil Procedure code it is possible to get an injunction as a relief for such acts. Assuming this provision is introduced in the patent law the injunction has to be obtained from the civil courts and therefore there will not be any additional advantages on account of the same.

c) Restoration of the term of patent lost due to delays in obtaining the original regulatory approval. The only reason that this is being asked is because of the obvious market advantages enabling the patent holder to reap the benefits of the market for another five years.

Prohibition on approval of the generic drugs for sale in India during the term of the patent to ensure that by the time the approval is obtained another few years passes and the market share of the patent holder is

46 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.

47 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”

48 See note 122

intact during this term. This extends way beyond the scope of the term of patents stipulated under TRIPS. The reason quoted for seeking such an obligation is that the United States law allows such a bolar provisions. However, TRIPS nowhere obligates India to follow the United States law nor does TRIPS oblige India to provide more than a level playing field for the pharmaceutical companies. It is notable that the provision seeking for the prohibition of the generic drugs sale could be read as unconstitutional affecting the right for equal opportunities. The companies that seek these extensively pro market provisions in Indian law quoting the American law should be aware that in the United States there are more stringent medical and FDA guidelines that serve by themselves as a check on the excesses. However, till such laws are in place in a country like India where excesses are even likely to go unnoticed because of bad enforcement mechanisms (and unfortunately TRIPS is not linked with such other legislation) such provisions may have an adverse effect on the public health and history does reveal that even companies like Pfizer that follow the guidelines in the US have disregarded public health and individual dignity for profits.

The Canadian patent law has a similar provision with a condition that the patent holder should be given a notice of the intention to use the invention. The law that was introduced in Argentina in 1996 has a similar law that is not linked with the extension of the term.

50 Article 21 of the Constitution of India, 1950
51 Joe Stephens, The Body Hunters: As drug testing spreads, profits and lives hang in balance, (Pt. 1), The Washington Post, A01 (December 17, 2000). This article, the first of a series of six articles, details some of the experiments that are conducted in the third world without any corporate ethics whatsoever on innocent children. It particularly details the studies conducted by Pfizer and its experiments even though authorities never approved marketing the antibiotic for children in the USA. Pfizer specifies that though an experiment of this nature would never have been cleared in the USA, it won independent approval of the authorities in Nigeria. Such a situation of approval is similar to what is likely to happen in India and hence it is imperative that the Indian law is not as market oriented as the American law is in some specified areas.
52 Supra note 121
PATENT LEGISLATION – SALIENT FEATURES

PATENTS (AMENDMENT) ACT 2002-Salient features

a) The definition of the term “invention” was modified in consonance with international practices and consistent with TRIPS Agreement.

b) Section 3 of the present Act was 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 was 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, was added.

e) Uniform term of patent protection of 20 years for all categories of invention as per Article 33 of the TRIPS Agreement was prescribed.

f) The provisions relating to compulsory licensing was modified to suit the public interest requirements and also to comply with TRIPS Agreement

g) A provision was 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 was incorporated for obtaining marketing approval from the appropriate regulatory authorities before the expiration of the patent term.

i) Several provisions was incorporated for protecting bio-diversities and traditional knowledge.

j) The provisions relating to national security was strengthened.

k) A provision was 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 was incorporated with a view to simplifying and rationalizing the procedures.
Additionally the Term of every patent which is in force including a patent restorable U/S. 60 as on 20.5.2003 has now become 20 years from date of filing. Time for restoration of a ceased patent U/S 60 has now increased from 12 months to 18 months; as such an application for restoration of a patent ceased on or after 20th May, 2003 can be filed within 18 months from the date of ceasing.

A new definition of “Invention” meaning a new product or process involving inventive steps and capable of industrial application has now come into force. A method or process of testing during the process of manufacture will now be patentable. Process defined U/S 3(i) in case of plants, are now patentable while a process for diagnostic and therapeutic has now been considered as non patentable. A list of Authorized Depository Institutions have been notified in the Gazette Of India, Part II, Section 3 sub-section (ii) dated 20.5.2003 for depositing the biological materials mentioned in the specification at the time of filing a patent application.

The source of Geographical origin of the biological material used in invention is required to be disclosed in the specification. 18 months publication has been introduced, therefore, every patent (except in which a secrecy direction is given U/S 35) will now be published just after 18 months from the date of filing/priority and will be open for public on payment. As such the filing intimation being published in the Gazette immediately after filing has been stopped. A request for examination system has been introduced and therefore all the patent applications in which First Examination Report has not been issued on or before 19th May, 2003 will now be examined U/S 12 only after filing a request for examination on Form –19 with prescribed fee.

The applications for patent will now be examined in serial order in which the request for examination is filed. In case the application has been filed before the commencement of this Act, the request shall be made within a period of twelve months from the date of commencement of the Act i.e. 20th May 2003 or 48 months from the date of application, whichever is later. Provision for filing request for examination by any other interested person (other than applicant) also has been introduced. Provision for the
PATENT LEGISLATION – SALIENT FEATURES

withdrawal of application by applicant any time before grant has been introduced. Time for putting the application in order for acceptance U/S 21 has now been reduced from 15/18 months to 12 months. Ground of opposition U/S 25 as well as revocation U/S 64 have been enlarged by adding following ground:

a. disclosure or wrongly mentioning the source of geographical origin of biological material used for invention;

b. Anticipation having regard to the knowledge oral or otherwise available with in local or indigenous community in India or elsewhere.

c. Section 39 in modified form prohibiting filing patent application outside India, inventions limited to the fields of defence purposes or atomic energy has been reintroduced.

d. Opposition Proceedings U/S 25 have been simplified and shortened, fixing hearing is not compulsory, if the applicant does not file reply statement and evidence, application will be deemed to have been abandoned.

e. Provision for extension of time up to 6 months for paying the overdue renewal fees initially i.e. renewal fees, which have become due, due to the late grant of patent can now be paid within 9 months from the date of record by taking an extension on Form-4.

f. Fees required to be paid on documents can now be paid within 1 month from its date of filing. Provision for allowing Paris Convention Priority has been extended to group or union of countries or inter governmental organizations, therefore, 12 month priority will also be available to applications filed in EPO, AIRPO, OAPI and EAPO.

Patent (Amendment) Act 2005 –Salient Features

1. In the definition of what are not inventions, the amendment now says “Mere new use for a known substance” is not an invention. In other words if the applicant can substantiate that it is new use for a known substance with some technical input such new use can be patented.1

53 1 3. Amendment of section 3.—In section 3 of the principal Act, for clause (d), the following shall be substituted, namely:—“(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of
2. A computer program per se is not patentable but its "technical application to industry or a combination with hardware" is patentable. The scope of patentability of a computer program has now been widened and is more or less on lines with US Patent grant.

3. A mathematical method or business method or algorithms are not patentable.

4. The provision prohibiting product patent for food, medicine, drug and chemical processes has been removed. In India with effect from January 2005 product patent is available for medicine, drug, chemical processes and food. This is the most important amendment introduced by the new Ordinance. Product patent regime in respect of drug, medicine, food and chemical processes is implemented in India.

that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, 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;”.

2 3(K) a mathematical or business method or a computer program per se or algorithms. Computer program product is claimed as “A computer program product in computer readable medium”, “A computer-readable storage medium having a program recorded thereon”, etc. In such cases the claims are treated as relating to software per se, irrespective of the medium of its storage and are not held patentable. Examples in respect of other categories of subject matter are Scheme or method of bookkeeping, Business method in the field of accounting. Method of tax collection.

3 Omission of section 5.–Section 5 of the principal Act shall be omitted- original act read as Chapter II - - - - - 5. Inventions where only methods or processes of manufacture patentable (1) In the case of inventions- (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semiconductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances them selves, but claims for the methods or processes of manufacture shall be patentable. [(2) Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of section 2, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA.]
5. If a patent application is accompanied by a provisional specification, the complete specification should be filed within 12 months of filing of the application. Otherwise the application shall be deemed to be abandoned.

6. A patent application shall be examined only on a request in prescribed manner. Without a request the patent applications would not be examined as a matter of routine as it was prior to the year 2003.

7. Provisions relating to Exclusive Marketing Rights (EMR) have been removed. EMR provision was introduced in India in the year 1999 in compliance with TRIPS as product patent for drug and medicine was not available in the Indian Act. As product patents can now be granted for Drugs, medicines, food, and chemical processes the EMR provision has become redundant and has been repealed.

---

4 Amendment of section 9.—In section 9 of the principal Act,— “(1) Where an application for a patent (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) is accompanied by a provisional specification, a complete specification shall be filed within twelve months from the date of filing of the application, and if the complete specification is not so filed, the application shall be deemed to be abandoned.”;

5 Amendment of section 11A.—In section 11A of the principal Act,— sub section(2) The applicant may, in the prescribed manner, request the Controller to publish his application at any time before the expiry of the period prescribed under sub-section (1) and subject to the provisions of sub-section (3), the Controller shall publish such application as soon as possible.

6 Substitution of new sections for sections 25 and 26.—For sections 25 and 26 of the principal Act, the following sections shall be substituted, namely:—“25. Opposition to the patent.—(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent… (2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner… (3) (a) Where any such notice of opposition is duly given under sub-section (2), the Controller shall notify the patentee. (b) On receipt of such notice of opposition, the Controller shall, by order in writing, constitute a Board to be known as the Opposition Board consisting of such officers as he may determine and refer such notice of opposition along with the documents to that Board for examination and submission of its recommendations to the Controller. (c) Every Opposition Board constituted under clause (b) shall conduct the examination in accordance with such procedure as may be prescribed. (4) On receipt of the recommendation of the
8. When a patent has been published but has not been granted, any person can make a representation to the Controller of Patents requesting him to refuse the application on the ground of lack of novelty, inventive steps, and industrial applicability. The Controller shall consider such representation and dispose it off. The person making the representation is not a party to the proceeding. After the grant of a patent but before the expiry of the period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller.

9. Only after grant of patent the application, specification and documents related thereto are opened for public inspection.

10. The Act now provides for compulsory license for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems provided compulsory license has been granted by such country. To avail of this provision, the applicant should satisfy two conditions viz.

(a) The country to which export has to be made has insufficient or no facility to manufacture.

(b) The recipient country should grant compulsory license for import and sale of the drug.

Opposition Board and after giving the patentee and the opponent an opportunity of being heard, the Controller shall order either to maintain or to amend or to revoke the patent. (5) While passing an order under sub-section (4) in respect of the ground mentioned in clause (d) or clause (e) of sub-section (2), the Controller shall not take into account any personal document or secret trial or secret use.

7 Insertion of new section 92A.—After section 92 of the principal Act, the following section shall be inserted, namely:—“92A. Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances.—(1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned products.”
11. The Act also provides for appeal from the order of decision of the Controller to Intellectual Property Appellate Board (IPAB). The power of revocation is also conferred with IPAB.\(^8\)

---

\(^8\) Substitution of new section for section 117G.–For section 117G of the principal Act [as inserted by the Patents (Amendment) Act, 2002 (38 of 2002)], the following section shall be substituted, namely:— “117G. Transfer of pending proceedings to Appellate Board.–All cases of appeals against any order or decision of the Controller and all cases pertaining to revocation of patent other than on a counter-claim in a suit for infringement and rectification of register pending before any High Court, shall be transferred to the Appellate Board from such date as may be notified by the Central Government in the Official Gazette and the Appellate Board may proceed with the matter either de novo or from the stage it was so transferred.”