CHAPTER-II

INDIAN PATENTS ACT: AN OVERVIEW

2.1 INTRODUCTION

India is a unique country having its own riches blessed with treasures of wealth, spirituality, moral values where people practiced and adopted the principles of nonviolence and peace. Spiritual elevation was sought not for the sake of individual’s attainment of self realization and enlightenment but to serve for the service of the mankind. Social welfare was given much precedence over that of individual’s vested interest. When we make a reference to the great epics of Ramayana and Mahabharata we come to know that whenever man has tried to deviate from the principles of dharma he has met with a bitter consequence. Many of our ancestors, rishis, saints and great spiritual leaders have done their best to resolve the crisis that existed in the society for its welfare.

India is looked by the world with a different perspective when it comes to our culture, traditions, human and moral values, acceptance to the practice of religions, family system, unity and integrity, and the patience they have in keeping the spirit going. India had a different style of teaching which was called as the Gurukula system where in the students were put to rigorous tests as to intellect, morality, character and the student who sets a high standard of character and upholds dharma was held to be eligible for getting education the only purpose for such a practice was to see that the knowledge so transferred is not commercially utilized or used for the purpose of individual interest. We get a large number of instances in this regard where people had an ulterior motive were denied with getting the knowledge. The spiritual gurus have made it a condition that they would impart education or a secret only on getting the assurance that education or knowledge should not be used for the self benefit or for doing the business. This type of practice is still in existence in many of the villages in India.

One such practice can be seen in village Kalagi of Chitapur taluka in Gulgarga district, where the medicine for the fractured broken bone is prepared by the leaves given to the needy patients which is unique medicine which joins the bones by mere application of the medicine, this ensures that the patient does not require any kind of plaster and to hold the broken part of the body still without
making any movement and the person who gives the medicine does so at free of cost not a single pie is charged from him. The secret of producing that medicine is currently practiced and this knowledge is transferred by their ancestors subject to the condition that to whom such knowledge is given should take an oath not to use that medicine for making a lively hood or for commercial purpose. It is a concept and spiritual belief in Indians that the secret so disclosed by the Gurus works only if it is utilized for the welfare of the people similarly the antidote for the snake bite to neutralize the snakes poison and for curing jaundice is still in practice in few of the villages where in allopathic medicines does not cure the disease cent percent.

India has never believed and practiced the concept of intellectual property rights as a property that can be utilized for the commercial purpose in no instance we can see an example of commercial utilization of intellectual property. If at all they are used is used for the betterment of the welfare of the people if this purpose is not served than they thought it better to destroy the secret than being misutilised or used for commercialization. The history reveals a different story altogether as regards the knowledge being destroyed when ever used for commercial purpose the examples that may be quoted are large in number it was believed that the army of Tipu Sultan had the knowledge or technique used in missiles, the art of navigation and navigation was born in the river Sindh 6000 years ago. The term ‘navigation’ is derived from the Sanskrit word Navgath and navy is also derived from the word ‘nou’. Sushruta is regarded as the father of surgery over 2600 years ago he conducted complicated surgeries like cataract, artificial limbs, fractures, urinary stones or kidney stones and also plastic surgeries. Budhayana the Indian mathematician had explained the concept what today is popularly known as Phythagorous theorem as early as in 6th Century but in vain we have lost it and that knowledge was withheld due to the reason that the knowledge would be utilized for commercial purpose.

Such was the heritage of India which was ready to extinguish the knowledge rather than put the knowledge for commercial exploitation they did so because of the belief that when a person works for commercial gain suppressing the interest of the general public would take a person to hell and it was deemed as a curse for the wrongful activities the person is attached with samskaras and carries forward for the future life hence they had the main object in their life to work for the welfare of
the society. India has never believed in protecting the intellectual property for personal gains or to exploit commercially the existing knowledge. The concept of protecting and exploiting the intellectual property which is mainly in the form of intangible assets are recognized by the western countries and India was influenced by the rule of Britisher’s who came to India for the purpose of trade and gradually invaded India and caught hold of many kingdoms under their rule hence most of the Indian knowledge got corrupted loosing the originality of the Indian customs and traditions. The ancient scriptures like Vedas, Upanishads provided spiritual solace but also included in it a rich resource of knowledge of science and art. The knowledge was not an overnight outcome but was the result of constant and persistent effort made by our ancestors at the same time people in other parts of the world were in rudimentary stages. Though India was known as a knowledge hub of human wonders in ancient days which was far ahead of other countries and were treated to be the gift of Almighty God and used strictly for the human welfare. The ancient knowledge at some point of time has not been fully passed to the future generations by our ancestors for the reason that the knowledge would be utilized for personal gain. Most of the scientific knowledge were possessed was occupied and stolen by the western countries. Our ancestors being generous propagated such vital information for the benefit of the mankind without having a forethought of protecting their inventions and innovations, which in the later years proved fatal.¹

2.2 KNOWLEDGE AND PROPERTY

Knowledge is considered to be the product of individual creativity today but, which was considered as the most precious gift, which had no limitations of time and space, was freely given to the aspirants from the guru subject to the condition that the knowledge would not be utilized for personal gain or commercial exploitation which was popularly known as Guruparampara. The guru teacher got the knowledge from his Adi guru after adding his expertise and experience passed it to his deserving students, this was true to all most all scientific traditional knowledge.

“Let noble thoughts come to us from everywhere let all living beings live happily, free from the fear of death and diseases” and many more such ideals were

¹ http://www.en.Wikipedia.org/wik/patents
the guidelines for the scientists who worked for the betterment of every living creature. They were so principled and selfless that thinking of petty personal benefits was unknown, unheard and unthinkable too.

Indian society has inherited a rule that each individual owed certain duties and debts also known as rinas. The rinas or debts were towards the parents, gurus and to the motherland or society for all that has been bestowed upon him. When a person is executing a duty or repaying the debt by contributing something to the society what can he expect in return except the feeling of intense fulfillment. Indian society has always deemed and followed the principle that if any invention or a new thing is invented or found was dedicated to the society instead of using it for the personal gain offering good to the society was treated to be a salutation to the god, guru, parents and the ruler and in turn they got the blessing from the people and in some cases was awarded with some benefits and special reward as a super human which they felt would contribute for their liberation and paves path to the heaven after death.

According to the Yejurveda 26-2, “just like I preach the voice that brings welfare for all human beings, thou shall also disseminate the same to all without distinction of caste and sex”. It was laid down in Atharva Veda (10.28.7) “when human beings, the children of the supreme being or the supreme sage, yearn for alms of knowledge, the people who wish not to disseminate Vedic knowledge, become the fallen ones along their progeny, and also lose all fortunes and pleasures,” Yajnavalkya Smriti (II-212) points out, “Since Vedas reflect all principles of justice, the person who imparts Vedic knowledge by way of gift attains salvation”. Religious benefit was contemplated for learning, reciting and passing on to others religious and other such knowledge. Further, Sanatana dharma (Scholars duty) dissuades the learner from avarice. Yajnavalkya Smriti (II-129) prescribed, “Since money goes against the practice of self study, a scholar shall abstain from aspiring for it”. Thus enlightenment and reform rather than economic growth and gain were the object of teacher-disciple relationship. Baghavadgita preaches sacrifice made in the form of knowledge is a superior sacrifice in all forms of material things, for all actions culminate in knowledge (IV-39), knowledge is provider of supreme peace it is the devoted and faithful work that constitutes the basis of knowledge, through work, sacrifice and distribution that one’s entitlement
to claims on material things may be projected; never should one aspire for the property of another (Ishopanishad). During the Smriti period, the practice of obtaining wealth by scholarship became an approval (Narada smritil-41). The approach of sacrifice by a disciple towards teacher in the form of Gurudakshina is reflected in the Ekalavya story of Mahabharata, wherein the disciple says that

“To return to the guru what he himself has given, is it a sacrifice?

No, it was the highest gain; it is the summum bonum of one’s life”

Such was the respect given to the guru sheeshya relationship that was the return to the guru by the disciple, even though the demand of royalty in a punitive manner was accepted by the sheeshya if it was felt well in the eyes of the guru. The knowledge so earned was taken away by his guru, without having a second thought the sacrifice was given by the sheeshya. The rationality of the concept of property in learning or gaining knowledge is seen in Smritis which provides that “one should avoid using the learning of others and their houses, vehicles, furniture’s and gardens” on analysis we can make out that “knowledge brings modesty; from modesty comes worthiness (entitlement); worthiness would bring wealth; from wealth flows charity. This is the path of happiness” (Nityaniti 147). It clearly shows that the thought deeply embedded in this like knowledge, its product, and property is also not an end by itself but one that shall be mellowed in the warmth of justice for attaining social happiness. Action linked to knowledge brings prosperity whereas the laziness is the root cause of all penury (Yejurveda).

Gaining knowledge through the learning is the internal beauty, friend and guide that is the means to success and royal recognition as it liberates human beings from mind blinding passions of life had put knowledge itself was a hidden treasure. The relation between knowledge and property weaved on ideological premise would not have been pragmatic for an advance knowledge system of India for centuries but for the royal and philanthropic support generously extended to cultural creations. Gift giving was regarded as bringing personal merit and social happiness, an investment in human community for everybody’s good, and a tool of distributive justice. Islamic laws says that no one should have access to each other’s property in an unlawful manner which takes the right of other persons the right to property should be recognized in such a manner that it does not violate the rights so as to put him into hardships. It is during the colonial period that modern law of intellectual
property was superimposed upon a system pre-eminently knowledge dissemination-oriented, which flourished during more than five millennium with a swan song of avoiding unjust enrichment and undeserved misery. Technology is the way inputs in the production process are transformed into output. It is believed that ideas (particularly the innovative ones) improve the technology of production.

A new idea allows a given bundle of inputs to produce more or better output, making the production process more efficient. There are various examples of ideas and technological improvements that can happen. Moore’s Law (attributed to the former chairperson of Intel) asserts that the number of transistors that can be packed onto a computer chip doubles approximately every 18 months.

There are different attributes of ideas. Ideas are non-rivalrous (indivisible) unlike most goods (which are tangible). But ideas are considered as excludable or partly excludable. Non-excludability means that once an idea is created everybody can use it; nobody can be excluded. There is always a cost associated initially to develop the idea, which can be termed ‘fixed cost’. Once the idea is created it can be replicated and sold without any additional cost. So, marginal cost of producing every extra unit of idea becomes zero. Therefore, the firm who takes up the onus of creating and selling ideas should charge zero prices from the consumers, if one follows the principle of marginal cost pricing under perfect competition. But if the firm follows such a rule, then it cannot recover the cost of developing the idea, and can undergo losses. Therefore, it has to keep a price, which can at least recover the cost of developing that idea. So, it has to move away from the principle of perfect competition i.e. marginal cost pricing, and move towards the principle of imperfect competition i.e. price should be greater than the marginal costs. Therefore, it has to keep a price, which can at least recover the cost of developing that idea. So, it has to move away from the principle of perfect competition i.e. marginal cost pricing, and move towards the principle of imperfect competition i.e. price should be greater than the marginal costs. As the firm produces more and more of the idea, the average cost declines and the firm get scale-effect. Due to fixed cost and zero marginal cost associated with the production of idea, there are increasing returns to

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3 Mr. Shambhu Ghatak authors the article. Patents: A Case History of Indian Drugs and Pharmaceutical Industry “at: shambhughatak@yahoo.com visited on 15th December 2009.
scale. The institution of patenting, intellectual property rights and copyrights becomes important, to give the original inventor the incentive to create new ideas or to undertake R&D.\(^4\)

In the third world countries, traditional attitudes toward class, gender, caste and kinship, does not allow entrepreneurship to develop to its full potential. Undertaking research and development of new products and ideas are subject to not only intellect, availability of resources and capital, but also dependent on enterprising ability of firms and individuals as well as enabling environment and institutions. Intellectual property laws deals with abstract objects, and not physical objects. However, like other property rights, intellectual property rights are relations between individuals. Intellectual property rights are very much related to the market. They have an important role in constituting markets in information. Given the overtly economic character of intellectual property legislations, one possibility worth investigating is that economic theories, which may or may not be contradictory to one another, provides a justification for enactment of intellectual property rights.

These rights can be different from each other in terms of legal detail and character. A patent monopoly gives the owner rights against the independent discoverer of the same invention, while copyright offers rights against copying but does not prohibit the independent creation of the same work. From the point of view of economics, property rights must be the best way to ensure that individuals devote sufficient resources to the creation of abstract objects. Intellectual property rights have to be based on the outcome of a cost-benefit calculation from the point of view of economic rationality. Patent statutes are meant to protect inventions.\(^5\) Protection is conditional upon satisfying various criteria of which novelty and inventiveness are two important examples. According to historical facts, connection between intellectual property, science and economic development is contingent and local rather than necessary and universal. Imperial China for example achieved spectacular outcomes in science without relying on intellectual property rights.\(^6\)

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\(^5\) Drahos, Peter, A Philosophy of Intellectual Property, Dartmouth, 1996.
\(^6\) Needham, J., the Grand Titration, 1969.
2.3 INDIA’S PATENT POLICY

India has a long history of patent policy which was framed after enormous study. India’s approach to patents differs from those of industrialized countries in that India sees patents as a tool of public policy. India’s policy is being challenged by the demand to reform IPR laws to conform to TRIPs. This section provides an overview of India’s patent policy.

2.3.1. India’s Patent Policy in Pre-TRIPs Period

India’s patent policy focused on balancing developmental concerns with the need for promoting innovations. India viewed patents as a tool for economic development and restricted the scope and term of patents. The sentiment in India on the issue of patents, especially on pharmaceuticals, is illustrated by an oft-quoted statement made by Indira Gandhi at the World Health Assembly in 1982:

“The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death”.7

The philosophy of India’s Patents Act of 1970 varies enormously from the framework being established under TRIPs. There are several knowledge and information areas which India considers non-patentable. India has a large community of scientists and researchers among whom publication rather than gaining patents has been a concern. G.V. Ramakrishna, Chairman of the Disinvestment Commission points out that in India, “We (Indians) are accustomed to the notion that knowledge is free. Our whole orientation has to change from one that stresses intellectual attainment to one that protects intellectual property.”8 Industrialised nations conceive of patents as a fundamental right comparable to the right of physical property, whereas developing nations view it as “fundamentally as an economic policy question.”9

From the perspective of developed countries, intellectual property is a private right that should be protected as any other tangible property, but for developing nations, intellectual property is a public good that should be used to promote economic development.10

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7 Quoted in Jean Lanjow, “The Introduction of Pharmaceutical Product Patents in India: ‘Heartless Exploitation of the Poor and Suffering’?, Economic Growth Centre, Yale University, August 26, 1997, p. 1
India has always believed in the Principle of Dharma and wanted that this Principle be envisaged in the Laws that it enacts. On this basis Patents Law was legislated so that the fruits of innovation be reached to the least person and no person is deprived of it as India was against the commercialization of one's own intellect.

2.4. THE MAIN FEATURES OF THE ORIGINAL INDIAN PATENTS ACT, 1970

1. The Act tries to strike a balance between the rights of the patent holder and his obligation to the society that grants him such rights.

2. The basic philosophy of the Act, as laid down in Section 83, is that patents are granted to encourage inventions to accelerate indigenous industrial growth by securing their working in India on a commercial scale. And, those patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

3. The Act totally excludes atomic energy and methods of agriculture from patentability. One cannot obtain any sort of patent whatsoever in these fields (Section 3).

4. The Act permits product patents for all inventions except food, medicines, drugs and Substances produced by chemical processes; in these fields only process patent is available because food and health are crucial for the well-being of the people. Process patents in these areas enable the other competitors to find new, improved and economical processes for producing the same product.

5. Section 53 provides patent protection for a period of 14 years from the date of filing. In case of food and medical drugs the period of protection is limited to seven years from the date of filing the patent or five years from the date of sealing, whichever is earlier. This shorter period of protection in case of food and medicines is believed to be necessary to prevent the patentee from exploiting the needs of society by charging exorbitant prices for the patented article. Further, in the field of medicine, the rate of obsolescence is high as new and improved molecules keep replacing the existing ones.

6. The Act contains provisions for compulsory working of a patent. The Working of a patent means manufacturing the product in India. The patentee cannot hold

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the patent in India and import the product from another country, thereby compelling the Indian consumer to pay an excessive price.

7. In public interest, patents are subject to strict and extensive governmental control and use. The provision on Compulsory Licensing under Section 84 of the Act ensures the working of the patent after three years from the date of sealing. If the patent holder ignores this provision, any person may apply for compulsory license and he shall be licensed to manufacture the product. The rationale of compulsory license is that the state undertakes to protect IPRs only to ensure that new products are available cheaply and in abundance. Hence compulsory license is issued if it is in public interest or if the manufacturer does not work the patent.

8. Every patent for an invention relating to a method or process for manufacture of Substances intended for use, or capable of being used, as food, medicines, or drugs, or relating to substances prepared or produced by chemical process (including alloys, optical glass, semi-conductors and inter-metallic compounds) shall be deemed to be endorsed “Licenses of Right” from the date of expiry of three years after the sealing of the patent.

This patent law which was a model for other developing countries like Argentina, Mexico, Egypt, Brazil and Chile, has been replaced by the Indian Patent Act, 1999, which is modeled on the basis of the TRIPs (Trade-Related Aspects of Intellectual Property Rights) Agreement. This amendment seeks to implement the obligations that India has taken in the field of patents by signing the TRIPs Agreement. The bill generally aims at making the 1970 Patents Act as TRIPs compliant as possible.

Besides TRIPs, India is also a member of the following international treaties related to intellectual property rights:

a) Convention establishing World Intellectual Property Organization (WIPO)
b) Paris Convention for the protection of Industrial Property with effect from December 7, 1998
c) Patent Cooperation Treaty (PCT) with effective from December 7, 1998
2.5 PROVISIONS OF TRIPs

The TRIPs Agreement is one of the fifteen Agreements listed in Annex I of the Marrakesh Agreement establishing WTO. Though retaining the basic principle of mutuality and *quid pro quo* for patent grant, the TRIPs Agreement has widened the scope, duration, and strength of patent protection. The text:

1. Extends the scope of patentable subject matter to any invention, whether product or Process, in all fields of technology [Article 27.1];
2. Enlarges the period of patent protection to 20 years [Article 33];
3. Deems importation as equivalent to working of patent [Article 27.1];
4. Protects the right holder against discrimination on the grounds of place of invention, place of production and field of technology [Article 27.1];
5. Limits the scope of compulsory licenses, licenses of right, government/third party use [Article 31];
6. Reverses the burden of proof.

The demanding TRIPs provisions enumerated above are not to be read in isolation. They have to be interpreted in the light of other beneficial provisions found in the preamble and Articles 2.1, 7, 8, 27(1), 27(2), 27(3), 30 and 31 of the TRIPs Agreement. The TRIPs attempts to balance the rights and privileges of the right holder with his obligations and responsibilities to the society. This is succinctly stated in the preamble which takes into account the need to promote effective and adequate protection of IPRs but at the same time stresses the need to ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade.

Article 2.1 of the text makes Article 5 of the Paris Convention of 1967 an integral part of the TRIPs text. Therefore TRIPs, through Article 5A of the Paris Convention, empowers the member states to take legislative steps and to provide in their patent laws, compulsory licensing to prevent and control abuses which arise due to “failure to work” or “insufficient working” of patents. Similarly, TRIPs, through Article 5B of the Paris Convention, admits lack of local working as a ground for issuing compulsory license.

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The principles of the TRIPs agreement are laid out in Article 8. Article 8.1 permits the members, while they are formulating or amending their national patent laws and regulations, to adopt measures necessary to protect health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are not inconsistent with the provisions of the TRIPs Agreement and Article 8.2 accepts the need to prevent the abuse of IPRs by the patent holder. Though Article 27.1 extends the scope of patentable subject matter, it also clarifies that only inventions (and not discoveries) are patentable. Further, it adds that for an invention to be patentable, it should be new, it should involve an inventive step, and it should be capable of industrial application.

Further, Article 27.2 reserves powers for member states to exclude from patentability such inventions as may be necessary to protect public order or morality or for protection of life, health, and environment. And Article 27.3 permits members to exclude from patentability: (1) diagnostic, therapeutic and surgical methods for treatment of humans and animals; and (2) plants and animals.

2.6. THE INFLUENCE OF ENGLAND ON INDIAN PATENT LAW

Patent law in India had its origins in the patent system introduced by Great Britain\(^\text{13}\) which ruled India for almost four centuries.\(^\text{14}\) It is well documented that the British influence in India had its beginning in 1600 with Queen Elizabeth I’s chartering of the “Governor and Company of Merchants of London trading into the East Indies\(^\text{15}\),” The English East India Company (“The Company”), which first came to India in 1608 and laid the foundation for British rule over the next three decades.\(^\text{16}\) The British Crown was eventually forced to take full control of India from the Company in 1858 as a result of a massive revolt against the Company, which is also known as India’s First War of Independence.\(^\text{17}\)

The origin of Indian patent law can be traced to 1856, when a law was enacted in India to grant certain exclusive privileges to inventors for a period of

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\(^{15}\) Ibid.

\(^{16}\) Id. at 10, 12-17.

\(^{17}\) Id. at 90-91.
fourteen years. Since the 1856 law did not have the prior sanction of the British Queen, experts opined that the Legislative Council of India did not have the authority to pass it. The reason given was that since the grant of patents “in India was a prerogative of the Crown” any patent law passed by the Indian legislature required the prior permission of the Crown or its representative. Thus, the 1856 Act was repealed when the Indian Legislative Council passed Act IX of 1857; Act IX was followed by a new law enacted in 1859 that granted inventors the exclusive privilege to make, use, and sell their invention in India. The purpose of this legislation was to help British patent holders gain control over the Indian markets, and the law contained major restrictions on the importation of technologies and inventions. As a consequence, importation of technology became highly complex and prohibitively expensive.

The first Law Commission was established in 1834 under the Charter Act of 1833 under the Chairmanship of Lord Macaulay. This Commission was responsible for the codification of the Penal Code, the Criminal Procedure Code, and other legislation. The second, third, and fourth Law Commissions were instituted in 1853, 1861, and 1879 respectively. During a span of fifty years, the various commissions had recommended legislations on a variety of subjects, based mostly on the adaptation of English laws to Indian conditions. The Patents Act was one such piece of legislation. The first Indian patent legislation was modeled along the same lines as the British Patents Act of 1852.

India was an English Colony for more than one hundred years before gaining its independence in 1947, and India’s earliest patent laws were based upon those of England. The East India Company introduced patent laws in India with the Patents Act of 1856, which resulted from the recommendations of the Lord Macaulay Law Commission. This Act was followed by the Indian Patents and Design Act of 1911 replaced all previous legislation. India was fighting for independence throughout this period, and all of these patent laws were passed to accommodate the needs of the colonial British Empire at the expense of India.

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19 Ibid at p179
20 Tanuja Garde, India in Intellectual Property in Asia: Law, Economics, History and Politics, 55, 57 (Paul Goldstein and Joseph Straus eds., 2009).
series of amendments, such as the 1859 amendment which introduced “exclusive privileges for making, selling, licensing, and using inventions.” The Patents and Designs Protection Act of 1872 provided protection for industrial designs and was followed by the Protection of Inventions Act of 1883. The Acts of 1872 and 1883 were combined to make the Inventions and Designs Act in 1888. At the time of independence, the British based Indian Patents and Design Act of 1911 was still the existing patent law.

Patent law in India continued to be developed and refined over the next several decades. In 1872, the Patents and Designs Protection Act was enacted, and in 1883 the Protection of Inventions Act was enacted. Finally, in 1888, both these laws were consolidated in the Inventions and Designs Act. The British enactment of the Indian Patents and Designs Act, 1911, created a system of patent administration in India under the supervision of a Controller of Patents. The term of patents under the 1911 Act was for sixteen years after the filing date, and in certain cases it could be extended up to seven additional years. The 1911 Act remained in force with certain amendments and continued to govern the Indian patent system even after India got its independence from Britain in 1947. It was finally repealed by the Patents Act of 1970. All versions of patent law enacted by the British in India allowed for product patents in all fields of technology, including pharmaceuticals.

Even during that period, courts in British India had to deal with a number of patent infringement disputes. When India finally got independence from Britain in 1947, it had a huge population of 400 million people that represented one-fifth of the world’s population. However, the nation at that time was among the poorest in the world. Slowly, Indian policy makers turned their attention to an impoverished domestic economy and eradication of the remnants of colonization. While doing

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23 Coming into Compliance with TRIPs: A Discussion of India’s New Patent Laws. www.cardozoaelj.net/issues/08/Colin.pdf visited on 23.05.2010
28 One such infringement case was Gillette Indus. Ltd. v. Yeshwant Bros., 1937 A.I.R. 40 (Bom.) 347 (India).
so, they observed that even though India had made some progress in industries like steel production, they observed that even though India had made some progress in industries like steel production,\textsuperscript{31} India’s indigenous pharmaceutical industry had been in very bad shape as a direct result of the 1911 Act.\textsuperscript{32} The indigenous pharmaceutical industry was highly critical of this Act, as it prevented them from manufacturing reverse-engineered drugs for which foreign pharmaceuticals held a product patent in India.

Even after India got its independence, its drug industry was tightly controlled by the multinational companies,\textsuperscript{33} and most life-saving drugs like insulin, streptomycin, and penicillin were wholly imported.\textsuperscript{34} Furthermore, a very unpopular judgment of the Bombay High Court in 1968\textsuperscript{35} that favored a foreign patent holder over a local drug manufacturer accelerated the Indian government’s resolve to implement drastic changes in the patent law that would enable Indian companies to make drugs at much cheaper prices.\textsuperscript{36}

The Bombay High Court judgment mentioned above dealt with a patent infringement suit filed by the owners of an Indian patent for the manufacture of new sulphonyl-urea compounds, salts of those compounds, and of anti-diabetic medications containing those compounds.\textsuperscript{37} One of the chemical compounds covered by the patent was Tolbutamide, and “since 1957 the plaintiffs had been marketing it as an anti-diabetic drug in India and all over the world under the trademark ‘Rastinon’.

The main argument raised by the plaintiffs was that the defendant had wrongfully infringed upon their patent by manufacturing, preparing, and selling Tolbutamide by the use of the invention disclosed in the plaintiffs’ patent. The first defendant admitted that it had manufactured Tolbutamide, but claimed that it “had been manufactured by the application of the processes mentioned in another patent,” held by the Haffkine Institute of Bombay, the second defendant. The first defendant


\textsuperscript{32} See generally Sudip Chaudhuri, The WTO and India’s Pharmaceuticals Industry: Patent Protection, TRIPs, and Developing Countries 128 (2005).


\textsuperscript{34} See Planning Commission, Government’ of India, 1st Five Year Plan ch. 32 paras. 94-99 (1952), available at http://planningcommission.nic.in/plans/plarel/fiveyr/default.html.

\textsuperscript{35} See generally Farbwerke Hoechst and Bruning Corp. v. Unichem Lab., 1969 A.I.R. 56 (Bom.) 255 (India).


\textsuperscript{37} Farbwerke Hoechst and Bruning Corp., 1969 A.I.R. 56, at para. 1.
also raised a counter-claim to revoke the patent “on the grounds of insufficiency of description, lack of novelty, want of inventive step and lack of utility.” The Court held the patent to be valid and restrained the first defendant from further infringement upon the plaintiffs’ patent.\textsuperscript{38} It should be noted that the process of drafting a patent law in-tune with India’s needs began immediately after independence.\textsuperscript{39}

After independence, India altered its patent system to better suit its own national goals. The Indian government appointed two committees, the first in 1949, the Tek Chand Committee (1948-1950), and the second in 1957, the Ayyangar Committee (1957-1959), to review India’s patent laws system and to suggest modifications in them. The Justice Tek Chand Committee found that India’s ill-defined patent provisions enabled multi-national companies to gain patent rights beyond the scope of their inventions, and it recommended the incorporation of compulsory license provisions to reduce the potential for abuse of monopolies. Based on the interim report, the Patents and Design Act of 1911 was modified in 1952, and in 1953 the Controller of Patents became authorized to grant licenses, on patents, on foods, medicines, etc. The Tek Chand Committee did not lead to many lasting improvements to the patent laws; however, a second committee was needed.

The Ayyangar Report of 1959 is significant for India and other less developed nations because it analyzed “the adaptability of foreign patent regimes and policy options to address national issues” and “highlighted the best practices in foreign patent regimes and examined their suitability to address public health and economic concerns of under developed economies.” The Ayyangar Committee examined some issues that continue to be debated in the WTO today, including: “(1) whether patenting food, chemical, and pharmaceutical inventions can affect the underprivileged section’s accessibility to these products; and (2) whether compulsory licensing can enable accessibility while at the same time promoting innovation”.\textsuperscript{40} After a lengthy study and much debate, the reports of these two committees led to the Patents Act of 1970 (“Patents Act, 1970”). “The objectives of the Act as listed in its text are unapologetically protectionist, which is not surprising

\textsuperscript{38} Farbwerke Hoechst and Bruning Corp., 1969 A.I.R. 56, at para. 21.
in view of Committee’s findings. Modern India had set a goal to free itself from foreign monopolies and establish strong domestic industries”.

2.7. HISTORY OF INDIAN PATENT LAW

The first legislation in India relating to patents was the Act VI of 1856. The objective of this legislation was to encourage inventions of new and useful manufactures and to induce inventors to disclose secret of their inventions. The Act was subsequently repealed by Act IX of 1857 since it had been enacted without the approval of the British Crown. Fresh legislation for granting ‘exclusive privileges’ was introduced in 1859 as Act XV of 1859. This legislation contained certain modifications of the earlier legislation, namely, grant of exclusive privileges to useful inventions only and extension of priority period from 6 months to 12 months. This Act excluded importers from the definition of inventor. This Act was based on the United Kingdom. Act of 1852 with certain departures which include allowing assignees to make application in India and also taking prior public use or publication in India or United Kingdom for the purpose of ascertaining novelty.

In 1872, the Act of 1859 was consolidated to provide protection relating to designs. It was renamed as “The Patterns and Designs Protection Act” under Act XIII of 1872. The Act of 1872 was further amended in 1883 (XVI of 1883) to introduce a provision to protect novelty of the invention, which prior to making application for their protection were disclosed in the Exhibition of India. A grace period of 6 months was provided for filing such applications after the date of the opening of such Exhibition.

This Act remained in force for about 30 years without any change but in the year 1883, certain modifications in the patent law were made in United Kingdom and it was considered that those modifications should also be incorporated in the Indian law. In 1888, an Act was introduced to consolidate and amend the law relating to invention and designs in conformity with the amendments made in the U.K. law.

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The Indian Patents and Designs Act, 1911, (Act II of 1911) replaced all the previous Acts. This Act brought patent administration under the management of Controller of Patents for the first time. This Act was further amended in 1920 to enter into reciprocal arrangements with UK and other countries for securing priority. In 1930, further amendments were made to incorporate, inter-alia, provisions relating to grant of secret patents, patent of addition, use of invention by Government, powers of the Controller to rectify register of patent and increase of term of the patent from 14 years to 16 years. In 1945, an amendment was made to provide for filing of provisional specification and submission of complete specification within nine months.

After Independence, it was felt that the Indian Patents and Designs Act, 1911 was not fulfilling its objective. It was found desirable to enact comprehensive patent law owing to substantial changes in political and economic conditions in the country. Accordingly, the Government of India constituted a committee under the Chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949 to review the patent law in India in order to ensure that the patent system is conducive to the national interest. The terms of reference of this Committee includes as follows:

1. to survey and report on the working of the patent system in India;
2. to examine the existing patent legislation in India and to make recommendations for improving it, particularly with reference to the provisions concerned with the prevention of abuse of patent rights;
3. to consider whether any special restrictions should be imposed on patent regarding food and medicine;
4. to suggest steps for ensuring effective publicity to the patent system and to patent literature, particularly as regards patents obtained by Indian inventors;
5. to consider the necessity and feasibility of setting up a National Patents Trust;
6. to consider the desirability or otherwise of regulating the profession of patent agents
7. to examine the working of the Patent Office and the services rendered by it to the public and make suitable recommendations for improvement; and
8. to report generally on any improvement that the Committee thinks fit to recommend for enabling the Indian Patent System to be more conducive to national interest by encouraging invention and the commercial development and use of inventions.

The committee submitted its interim report on 4th August, 1949 with recommendations for prevention of misuse or abuse of patent right in India and suggested amendments to sections 22, 23 and 23A of the Patents and Designs Act, 1911 on the lines of the United Kingdom Acts 1919 and 1949. The committee also observed that the Patents Act should contain clear indication to ensure that food and medicine and surgical and curative devices are made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee.

Based on the above recommendations of the Committee, the 1911 Act was amended in 1950 (Act XXXII of 1950) relating to working of inventions and compulsory license/revocation. Other provisions were related to endorsement of the patent with the words ‘license of right’ on an application by the Government so that the Controller could grant licenses.

In 1952 (Act LXX of 1952) an amendment was made to provide compulsory license in relation to patents in respect of food and medicines, insecticide, germicide or fungicide and a process for producing substance or any invention relating to surgical or curative devices. The compulsory license was also available on notification by the Central Government. Based on the recommendations of the Committee, a bill was introduced in the Parliament in 1953 (Bill No.59 of 1953). However, the Government did not press for the consideration of the bill and it was allowed to lapse.

In 1957, the Government of India appointed Justice N. Rajagopala Ayyangar Committee to examine the question of revision of the Patent Law and advise government accordingly. The report of the Committee, which comprised of two parts, was submitted in September, 1959. The first part dealt with general aspects of the Patent Law and the second part gave detailed note on the several clauses of the lapsed bills 1953. The first part also dealt with evils of the patent system and solution with recommendations in regards to the law. The committee recommended retention of the Patent System, despite its shortcomings. This report recommended major changes in the law which formed the basis of the introduction
of the Patents Bill, 1965. This bill was introduced in the Lok Sabha on 21<sup>st</sup> September, 1965, which however lapsed. In 1967, again an amended bill was introduced which was referred to a Joint Parliamentary Committee and on the final recommendation of the Committee, the Patents Act, 1970 was passed.

This Act repealed and replaced the 1911 Act so far as the patents law was concerned. However, the 1911 Act continued to be applicable to designs. Most of the provisions of the 1970 Act were brought into force on 20<sup>th</sup> April 1972 with publication of the Patent Rules, 1972.

This Act remained in force for about 24 years without any change till December 1994. However, the Act of 1970 was amendment to comply with TRIPs Agreement. An ordinance effecting certain changes in the Act was issued on 31<sup>st</sup> December 1994, which ceased to operate after six months. Subsequently, another ordinance was issued in 1999. This ordinance was subsequently replaced by the Patents (Amendment) Act, 1999 that was brought into force retrospectively from 1<sup>st</sup> January, 1995. The amended Act provided for filing of applications for product patents in the areas of drugs, pharmaceuticals and agro chemicals though such patents were not allowed. However, such applications were to be examined only after 31-12-2004. Meanwhile, the applicants could be allowed Exclusive Marketing Rights (EMR) to sell or distribute these products in India, subject to fulfillment of certain conditions.

The second amendment to the 1970 Act was made through the Patents (Amendment) Act, 2002 (Act 38 of 2002). This Act came into force on 20<sup>th</sup> May 2003 with the introduction of the new Patent Rules, 2003 by replacing the earlier Patents Rules, 1972.

The third amendment to the Patents Act 1970 was introduced through the Patents (Amendment) Ordinance, 2004 with effect from 1<sup>st</sup> January, 2005. This Ordinance was later replaced by the Patents (Amendment) Act 2005 (Act 15 of 2005) on 4<sup>th</sup> April, 2005 which was brought into force from 1-1-2005. 42

The Patents Act, 1970, was very weak for particular inventions, especially pharmaceuticals. The Act did not provide protection for products vital to the Indian economy, such as agricultural and horticultural products, atomic energy inventions,

and all living things. A “stated objective of the Indian Patents Act, 1970, was the development of an independent Indian pharmaceutical industry. The abolition of pharmaceutical product protection from the inherited British colonial law was seen as the key element in advancing this objective.”

“The Patent Act provided protection for method or processes of manufacture, but did not provide protection for compositions of matter such as medicine or drugs, food, or any other substance “prepared or produced by a chemical process”. In addition, the method or process patents for medicines, food, or drugs expired quickly and lasted only “five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter. . .” Because medicine process patents expired, either five years from the grant of the patent, or after overcoming opposition and passing examination, or seven years from the time of application, whichever is shorter, “it is possible that a patent which is opposed will expire before the opposition is concluded.” Under India’s patent regime, patents for other inventions expired after only fourteen years from the date of the patent. In contrast to these short periods, the minimum term of protection under the TRIPs Agreement is twenty years from the date of filing for any kind of patent.

Under the Patents Act, 1970, the examination and opposition procedures were lengthy. Patent examiners had to ensure that applications were in compliance with the procedural requirements of the Patent Act, and to determine whether there was any “lawful ground of objection to the grant of the patent” Patent examiners had to file a report with the Controller of Patents listing any objections to the grant of the patent within eighteen months after receiving a patent application. Objections could relate to the claims and the specification or anticipation of any claims. The Controller had to report any objections to the applicant and give the applicant an opportunity to amend its application. If the applicant fixed all of the objections and the Controller accepted the complete specification, it was then advertised in the Official Gazette. After public advertisement, any person could give notice of opposition to the patent within four months of the publication date. If there was a public opposition, the Controller had to “notify the applicant and give the applicant

44 Sec 5 of the Indian Patents Act,1970.
45 Article 33 of TRIPs Agreement
46 Sec 23 of the Indian Patents Act, 1970
and the opponent an opportunity to be heard before deciding the case.” If the application was finally accepted, a patent would be granted if the applicant requested sealing.

Under the weak regime of the Patents Act, 1970, there was little incentive for pharmaceutical companies in India to perform original research and to develop new drugs. Because pharmaceutical compounds could not be patented, and because process patents expired rather quickly, there was little financial incentive to perform long and costly research and development. To account for India’s pharmaceutical needs, a large generic pharmaceutical industry with over sixteen thousand firms developed. These firms were well suited to reverse-engineer pharmaceuticals developed and patented in foreign countries, and to design a new process for producing the same patented drug in large quantities. The Patents Act, 1970, gave the Indian generic pharmaceutical industry a great competitive advantage by allowing Indian firms to copy patented pharmaceuticals developed by foreign pharmaceutical companies by simply designing a new method to make the same patented drug. Additionally, the Act placed the burden of proof on the patentee to prove infringement.

To successfully claim infringement of process patents, a patent holder must prove that his particular product could only have been made through his patented process if the product could be made through any other possible process, the suit for infringement would fail. Because the Indian firms did not have to spend the same amount of time and money in research and development that other pharmaceutical companies did, they could sell the same drugs at a fraction of the price in the United States and Europe. “Indian drug makers have manufacturing costs almost 50 percent below that of multinational drug makers in Europe and the United States, and India’s drug discovery cost remains at almost one-tenth of that in the Western world”.


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48 Sec 107 of Indian Patents Act,1970

The present laws are the outcome of various amendments made to the Patents Act, 1970, and the Patent Rules, 2003, designed mainly to meet the requirements of TRIPs and India’s obligations under international agreements.\(^\text{51}\)

Some of the largest changes were made concerning the mandatory requirement of introducing product patents for drugs, food products and chemicals by January 1, 2005. TRIPs, however, does not extend to drugs that were already on the market, and only covers a newly discovered chemical entity.

2.8. PATENT AMENDMENTS IN INDIA AFTER TRIPs AGREEMENT

TRIPs provided a three-stage frame for countries such as India which did not grant product patent rights in pharmaceuticals, when TRIPs came into force on 1 January, 1995:

1. Introduction of a facility (“mail box”) from January 1, 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications will not be processed for the grant of a patent until the end of 2004. But Exclusive Marketing Rights (EMRs) can be obtained for that application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.

2. Compliance, from January 1, 2000 with other obligations of TRIPs, namely, those related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof and so on, and

3. Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mail box are also required to be taken up for examination from January 1, 2005.\(^\text{52}\)

An Ordinance was actually introduced a day before TRIPs came into effect. But the Ordinance lapsed because it could not be followed up with the necessary legislation within the stipulated time required. Then the government introduced a


\(^{52}\) See ”Amendments to the Patents Act, 1970: Background Note,” Department of Industrial Policy and Promotion, Ministry of Commerce, New Delhi. See also the website of the Controller General of Patents, Designs and Trademarks, Government of India (www.patentoffice.nic.in).
Bill and it was passed in the Lok Sabha. But in the Rajya Sabha, where the opposition was in a majority, the Bill was stalled (the Bill was referred to a Parliamentary Select Committee) and the report could not be submitted by the time the Parliament was dissolved in May 1996, and India had to comply with the requirements of the TRIPs agreement by April 1999. Again a Bill was introduced, and this time it was passed in the Rajya Sabha on 22 December 1998, but the Bill could not come up for consideration in the Lok Sabha. Ultimately an Ordinance was promulgated followed by an Act passed in March 1999. The Patents (Amendment) Act, 1999 amended the Patents Act, 1970 with retrospective effect from 1 January, 1995 to implement mail box facilities and EMRs. Another Bill was introduced in the Rajya Sabha in December, 1999 to bring about the other changes in the patent regime as mentioned under (2) above. This Bill too faced similar hurdles and could not be passed immediately. The Bill had to be referred to a joint parliamentary committee. This committee consulted a large number of people including, lawyers, economists, industry representatives, NGOs and others. Several objections were raised. Some of these were incorporated and the committee submitted a revised Bill in December, 2001 (Joint Committee 2001). This Bill with a few changes was approved by the Parliament in May, 2002. The amended Act (The Patents Amendment), 2002 came into force on May 20, 2003.

The Patents (Amendment) Act, 2002 made 64 amendments to the Patents Act, 1970 relating to terms of patents (20 years), exceptions to exclusive rights, compulsory licensing and so on. A Third Amendment was necessary by the end of 2004 to replace the EMR system and to introduce product patent protection as mentioned under (3) above. A bill (The Patents (Amendment) Bill, 2003) was introduced in the parliament in December 2003. Though only two clauses were necessary to replace the EMR system and introduce product patents in all fields including pharmaceuticals, the bill actually included 70 other clauses. Before this bill could be passed, Lok Sabha was dissolved. After the elections, the new government which came into power in May 2004 refereed the issue of the Third Amendment to a Group of Ministers (GoM).

54 The text was accessed from www.patentoffice.nic.in. visited on 11th May 2011.
55 See Peoples’ Commission on Patents Laws for India 2003, pp. 20-22 for the list of the 64 amendments made.
Many public interest groups and others demanded that the recommendations of the GoM should be made public and a debate be held before finalizing the amendments. But this was not done. In fact even without discussing it in the parliament, full fledged product patent regime has been introduced in India from 1 January, 2005 through a presidential decree (the Patents (Amendment) Ordinance, 2004) issued on December 26, 2004.

2.9. THE INDIAN PATENT ACT (POST-TRIPs AMENDMENTS)

The first Indian patent laws were first promulgated in 1856. These were modified from time to time. New patent laws were made after the independence in the form of the Indian Patent Act of 1970. The Act has now been radically amended to become fully compliant with the provisions of TRIPs. The most recent amendment was made in 2005 which were preceded by the amendments in 2000 and 2003. India became a member of the Paris Convention, Patent Cooperation Treaty and Budapest Treaty.

The patent right is territorial in nature and inventors/their assignees will have to file separate patent applications in countries of their interest, along with necessary fees, for obtaining patents in those countries. A new chemical process or a drug molecule or an electronic circuit or a new surgical instrument or a vaccine is patentable subject matter provided all the stipulations of the law are satisfied.

The salient features of the Patents Act, 1970 were:

1. Elaborate definition of invention
2. No product patents for substances intended for use as food, drugs and medicines including the product of chemical processes
3. Codification of certain inventions as non-patentable
4. Mandatory furnishing of information regarding foreign application
5. Adoption of absolute novelty criteria in case of publication
6. Expansion of the grounds for opposition to the grant of a patent
7. Exemption of certain categories of prior publication, prior communication and prior use from anticipation
8. Provisions for secrecy of inventions relevant for defense purposes
9. Provision for use of inventions for the purpose of Government or for research or instruction to pupils

10. Reduction in the term of patents relating to process in respect of substances capable of being used as food or as medicine or drugs

11. Enlargement of the grounds for revocation of a patent

12. Provision for non-working as ground for compulsory licenses, licenses of right, and revocation of patents

13. Additional powers to Central Government to use an invention for purposes of government including Government undertakings

14. Prevention of abuse of patent rights by making restrictive conditions in license agreements or contract as void

15. Provision for appeal to High Court on certain decisions of the Controller


2.9.1 Patents Amendment Act, 1999

Even though India was given exemptions from implementing pharmaceutical/agrochemical product patents until 2005, it was mandated to set up a mailbox facility for such product patent applications filed during the TRIPs transition period and to assign each application a filing date.56

Another obligation under TRIPs was the provision dealing with the grant of EMRs for mailbox applications that met specified conditions during the transition period. India initially tried to implement the mailbox facility and grant EMRs by way of a presidential order.57 For various reasons the Indian parliament failed to pass the law dealing with mailbox facility and EMRs. This prompted the United States to utilize the WTO’s dispute resolution mechanism to address India’s failure to enact the

57 The Patents (Amendment) Ordinance, 1994, No. 13, Acts of Parliament, 1994 (India), available at http://www.wipo.int/clea/docs_new/pdf/en/in/in001en.pdf. Presidential authority for the promulgation of an ordinance is derived from Article 123(1) of the Indian Constitution. INDIA CONST. art. 123(1). Ordinances are promulgated as a stop-gap measure to deal with urgent situations when the Indian Parliament is not in session and the President of India is satisfied that circumstances exist which render it necessary for him/her to take urgent action. Id. Ordinances lapse six weeks after the meeting of the Parliament. Id. at art. 123(2)(a). The Patents (Amendment) Ordinance lapsed six weeks after the meeting of the Parliament.
mailbox and EMR regime into a law.\textsuperscript{58} The WTO’s Appellate Body held in December 1997 that India’s failure to make timely amendments to its patent laws had resulted in its non-fulfillment of obligations covered by Article 70.8(a) of the TRIPs Agreement, which mandated that India establish “a means” that adequately preserved novelty and priority of pharmaceutical product patent applications.\textsuperscript{59} Finally, in March 1999, the amendment was passed by the Indian parliament; India formally implemented the mailbox procedure for pharmaceutical product patent applications and gave it retroactive application from January 1, 1995.\textsuperscript{60}

Mailbox applications were deposited in a “black box,” and they were not taken out for examination until March 2005. During India’s ten-year TRIPs transition period, 26 mailbox applications were filed in the four branches of the Indian Patent Office.\textsuperscript{61} The framework for filing mailbox applications, in order to comply with the TRIPs transition requirements, ended for India on December 31, 2004. This means that the provisions dealing with mailbox applications/ EMRs became obsolete in 2005 and they have been repealed by way of the 2005 amendment.\textsuperscript{62}

Few applicants who filed mailbox applications during the TRIPs transition period took the additional step of seeking EMRs for their inventions. The grant of an EMR would have conferred the exclusive right to sell or distribute the invention in India for a period of five years from the date of the grant until either a patent was granted, or the application was finally rejected, whichever was earlier.\textsuperscript{63} An EMR was granted only for those inventions claimed in mailbox applications that further satisfied the following requirements:

a. an examination by the Indian Patent Office had established that the invention did not fall within any of the categories of subject matter considered as non-


\textsuperscript{62}Mukherjee, (Patents Amendment 2005 which states that Chapter IVA of the 1970 Law shall be omitted).

patentable inventions like business methods, frivolous inventions, mere admixture, or within the scope of the prohibition on patenting inventions relating to atomic energy.\textsuperscript{64}

b. The mailbox/EMR applicant had filed a patent application for the same invention, claiming the “identical article or substance” in a “convention country” on or after January 1, 1995;

c. The mailbox/EMR applicant had been granted a patent by the convention country on or after the date it filed its mailbox application in India;

d. The convention country had issued “approval to sell or distribute the Article or substance” in the convention country, “on the basis of appropriate tests conducted” in the convention country on or after January 1, 1995;

e. An authority on behalf of the Indian government had given approval to sell or distribute the article in India.

2.9.2 The Patents (Amendment) Act, 2002

Although the 2002 amendment brought into force numerous changes, the most significant was the extension of the patent term to twenty years.\textsuperscript{65} The 2002 Act amended the 1970 law to ensure that the terms of all patents granted in India would expire twenty years after their application filing date. Before this amendment, Indian process patents granted in the field of pharmaceuticals lasted for only five years from sealing, or seven years from the date of the patent, whichever was less, while the term of all other types of patents was fourteen years from the date of the patent.

The 2002 amendment cemented India’s accession to the Paris Convention\textsuperscript{66} and Patent Co-operation Treaty. The two treaties are administered by WIPO, and India signed both in 1998.\textsuperscript{67} This meant that India had to make its laws consistent with the Paris Convention’s national treatment principle—which prohibits discriminatory treatment of

\textsuperscript{64}The Patents (Amendment) Act, 2002, No. 38 sec. 24A(2), Acts of Parliament, 2002 (India) (non-patentable inventions are covered under Section 3 and inventions relating to atomic energy are covered in Section 4).

\textsuperscript{65}The Patents (Amendment) Act, 2002, No. 38 sec. 2, Acts of Parliament, 2002 (India), available at http://www.ipindia.nic.in/ipr/patent/patentg.pdf (amending section 53). This was mandated by Article 33 of the TRIPs Agreement.


foreign applicants—as well as its right of priority—which permits foreigners who have previously filed a patent application in their home countries a twelve-month priority period within which they can file an application for the same invention in India, while still retaining the benefit of their earlier home country filing date.

The 2002 amendment brought into force other changes aimed at bringing India’s patents law in tune with the TRIPs Agreement, including new definitions of invention and inventive step,68 and new exclusions from patentable subject matter like business methods,69 algorithms, and traditional knowledge.70 The amendment also reversed the burden of proof provision involving cases of process patent infringement71 and streamlined the compulsory licensing framework.72 The 2002 amendment also paved the way for patentability of microorganisms.73

The 2002 amendment provides three grounds for seeking a compulsory patent license. First, the law provides the broadest grounds for seeking a compulsory patent license in the case of non-working of patented inventions.74 Such a license can be sought only three years after the sealing of the concerned patent.75 Second, there is another provision for grant of compulsory licenses on notification of the Indian government in circumstances of national emergency or extreme urgency like the breakout of epidemics.76 Third, there is a provision for compulsory licenses in the case of certain patents that are essential to the efficient working of other patented inventions.77 The 2002 amendment abolished the concept of Licenses of Right.78 Under this concept, process patents pertaining to medicines and food “were automatically deemed to be endorsed with the words ‘licenses of...

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69 Id. at sec. 4 (adding section 3(k)).
70 Id. at sec. 4 (adding section 3(p)).
71 Id. at sec. 43 (adding section 104A).
72 Id. at sec. 39 (substituting the previous provisions with a whole new chapter dealing with Compulsory Licensing, Chapter XVI).
73 Id. at sec. 4 (adding section 3(j) dealing with plant varieties. India drafted a new law called Protection of Plant Varieties and Farmer’s Rights 2001 to give effective protection to plant varieties.)
74 Id. at sec. 84(1).
75 Id. at sec. 84.
76 Id. at sec. 92.
77 Indian Patents Act Amendment 2002. at sec. 91.
right’, which would make them available for compulsory licensing by all applicants three years after the patent grant.

The second amendment to the 1970 Act was made through the Patents (Amendment) Act, 2002 (Act 38 of 2002). This Act came into force on 20th May, 2003 with the introduction of the new Patents Rules, 2003 by replacing the earlier Patents Rules, 1972. Salient features of the Patents (Amendment) Act, 2002 were:

1. Further codification of non patentable inventions
2. 20 years term of patent for all technology
3. Provision for reversal of burden of proof in case of process patents
4. Provisions of compulsory licenses to meet public health concerns
5. Deletion of provision of license of right
6. Introduction of system of deferred examination
7. Mandatory publication of applications after 18 months from date of filing
8. Provision for process patent for micro organisms
9. Establishment of Appellate Board
10. Provision for parallel imports
11. Provision for exemption from infringement proceedings for use of a patented invention for obtaining regulatory approval for product based on that patented invention.
12. Provision to protect biodiversity and traditional knowledge.

The third amendment to the Patents Act, 1970 was introduced through the Patents (Amendment) Ordinance, 2004 with effect from 1st January, 2005. This Ordinance was later replaced by the Patents (Amendment) Act, 2005 (Act 15 of 2005) on 4th April, 2005 which was brought into force from 1st January, 2005. The salient features of this amendment are:

1) Extension of product patents to all fields of technology including food, drugs, chemicals and micro organisms.
2) Deletion of the provisions relating to Exclusive Marketing Rights (EMRs)
3) Introduction of a provision for enabling grant of compulsory license for export of medicines to Countries which have insufficient or no manufacturing capacity to meet emergent public health Situations
4) Modification in the provisions relating to opposition procedures with a view to streamlining the system by having both pre-grant and post grant opposition in the Patent Office

5) Strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies

6) Rationalization of provisions relating to time-lines with a view to introducing flexibility and reducing the processing time for patent application.

2.9.3. The Patents (Amendment) Act, 2005

The last step in India’s implementation of the changes required to make its patent law TRIPs compliant happened by way of the 2005 amendment. Through this amendment, Indian law, for the first time since 1970, allowed patent protection to substances capable of being used as pharmaceuticals, food, and agro-chemicals.79 The 2005 amendment was preceded by a presidential ordinance in 2004.80 After its promulgation, there were intense debates about the scope of various provisions, but the Indian Parliament enacted the 2005 amendment after making changes in the ordinance.

The 2005 amendments contain many controversial features that have caused many disputes. They include elaborate provisions concerning what is and is not considered patentable subject matter,81 a new definition of the “inventive step” criterion of patentability,82 procedures governing both pre- and post-grant opposition,83 and a more liberal framework for compulsory licensing.84

2.9.4. Main Provisions of Patents (Amendment) Act, 2005

The Patents (Amendment) Act, 2005, (“Patents Act, 2005”) was signed into law by the President of India on April 4, 2005, published in the Gazette of India, and brought India’s patent laws fully into compliance with TRIPs. “This bill amends India’s previous Patents Act to incorporate stricter patent laws, while

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82 These changes inserted by substituting section 2 (ja) of the 1970 Law with a new definition. Id.
83 These changes inserted by substituting Sections 25 and 26 with a new definition. Id. at sec. 23.
84 These changes inserted by adding Section 92A to the 1970 Law. Id. at sec. 55.
simultaneously continuing to protect India’s domestic pharmaceutical sector and the public health of her citizens.” The Patents Act, 2005, altered the former definition of “pharmaceutical substances” to “any new entity involving one or more inventive steps.” This means that the pharmaceutical must be new and not just an insignificant change from a previously patented entity. The new law states:

“the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or 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”.

This means that small, insignificant improvements in known compounds, such as just adding a simple chemical group such as salts, esters, ethers, etc., or the discovery of any new property or new use of a known substance will not result in a patentable invention unless there is substantial improvement in efficacy. For example, a product, such as aspirin, cannot be patented every time someone discovers a new use for aspirin. This modification of the law prevents drug manufacturers from making variations on the same drug to extend the patent life beyond the original 20 years and thus delaying the entry of generics into the market. The Patents (Amendments) Act, 2005, is literally a list of amendments to the Patents Act, 1970, not a reprinting of the law as a whole, and incorporates several major changes to the old patent act.

The Patents Act, 2005 omits section 5 of the Patents Act, 1970, to allow product patent protection in addition to the existing process patent regime in all fields of technologies which includes the areas of food, medicine, and drugs. The new Act also includes a provision for publication of patent applications. New applications are to be published eighteen months from the date of filing or from the date of priority, whichever is earlier; there is also an option for an early publication of the application if requested by applicant. The Patents Act, 2005 also rewrote the sections on opposition to patents, pre-grant and post-grant. Pre-grant opposition can now be filed anytime after publication but before the grant of patent. Prior to this amendment, the time Post-grant opposition to a patent can now be filed up to one year from the date of publication of the grant of a patent. The amendment also

rewrote all grounds for pre-grant and post-grant opposition to comply with TRIPs period for pre-grant opposition was only four months from the date of advertisement of the acceptance of a complete specification.

Several provisions in the Patents Act, 2005 speed up the process of reviewing and granting patents. The time frame for examination of patent applications was substantially changed by the new law. Earlier, the time period to put the application in order for acceptance was 12 months from the date of the first office action. In the meantime, the first office action had to be replied to within four months of its receipt. The new Rules prescribe a total time period of six months to put the application in order for grant. This period is extendable by three months. Upon filing the Request for Examination, the Controller of Patents will refer the application to an Examiner. The law does not prescribe a time limit to do so. The Examiner, on receipt of such reference, must issue an Office Action within one month and not later than three months from the date of reference.

In addition, “provisions relating to acceptance of complete specification, advertisements of acceptance of complete specification and effect of acceptance of complete specification have been omitted. There will now be direct grant of Patent.” The old provisions which dealt with the requirement of sealing of Patent were also omitted by the new Act. Indian legal officials have also recently opened at least ten new regional patent offices in order to speed up the patent process. The processing time limits for examination of patents have been reduced from forty-eight months to thirty-six months. “Apart from major changes, one of the positive aspects of the present Act is that by amending the various sections rigidity in the time-line is replaced by greater flexibility.”

When India joined the WTO in 1995, India was forced to create a means for filing pharmaceutical product applications. However, India did not have to review these applications until January 1, 2005, when the developing member transition period ended. To satisfy this requirement, India set up a “mailbox” system to receive, but not review, pharmaceutical applications. Under the Patents Act, 2005,

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patent applications in the mailbox before January 1, 2005, receive patent rights only from the date of the patent grant, not from the date of filing. Because the 20-year patent protection period begins from the date of filing, however, some pharmaceutical patents will have a short patent life once issued. In addition, after a patent is granted, patent-holders are only entitled to receive reasonable royalties from enterprises which have made significant investments and were producing and marketing the newly patented product prior to January 1, 2005, and which continue to manufacture the product even after grant of the patent, and no infringement actions can be brought against such companies. “Royalty payments commence on the date of the patent grant aid . . . no retroactive royalty’s from the patent’s filing date having to be paid.” “This ‘means Indian companies have got compulsory licenses for the 200-odd new molecules that have been patented in the past five years.”

The Patents Act, 2005, also provides compulsory licensing for the manufacture and export of pharmaceutical products to any country having insufficient or no manufacturing capacity of its own to address public health problems. This allows the Indian government to license the use of a patent to a third party, without the patent owner’s consent, for domestic production in India. Before granting the compulsory license, the applicant must only make efforts to obtain a license from the patent holder for a “reasonable period,” which is “construed as a period not ordinarily exceeding a period of six months.” If the “compulsory license is granted with a pre-dominant purpose of supply in Indian market the licensee may also export the patented product, if need be” “Finally, a compulsory license may be issued that allows a patented product to be exported in order to remedy an anticompetitive practice. These provisions benefit India’s generic pharmaceutical companies, encourage domestic production, and protect the public health of her citizens by preventing abuse of an invention’s patent protection.”

The distinction between a process and product patent is critical to a discussion of pharmaceutical patents and public health. A product patent protects a material thing or substance. This thing or substance may for example be a new chemical substance (often referred to as a “new chemical entity”) or anew machine or apparatus. A product patent means that no one may make the product without the authorization of the patent holder. Thus, the scope of protection is wide in the case

of a product patent. A process patent protects the manner in which a particular output is achieved.\textsuperscript{89} For example, where a pharmaceutical substance is already known, inventive activity may result in a new method to produce the substance more efficiently or less expensively. The known pharmaceutical substance mayor may not be covered by an existing patent. Nevertheless, a patent may protect the new and more efficient procedure developed by the inventor. In case of a process patent, third parties may not use the patented process without authorization—but they cannot be prevented from using a different process to obtain the same result. Maintaining the distinction between product and process patent claims is critical to ensuring continuing innovation in the pharmaceutical industry and access to affordable medicines.

Historically, many countries adopted a policy and legal framework that did not grant product patents in the field of pharmaceuticals, foods, chemicals and fertilizers. Such policies facilitated the development of a domestic generic drug industry in countries such as India. The TRIPs Agreement\textsuperscript{90} mandatorily requires the adoption of product patents in all fields of technology. Several countries including India have amended their patent law to ensure compliance with this requirement; hence it is critical to understand how process and product patent claims operate in tandem.

2.9.5. Compulsory License as Flexibility in Indian Patents Act

Compulsory Licensing (CL) allows governments to license third parties (that is, parties other than the patent holders) to produce and market a patented product or process without the consent of patent owners. Chapter XVI i.e. Sections 82 to 94 of the Patents act, 1970 deals with ‘Working of Patents, Compulsory Licenses and Revocation’. Chapter XVII also deals with use of inventions for the purpose of government and acquisition of inventions by Central Government.

Chapter XIII i.e. Rules 96 to 102 of Patents Rules, 2003 deals with ‘compulsory license and revocation of patent’.

Sec.84 of Patents Act, 1970 deals with general Compulsory Licences to be issued by the Controller on application.

\textsuperscript{90} Article 27(1) TRIPs Agreement.
Any time after three years from date of sealing of a patent, application for compulsory license can be made, provided

a) reasonable requirements of public have not been satisfied;

b) patented invention is not available to public at a reasonably affordable price;

c) Patented invention is not worked in India.

Table-1: Overview of Implementing CL Measures in India

<table>
<thead>
<tr>
<th>Legal Basis</th>
<th>Patents Act, 1970 (as amended in 2005) (Section 92A) and Patents Rules, 2003 (as amended by S.O. 1418 (E) of 28 December 2004) (Chapter XIII)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification to TRIPs Council</td>
<td>IP/N/1/IND/P/2</td>
</tr>
<tr>
<td>Scope</td>
<td>Export</td>
</tr>
<tr>
<td>Diseases/Products/IPRs Covered</td>
<td>Public health problems Any patented product or product manufactured through a patented process of the pharmaceutical sector, including active ingredients and diagnostic kits required for their use</td>
</tr>
<tr>
<td>Eligible Importing Countries</td>
<td>Any country with insufficient or no manufacturing capacity in pharmaceutical sector for the concerned product(s) to address public health problems</td>
</tr>
<tr>
<td>Competent authority for CL grant</td>
<td>Controller General of Patents, Designs and Trade Marks</td>
</tr>
<tr>
<td>Pre-Grant Conditions</td>
<td>IC has granted CL or it has, by notification or otherwise, permitted importation of the patented pharmaceutical product(s) from India. Application for CL to set out the applicant’s interest and terms and conditions of the licence that he is willing to accept</td>
</tr>
<tr>
<td>Quantity</td>
<td>Not prescribed by the Patents Act. But: CL is granted solely for manufacture and export of the concerned pharmaceutical products to IC under such terms and conditions specified by the Controller General of Patents, Designs and Trade Marks</td>
</tr>
<tr>
<td>Duration of the Compulsory License</td>
<td>As per the terms and conditions specified by the Controller General of Patents, Designs and Trade Marks in the decision granting the CL</td>
</tr>
<tr>
<td>Remuneration</td>
<td>As per the terms and conditions specified by the Controller General of Patents, Designs and Trade Marks in the decision granting the CL</td>
</tr>
<tr>
<td>Notification/Publication Requirements</td>
<td>Terms and conditions of CL to be published by the Controller General of Patents, Designs and Trade Marks</td>
</tr>
<tr>
<td>Transparency and Safeguards Against Diversion</td>
<td>No specific provision. But: CL to be granted solely for manufacture and export of the concerned pharmaceutical products, as per the terms and conditions specified by the Controller General of Patents, Designs and Trade Marks in the decision granting the CL which must be published. This is viewed as ensuring transparency and appropriate safeguards</td>
</tr>
<tr>
<td>Other</td>
<td>Decision regarding grant of CL under Section 92A is without prejudice to export of pharmaceutical product produced under CL under any other provision of the Patents Act, 1970</td>
</tr>
<tr>
<td>Regulatory Approval</td>
<td>No specific provision in Patents Act, 1970. Approval is based on Drugs and Cosmetics Act, 1940</td>
</tr>
<tr>
<td>Good Faith Clause</td>
<td>No</td>
</tr>
<tr>
<td>Acceptance of TRIPs Protocol</td>
<td>26 March 2007 (WT/Let/572) – after adoption of implementing legislation</td>
</tr>
</tbody>
</table>

Applicant’s capability including risk taking, ability of the applicant to work the invention in public interest, nature of invention, time elapsed since sealing, measures taken by patentee to work the patent in India will be taken into account by the Controller of Patents before granting licence. In case of national emergency or other circumstances of extreme urgency or public non commercial use or an establishment of a ground of anti competitive practices adopted by the patentee, the above conditions will not apply.

Section 92 of Patents Act, 1970 deals with special provision for compulsory licenses on notifications issued by Central Government. If the Central Government is satisfied in respect of any patent in force, in case of national emergency or extreme urgency or in case of public non-commercial use, then compulsory licenses can be granted at any time to work the invention and make a declaration in this regard in the Official Gazette.

Section 92A of Patents Act, 1970 provides for compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. This section is an “enabling provision” for export of pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector in certain exceptional circumstances, to address public health problems. Such country has either to grant compulsory license for importation or issue a notification for importation into that country.

2.10. CONCLUSION

India had a Patent Act which was a master piece legislation on Indian soil with deep rooted sentiments of Indian culture and traditions which did not provide for the product patents until 2005. It stood as an example to many countries which was able to protect Intellectual property and also balanced the public interest which put the Indian Pharmaceutical companies to take advantage and helped in manufacturing the medicines at a very low cost of production which ensured that the prices of medicines are within the reach of the general public and the manufacturers were free to utilize the technologies within the limitations for the welfare of the society and for suffering patients it was a God sent gift. The problem was first initiated when the developing and underdeveloped countries were asked to
comply with the strict implementation of TRIPs Agreement beginning with grant of process patents, exclusive marketing and mail box applications initiating in the year 1995-2005 during which India witnessed that the prices of the drugs were increased by the process patent holders but due to the reason of adopting reverse engineering the other manufacturers were able to produce the same medicines by different methodology. Hence this ensured that there were other alternatives available in the market which probably might not be possible under product patent regime and the affordability to life saving drugs and enforce right to health would be a distant dream for the poorer sections of the society and puts an extra burden on the middle class families. The health protection is very much essential and hence there is a binding on the patients to have those medicines which has been prescribed to them they don’t have any kind of choice before them. Though there were efforts taken to provide certain flexibilities as a measure for controlling the prices and affordability of medicines. There is a need to balance the issue of public health and IP protection by properly utilizing the flexibilities.