



## Indian Patent System Under Trips Agreement: Issues And Challenges

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### Abstract

*The Patent system of any country is an important tool for technological and industrial development. It effectively protect innovation by providing incentives to the inventors and ensuring adequate returns to the industry on the investment made by it for commercialization to invention. In this regard Indian Patent Act, 1970 has strike a reasonable balance between private incentives for innovators at one hand and the societal aspirations and industrialization objectives of country of the other. This balance is, however seems to be shifting under the TRIPs and WTO constraints. The new patent system emerged throughout the world, particularly, in India in consonance with the provision to TRIPs Agreement has attempted to globlize U.S. style of patent. It has disastrous implication not only agricultural sector and pharmaceutical sector but also on democracy and sovereignty of the nation. This paper makes an humble attempt to analyse the issues relating to Indian patent system under TRIPs Agreement and concludes that the patent law should neither become instrument for exploitation nor for monopolisation.*

**Keywords:** Product Patent, Compulsory Licensing, Exclusive Marketing Rights, Sui-generis system, Plant Breeder's Rights, Terminator Technology.

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## 1. INTRODUCTION

Intellectual Property Rights have acquired tremendous importance in view of its global ramification after the TRIPs Agreement had come into operation. It transformed from theoretical foundation as a juridical concept into pragmatic segment of the law relating to International Trade. The new patent regime under TRIPs Agreement where all Intellectual Property Rights are being protected in the name of individual rights, has become a subject of much consternation particularly to those countries whose intellectual property regime subordinate the individual to the social interest. India having a written constitution with socialism as one of its basic features has tried to dovetail the two irreconcilable and conflicting interests of the individual at one side and society at the other but more leaning in favour of social interest. Thus, the *Indian Patent Act, 1970* provides classic example of balancing and rewarding both the individual and society. For the larger interest of society, the Act has made provision for Working of Patent<sup>1</sup>, Compulsory Licensing<sup>2</sup> etc. which are inbuilt safeguard to protect the interest of the society at the time of emergency. In the same manner the Act does not provide for Product Patent for food, medicine or drugs and other chemical based production and its term of protection is 7 or 14 years.<sup>3</sup>

However, the Trade Related Aspects of Intellectual Property Rights (TRIPs) introduced in Uruguay Round of General Agreement of Tariff and Trade (GATT) has placed emphasis on the individual interest in the granting of patent by declaring all patent rights as private rights. This TRIPs Agreement which is multi-lateral treaty tries to advance the interest of the developed country by putting pressure on developing countries, also to treat patent right as purely private rights. Being a signatory to the WTO India has amended their patent law in conformity with the provision of TRIPs Agreement. The areas which are going to be affected by such change are Process Patent, Scope of Patentability, Duration of Patent, Working of Patent etc.

In view of above mentioned significance of the subject this topic has been selected to investigate various aspects of Indian Patent System in compression of TRIPs Agreement and its impact on various sectors (pharmaceutical, agricultural) of India.

## 2. EVOLUTION AND DEVELOPMENT OF PATENT LAW

### A. Patent: The Concept

The term patent is originated from latin word "*litterae Patents*" i.e. Letters Patent or open letters i.e. official document under the great seal, addressed by sovereign to all his subject at large, in which the crown confers certain rights or privileges, rank or title, on one or more individual including monopoly rights in respect of invention.<sup>4</sup> It is statutory grant of monopoly for working of an invention and vending the resulting products.<sup>5</sup> In the other words, Patent can also be defined as a statutory privilege granted by the Government to inventors or to other persons deriving their rights from the inventor, for a fixed period of years, to exclude other person from manufacturing, using or selling a patented product or from utilising a patented method or process. At expiration of the time for which the privilege has granted, the patented invention is available to the general

<sup>1</sup> Sec 83, *Patent Act, 1970*.

<sup>2</sup> Sec 84, *Patent Act, 1970*.

<sup>3</sup> Sec 53 *Patent Act, 1970*.

<sup>4</sup> Black Stone, *Commentaries on the law of England*, (Book, II ch. 21, S2) at 346.

<sup>5</sup> Raj Gopala Ayanger, *Report on the Revision of the Patent Law* (Govt. of India, 1959) at 9.

public or as it is sometimes put falls into the public domain. Hence patent and other intellectual or industrial property rights are statutory right or privilege created by statute.

The object of granting a patent is to encourage and develop new technology and industry. An inventor may disclose the new invention only if he is rewarded; otherwise he may work secretly. In consideration of the grant of monopoly for limited period the inventor disclose the detail of the new invention and the method of working it, so that after the expiry of monopoly period other can use the invention or improve upon it.<sup>6</sup>

### **B. Patent Law : A Historical Perspective**

The first recorded reference to patents seems to be in Aristotle's Politics, composed in the fourth century B.C., in the course of a discussion of rival description of good Constitution. Aristotle mentions a proposal by one Hippodamus of Miletos. According to Aristotle, Hippodamus called for a system of rewards to those discover things useful to the State.<sup>7</sup> After this isolated classical reference, the history of patent skips several historical epochs. The earliest recorded instances of granting letters patent was in 1331, where a patent is granted to Flemish Weaver, who wanted to practice his trade in England.<sup>8</sup> However, the first regular administrative apparatus for granting patents for invention arose in Venice in the late 15<sup>th</sup> century. The *Venetian Act* lays out all the essential features of a modern patent statute. It covers 'devices' that should be new and useful and not previously made in this commonwealth; provide a fixed term of ten years; set forth a procedure to determine infringement as well as remedy.<sup>9</sup> Patent came to Great Britain by this route, sometime middle of the 16<sup>th</sup> century. Initially, England was very backward in industrial development, therefore, sole object of the then patent system was the growth of industry. It was not necessary that the person to whom patent has been granted should be the same person who devised the invention. Similarly, the crown was not concerned whether the invention for which grant was given was a new manufacture.<sup>10</sup> The only condition was to establish a new industry in the realm and teach the trade to those willing to learn.<sup>11</sup> Thus in 1331, Edward II gave letters patent to the Flemish Weaver, John Kempe. In 1336, two Barbent Weavers were encouraged to settle in York. In 1338, three clock makers from Delft were given letters patent. Similarly in 1469, a German Johann Von Speyer, received an exclusive monopoly for the trade of printing. However, some letters patent was granted for invention.<sup>12</sup> The monopoly system developed in British regime became controversial, resulted into overcharging, manipulation of markets or a refusal to make a product available.<sup>13</sup> In the slightly later *cloth workers of Ipswich* case<sup>14</sup> patents of a limited duration were recognised. This led apportionment to come out with legislation which laid

<sup>6</sup> *Introduction to patent Law and Practice: The Basic Concept*, A WIPO Training Manual (WIPO General 1989, P. 672 E) represented in 1986 at 11.

<sup>7</sup> John Lock, *Two Treatises on Government* (2<sup>nd</sup> Edn. 1698) See also Merges, *Intellectual In The New Technological Age*, (N.Y.: Aspen Law and Business, 1996) at 3.

<sup>8</sup> For an early historical perspective see H. Brettr, *The United Kingdom Patent Act, 1977* (Oxford: ESC Pub. 1978) and W. Aldous, D. Young, A. Watson and S. Thorpey, *Terrell On The Law Of Patent* (London: Sweet & Maxwell, 14<sup>th</sup> Edn. 1990 )

<sup>9</sup> Mandich, *Venetian Patents (1450-1550)*, J. Pat and Trademark off. Society 166-177 (1948) at 30.

<sup>10</sup> *supra note*, 8.

<sup>11</sup> *Ibid.*

<sup>12</sup> A patent was granted by Henry VI to Flemish born John Utyman 1447 for his new method of making stained glass.

<sup>13</sup> *Darcy v. Allen* (1602) Co. Rep. 84b.

<sup>14</sup> (1604) Codbolot 252.

down a foundation of modern patent system.<sup>15</sup> Initially, there was no requirement for a written description of the invention to be provided by the applicant. In 1718, as the industrial revolution picked up steam, the provision of the specification became stringent requirement.<sup>16</sup> In 1835 as a consequence of judicial pronouncement<sup>17</sup> on Act known as *Lord Brougham's Act* was passed which enabled patentee to disclaim any part of his specification. This Act was amended by the Act of 1839, 1849, 1853, 1859, 1865 and 1870 with minor improvement regarding protection of invention. The patent Act of 1883 replaced the all above Acts.

Further *Patent and Design Act 1902* was passed on the basis of the Report of a Department Committee where novelty search was given effects. There were other Acts culminating in the *Patent Act, 1949*, based on same tradition. However, current Act, the *Patent Act, 1977* is different in that it was designed to take account of the European Patent Convention.

### 3. PATENT SYSTEM IN INDIA

The Indian patent system has historical root in the English Patent system. The first Act relating to patent right was passed in 1856 which granted 'exclusive privilege' to inventor for a period of 14 years. This Act was found defective and was, therefore, reenacted with modification under Act no. XV of 1859. In 1872 the *Patent and Design Protection Act* was passed which was followed by the *Protection of Invention Act* of 1883. These Acts were consolidated by the *Invention and Design Act 1907*. Subsequently, the *Indian patent and Design Act, 1911* was enacted on the lines of the *English Act 1907*, replacing all the previous Acts. This Act established for the first time in India a system of patent administration under the management of the Controller of Patent and Design.<sup>18</sup> After a careful scrutiny of the Act enacted, amended and modified during the period of 93 years (1856-1949) in pre independence India shows that then existing concern of the patent system in Indian was to protect British industry and trade. All the Act of India was the blue prints of English patent law. Therefore, when India got independence the patent system was subjected to review by committees.<sup>19</sup> Based on recommendations of the reports of the committees and also considering the changes proposed in the light of further examination by the Govt. of India a comprehensive and consolidated Patent Bill was introduced in the parliament in 1965 which, however, lapsed. An amendment Bill was introduced in the parliament in 1967. The parliament passed in its historical special sitting on the 19<sup>th</sup> August 1970 after a long debate and received the assent of president on the 19<sup>th</sup> Sept. 1970.

### 4. BASIC FEATURE OF PATENT ACT, 1970

Patent is statutory grant of monopoly for working of invention and vending the resulting product.<sup>20</sup> This is conferred for limited period and the right include right to exclude others from using the inventions.<sup>21</sup> In return for this right the inventor discloses detail of his innovation to the people. The basic criteria for obtaining patent are novelty, non obviousness and utility. This is

<sup>15</sup> *Statute of Monopolies*, 1624.

<sup>16</sup> *Liardet v. Johnson*, 1778, *Bovill v. Moore*, 1816, Dav, P.C. 400

<sup>17</sup> *Turner v. Writer* 1787, 1 Web P.C. 81 *Savory v. Prince*, 1823, 1 Web P.C. 83.

<sup>18</sup> P. Narayanan, *Law of Copyright and Industrial Design* (New Delhi, Eastern Law House, 2<sup>nd</sup> Edn. 1995) at 5.

<sup>19</sup> Tek Chand Committee, 1948, Arryanger Committe, 1957.

<sup>20</sup> Ramgopala Ayyanger, Report on the Revision of Patent Law (Govt. of India, 1959) at 9.

<sup>21</sup> *Terrell on the Law of Patent*, (London: Sweet & Maxwell, 13<sup>th</sup> Edn. 1982) at 1.

enshrined in the definition of invention. The question whether a particular invention is new and useful is often extremely difficult to decide as it depends upon the state of the prior art in the particular field which include prior publication on the subject and prior uses. Certain invention<sup>22</sup> which is related to public interest is not covered under patentable invention. The consideration of granting patent monopoly is disclosure of invention in the specification so that on expiry of the term the public can use such invention. Patent system is not created in the interest of the inventor but in interest of the national economy. So it is essential that the inventions are worked in India on the commercial scale.<sup>23</sup> To prevent the abuse of monopoly rights the Act provides for Compulsory Licensing<sup>24</sup> of the patented invention on certain grounds. In spite of the compulsory license if the patent is not worked in India it can be revoked for non-working. A patentee may devise various methods for extending the scope of monopoly right conferred by the grant by imposing restrictive condition on its purchaser or lessee of the patented article. Besides it, a patentee may also try to enjoy the monopoly even after patent ceased to be in force by imposing special condition in the contract. Thus, we can say that *Indian Patent Act, 1970* was drafted by keeping in mind the economic condition of the country so that the twin interest of inventor and economic condition of the country could be addressed.

#### **5. INDIAN PATENT SYSTEM UNDER TRIPS AGREEMENT**

The Uruguay Round of GATT negotiation resulted in the establishment of the WTO and the adoption of 27 other treaties covering a wide range of subject matter in 1995. TRIPs Agreement is probably one of the most debatable and the most comprehensive multilateral Agreement amongst all other subject of WTO. The advent of this new entry marks a radical development in the law of international trade coinciding with the liberalization of trade policies in the socialist and developing country.

India being a signatory of World Trade Organization (WTO) was under obligation to amend the *Indian Patent Act, 1970* to bring it in confirmatory with the provisions of TRIPs Agreement. Consequently Indian Govt. made some major change in its existing patent law. In this context we focus socio-economic and legal facet of different provisions of TRIPs Agreement *vis-a-vis* Indian patent law.

#### **A. Scope of Patentability and Indian Pharma Industry**

The scope of patentability has been greatly enhanced under TRIPs Agreement covered all inventions whether product or process<sup>25</sup>. On the other hand *Indian Patent Act, 1970* exempted certain area like food, drug and medicine from being covered by product patent.<sup>26</sup> The basic objective behind such legislation was to develop Indian pharma industry and to regulate price of the drug. Before 1970, Indian patent system was regulated by *Patent and Design Act, 1911* had strangled Indian domestic industries and rendered Indian market subservient to British industries. The foreign patent holder exploited the need of Indian people by importing essential

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<sup>22</sup> Sec-3. *Patent Act, 1970*.

<sup>23</sup> Sec-83 of the Act.

<sup>24</sup> Sec-84 of the Act.

<sup>25</sup> Art 27 (3) of the TRIPs Agreement.

<sup>26</sup> Sec-3 (d) of the Act.

items and drugs at exorbitant prices. Consequently, price of essential commodities like food stuff and medicine become far expensive and out of the reach of majority of the people.

This unfortunate situation was reversed by *Patent Act, 1970*. The new process patent regime made possible to the scientist and entrepreneurs to develop alternative process to produce basic drug covering various therapeutic groups. Consequently the process patent based pharma industry flourished throughout the country. The production of bulk drug has provided not only drug security in the country but also succeeded in getting access to foreign market. Under product patent system Indian companies no longer are able to produce new drugs invented abroad merely by finding alternative process for its manufacture.<sup>27</sup> It leads to absolute monopoly on patented product. Under this regime price of drugs would go up several times beyond the reach of poor people. Due to importation of drugs into Indian market Price Control Machinery would not be effective. The process technology based R & D programme would seriously affected, having no use under product patent system. The small scale units which are totally based on process technology would be wiped out from the market and generates unemployment at mass level. The adoption of uniform or non-discriminatory protection for all classes of invention under present socio-economic condition would reverse our patent system to pre-1970 status.

### **B. Protection of Microorganism**

The TRIPs Agreement further extended the scope of patentability by including microorganism, non biological and microbiological process for the production of plant or animals.<sup>28</sup> The objection to patenting microorganism usually merged into general charge that patenting life implies a failure to respect life. But society cannot have bread, wine, antibiotics vaccines *etc.* without the use of microorganism. Thus, this is laudable provision which must be introduced in the legislation of every country in conformity with their scientific infra-structure. The present amendment of patent law does not protect discovery of any living thing or non living substance occurring in nature where as a microorganism not occurring naturally but which is result of human intervention and experiment could qualify for protection.<sup>29</sup> There are many gray areas in defining the scope of patentable microorganism and microbiological process multilaterally. So Govt. should consider these entire dimensions in patenting life form.

#### **a. Sui- Generis Protection of Plant Variety and Indian Agriculture**

TRIPs Agreement exclude from patentability plants, animals and essential biological processers, for their production, however, directs that member shall provide for the protection of plant variety either by patent or by an effective *sui generis* system or any combination thereof.<sup>30</sup> The idea of protecting plant varieties has now gained general acceptance in the world. The importance attached to the protection of plant varieties not only for protecting the interest of breeders but also for the development of agricultural sector. In this regard the *Protection of Plant Varieties and Farmer's Rights Act, 2001* has enacted by the Govt. of India as a *sui-generis* protection of plant varieties. It seek of ensure in the main, protection of the plant breeder's rights, the farmer's rights and researcher's rights. It also contains provisions to facilitate equitable sharing of benefits arising

<sup>27</sup> Vandana Shiva, *Patents : Myths and Reality* (New Delhi: Penguin, 2001) at 89.

<sup>28</sup> Art. 27 (3) TRIPs Agreement.

<sup>29</sup> Sec 3 (j) of the Act.

<sup>30</sup> Art 27 (2)b TRIPs Agreement.

out of the use of plant genetic resources that may accrue to a breeder from the sale, disposal *etc.* of seed/planting material of a protected variety. The village and farming community be compensated in case of their traditional or local variety is being used for the development of new varieties. The Act covers all categories of plant but will not include micro-organism, terminator seeds *etc.* In order to be eligible for protection, a variety must be distinct, uniform and stable. The period of protection shall be eighteen years for tree and vines and fifteen years for other plants. Breeder's rights envisage that the breeder's authorization will be required for production and commercial sale of the productive or propagating material of a protected variety.

The basic objection with the Act is that it has covered all plant variety whether commercial or non-commercial<sup>31</sup> i.e. the crops related to food security of the millions and the cotton, soyabean, tea and other ornamental plants used for commercial purpose. It constitutes significant departure from existing regime. The twin rational of such denial are food security, the basic need whose fulfilment should not be governed by private commercial interest and free accesses and sharing of products and information in agricultural management. Unlike developed countries, in Indian plant breeding researches have been carried out largely through public funding. The seeds of new crop varieties flow freely to farmers and to the private company. Farmers are free to produce and sell the seed of these plant varieties and make profits. For breeding ever better varieties any of the imported plant can be used by any one for hybridization. Although the Act specifically banned registration of any variety containing technology such as Gene Expression Technology<sup>32</sup> i.e. Terminator Technology, at the same time bio-safety measures i.e. agricultural mono-culture and GE contamination by seed of protected variety have not found place in the Act.<sup>33</sup> There is no provision in the Act for obtaining the prior informed consent of farmer's breeder's. Claim can only be made after a variety is registered. From above discussion it is clear that Act introduced in compliance of TRIPs Agreement has adverse impact on Indian Agriculture. Thus, if the viability of Agriculture in the farmer dominated agricultural system is to be ensured, it is essential to look beyond the confines of narrowly defined regime of plant breeder's rights. Our legislature should, therefore, reconsider the IPR regime over the protection of plant variety under the paramount consideration of human right to food, health, environment and the socio-economic complexities and peculiarities of our country.

### C. Importation as Working of Patent

Section 83 of Indian Patent Act, 1970 provides that patent are granted to encourage in invention and to ensure that the inventions are worked in India on a commercial scale. It is not granted merely to enable patentees to enjoy a monopoly for the importation for the patented article. The provision of TRIPs Agreement<sup>34</sup>, however, diluted this provision governing 'working' and provides similar patent rights to imports as to the domestic production. Thus, when importation is treated at par with the domestic production, the working of patent i.e. setting up manufacturing plant, will become non-issue, unenforceable through domestic law. As consequence "compulsory licensing", sub-licensing or licenses of right, the instrument evolved to ensure 'working of patent' in the Indian patent of Act will also become non-issues.

<sup>31</sup> Sec 14 The Protection Of Plant Varieties And Farmers Rights Act, 2001. (herein after referred to as Act)

<sup>32</sup> Sec-29 (3) of the Act.

<sup>33</sup> *Supra* note 27 at, 81.

<sup>34</sup> Art-28 TRIPs Agreement.

#### D. Term of Patent

TRIPs Agreement provides that term of protection shall not end before the expiration of a period of twenty years contained from the filing date.<sup>35</sup> However, *Indian patent Act, 1970* provides that the term of protection for food and drugs is 5 to 7 years and in all other cases it is 14 years.<sup>36</sup> Since patent is available for product or processes, it would be possible particularity in the chemical based products like drug and pharma chemical, agro-chemical, alloys and food product, to take patent for new products for another spell of 20 years, claiming novelty of process to be patented. Moreover, after such a long period many drugs might become obsolete and ineffective towards the disease and such in cases disclosure of invention become futile and immaterial.

#### E. Reversal of Burden of Proof

Generally burden of proof lies on complaint or prosecution. But in case of reversal of the burden of proof the complaint is not required to provide any evidence in support of his charge. The person charged with the offence has to defend himself and prove his innocence. Art-34 of TRIPs Agreement provide for reversal of burden of proof in case of process patents. This clause reverses the onus of proving that patent infringement has taken place from the complainant to the defendant. In this context it is apprehended that patent holder will misuse the clause and falsely implicate the defendant. But we are of the opinion that there is nothing to worry about the special rule of evidence which is already present in the socio-economic legislating<sup>37</sup> in India. More over, many safeguards against false implication and malicious persecutions are available to us in the civil proceeding. What is essential here is that there should be pre-condition that the alleged process is identical to the patented one or he is unable through reasonable effort to determine the process actually used, must be established by patentee in the suit.

#### F. Transitional Agreement

With respect to the implementation of the Agreement part IV envisage five year transition period to every member country. In the case of countries which not provide product patent for drug and medicine additional period of five year is given to introduce such protection. If we closely examine the other relevant article then we find that there is virtually no transitional period available to the developing countries. Art -70.8 provides that a member state where law does not provide product patent shall provide an arrangement for mail-box in which application for patent for such invention can be filed. Patent application shall have to be accepted from 1-1-1995 though it would become effective from 1-1-2005. It shows introduction of product patent system from 1995. Between these periods *Exclusive Marketing Rights* shall have to be granted the period of five years to such pharmaceutical product, after obtaining the market approval or until product patent are rejected or granted by that member, whichever period is shorter. Under these situations when the patent application is filed or the EMR is obtained, virtually the process patent regime in the existing patent Act, 1970 would become in fructuous and non operative. Indian entrepreneur or scientist would find it beneficial to develop process for the new product. Although these provisos of TRIPs Agreement are self extinguishing in nature has already expired automatically on December 31, 2004. So it is now relevant for academic discussion only.

<sup>35</sup> Art-33 TRIPs Agreement.

<sup>36</sup> Art 53 Patent Act, 1970.

<sup>37</sup> Sec-123 of the *Customs Act, 1962*, Sec-14 of the *Essential Commodities Act, 1955*, *Prevention of Corruption Act, Drugs and cosmetics Act, 1940*.

## 6. CONCLUSION

The basic objective of patent is disclosure of invention for the benefit of mankind and at the same time legally protecting the inventor's rights. It intends to strike a reasonable balance between private incentives for innovators on one hand and the societal aspirations and industrialization objective of a country on the other. This balance is, however, seeming to be shifting under the TRIPs and WTO constraints. The new patent regime emerged throughout the world particularly in India in consonance with the provision of TRIPs Agreement has place emphasis on the individual interest in the granting to patent by declaring all patent right as private right. Since India has amended their patent law in conformity with the provision of TRIPs Agreement now we will have to accept emerging challenge of new patent regime and rise up to mark. India will have to enhanced R & D expenditure and upgrade research infrastructure so that we can take benefit of research and compete with the technologically advanced countries of the world. Our country have reservoir of scientific and technical man power but scientific result, are not yet getting translated into product due to lack of commercial capacity.

In the changing circumstance Indian industrialists and research institutions should collaborate with each other to cope with disadvantages of new patent regime specially when the modern biotech sector is highly scientific, sophisticated and involves skill making Indian industrialists in disadvantageous position. Patent literacy of this country is very poor and hence efforts should be made immediately to improve the awareness of patent literature in this country through curriculum, seminar, symposia etc. What is more important is to develop a patent culture in our country. It will enhance creative skill, competitive interest in the intellectual mind of the country. Once we are made to realize our energy and potential and necessity to compete, then the provision of the TRIPs Agreement will be taken as a boon but not as a bane.

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