TRADE RELATED INTELLECTUAL PROPERTY RIGHTS
- IMPACT OF PHARMA INDUSTRY

INDIAN LAW PERTAINING TO IPR

CHAPTER - VIII
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Introduction

Intellectual property (IP) contributes enormously to our national and state economies. Most of the industries across our economy rely on the adequate enforcement of their patents, trademarks, and copyrights, while consumers use IP to ensure they are purchasing safe, guaranteed products. It is believed that IP rights are worth protecting, both domestically and abroad. In this context, it is essential to understand the various IPR Acts. The Legislative Framework of IP Administration is as follows:

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I. COPY RIGHT ACT

Copyright law protects expressions of ideas rather than the ideas themselves. Under section 13 of the Copyright Act 1957, copyright protection is conferred on literary works, dramatic works, musical works, artistic works, cinematograph films and sound recording. For example, books, computer programs are protected under the Act as literary works.
Copyright refers to a bundle of exclusive rights vested in the owner of copyright by virtue of Section 14 of the Act. These rights can be exercised only by the owner of copyright or by any other person who is duly licensed in this regard by the owner of copyright.

**Copyright Amendment Bill, 2012**

The amendments introduced through Copyright (Amendment) Act 2012 can be categorized into:

- Amendments to rights in artistic works, cinematograph films and sound recordings.
- WCT and WPPT related amendment to rights
- Author-friendly amendments on mode of Assignment and Licenses
- Amendments facilitating Access to Works
- Strengthening enforcement and protecting against Internet piracy
- Reform of Copyright Board and other minor amendments

**The Copyright Rules, 2013**

The Copyright Rules, 2013 was notified by the Ministry of Human Resources and Development on 14th March 2013. These new rules are pursuant to the amendments and new provisions introduced to the Copyright Act, 1958 through The Copyright Act (Amendment) Bill, 2012. The Draft Copyright Rules were released in August by the Copyright Office inviting comments of stakeholders and experts. In October, the Ministry of HRD also conducted a meeting with stakeholders and experts regarding the Rules. We have reason to believe that while the Rules was finalised by the HRD ministry months ago, the Ministry of Law and Justice delayed in approving the Rules.

**The Copyright Rules, 2013 provide new rules for:**

1. Statutory licence for cover versions and broadcasting of literary and musical works and sound recording;
2. Compulsory licences for works withheld from public, unpublished and published works, for benefit of disabled;
3. Registration of Copyright Societies and Performer’s Right Societies;
4. Storage of transient or incidental copies of works;
5. Making or adapting the work by organisations working for the benefit of persons with disabilities;
6. Importation of infringing copies and technological protection measures.

II. PATENT ACT

India is among the world's top five drug producers in terms of volume, though its $7 billion market does not rank as high in value. Prices are low because of the profusion of generic drug makers and the competition among them - made possible through the old Patents Act of 1970. The procedure for obtaining a patent in India, and matters connected therewith are detailed in the Patents Act 1970 and Patent Rules framed thereunder. The Patents Act 1970 is modeled substantially on the U.K. Patents Act of 1949. The basic concepts of this law in India and U.K. being the same, the decisions of English Courts along with leading English authorities on the subject are often cited by lawyers and Judges alike in the interpretation of some of the provisions of the Indian Act. Not surprisingly, even decisions of Commonwealth Countries have persuasive value in Indian courts.

The Act of 1970 defines an invention as follows:

Invention means any new and useful:

i. art, process, method or manner of manufacture,

ii. machine, apparatus or other article,

iii. substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention.

Indian courts have held that a method or process is a "manufacture" if it (1) results in the production of some vendible product, or (2) improves, or restores to its former condition a vendible product, or (3) has the effect of preserving from deterioration some vendible products to which it is applied.

Before 1970, India's patent laws, like many others, were derived from its colonial days resulting into some of the world's highest drug prices. However, by 1970, India, along with other developing countries had adopted "process patenting regime". The Act of 1970 by granting "process patents" on drugs in combination with extensive use of fertilizers and pesticides not only led to low drug prices but also extended life expectancy and ended regular famines. In order to appreciate the gravity of the amendment and its repercussions on the international drug industry it is imperative to understand the difference between "product patents" and "process patents". Process patenting implies the patenting of the method of manufacturing a product. Under the Indian Patents Act of 1970, process patenting was provided for. Aside from the fact
that India has surplus flow of relatively cheap labor, it also has a long tradition of manufacturing drugs of various types. This resulted into several new techniques of making drugs cheaply. After the product has been manufactured with the patented process, it would then be known as patented product in patented in a country adhering to process patenting, such as India. Any other manufacturer cannot produce a product by the patented process, although the manufacturer can produce it by another process. Thus, patenting a product assumes a slightly different complexion from the patenting of a process.

The Act of 1970 stated that with regard to medicine or drug and certain classes of chemicals no patent is granted for the substance itself even if new, but a process of manufacturing the substance is patentable. Therefore, with respect to food, medicine or drugs, patents were granted only for the process of manufacture of the substance but not for the substance itself. Such restrictions on the grant of product patents do not exist in virtually any other country. All Western countries grant "product patents" on new inventions - i.e. the patent is granted for the substance itself. However, since 1970, India has granted "process patents," which allow another inventor to patent the same product as long as it was created by a "novel process". In pharmaceutical industry, it could mean that a tiny tweak in the synthesis of a molecule yields a new patent. Several companies can produce the same drug, creating competition that drives down prices and puts multinational corporations that spend millions of dollars in research and development at a serious disadvantage.

The old patent system allowed Indian pharmaceutical companies to copy drugs patented abroad by merely changing their manufacturing process. This served two purposes: one, it kept cost of drugs inexpensive in India; two, it also allowed a local pharmaceutical company to thrive which otherwise would have faced multi-million dollars lawsuit for patent infringement. By copying drugs other companies spent millions of dollars to develop, Indian pharmaceuticals companies could sell them at as little as one-tenth their original prices.

**The 2005 Amendments to the Old Law**

It is widely believed that the 2005 amendments were made mainly due to international pressure, as the World Trade Organization ("WTO") demanded that India observe international drug patents. In 1995, the WTO's Trade-related Intellectual Property Rights (TRIPS) agreement was reached in Marrakesh, Morocco, where India, along with many other countries, agreed to
grant 20-year patents on pharmaceutical products from January 1, 2005. The new WTO regime effectively outlawed the generic production of new medicines.

In March 2005, India's Parliament approved patent regulations to stop local drug makers from copying new drugs developed by other, primarily Western companies. The new law, amending India's 1970 Patent Act, affects everything from electronics to software to medicines, and has been expected for years as a condition for India to join the World Trade Organization. Previously, companies could copy drugs discovered or invented by other companies by tweaking the processes used to make them. As an executive of a leading Indian company puts it: "The winner used to be the guy who could copy faster. Now that has completely changed so that companies that don't innovate will die, especially in the pharmaceutical industry". The new patent system recognizes registered original drugs as products no matter how they are produced, thus making it illegal to copy drugs still under patent. Also, it appears that the 2005 amendments have done away with the practice of "evergreening" of pharmaceutical patents, where patent owners allegedly try to extend patent life through grant of new patents by minor "innovations" or improvements on formulations, dosage forms or minor chemical variations of an earlier patented product. However, the new law also makes it clear that any invention that enhances the known efficacy of the substance or results in a new product or employs at least one new reactant is patentable and that only the mere discovery of a new form or of any new property or new use of a known substance or process is excluded. It may not be too difficult to prove that the improved dosage form is more efficacious or that one new reactant is involved in the known process to make the product.

These amendments to India's patent law have sparked worries that Indian companies will face tough global competition, and that the cost of medicines would jump in poor countries now supplied by Indian generic drugs. Since 2000, the gathering momentum of the global popular outrage against a tighter patent regime has become a powerful countervailing force due to emergence of the AIDS crisis. Many international aid organizations use inexpensive Indian generic drugs to save money as they save lives. For example, India is a big supplier of low-price generic versions of drugs for treating AIDS. In Africa, exports by Indian companies, especially Cipla and Ranbaxy Laboratories, helped drive the annual price of antiretroviral treatment down from $15,000 per patient a decade ago to about $200 now. Though the new patent law is not as restrictive as many feared and won't dry up supply of today's generic AIDS drugs, international
organizations worry that the need to pay royalties or get licenses may constrict supplies of new drugs. All generic drugs could have been removed from the market. However, all the generic drugs already approved in India can still be sold, though sellers must pay licensing fees.

Nonetheless, many of India's innovative companies have welcomed the stronger patent protections saying that these changes have made India more competitive on global scale and will trigger further investment and innovation in India. It is expected that with the stronger patent protection, more multinational corporations will tap India's relatively inexpensive engineers, scientists and computer programmers for product design, drug development and clinical testing. In fact, multinational corporations such as General Motors Corp., Microsoft Corp. and Nokia Corp. already have research facilities in India. Financial and country analysts expect the research-outsourcing industry to grow to more than $10 billion globally in the next five years.

As India opens its markets and its companies venture abroad, companies are seeking to ensure that they profit from their own innovations. The list of top applicants in 2004 shows the importance of patents in global competition. Among the top applicants are Sony Corp, Procter & Gamble Co. and DaimlerChrysler AG - all with more than 300 applications each last year. From the Indian side, the top applicants include Dr. Reddy's Laboratories Ltd. and Ranbaxy Laboratories Ltd. - both have more than doubled their research-and-development spending to about 10% of revenue. Nicholas Piramal, a generics company based in Mumbai, India, has invested $100 million in research and development in the last couple of years. India's generic drug companies, which until now made money copying best-selling foreign drugs, has now increased spending on research with an eye to launch low-cost drugs for the global market. As Dr. Swati Piramal, director for strategic alliances and communications of Nicholas Piramal says: "If an Indian company makes a drug whose development costs are under $50 million, compared with a billion-dollar-plus development costs in the West, we will be able to change the paradigm of drug discovery."

**Ambiguities in the New Law**

The 2005 amendments to the patent law have many ambiguities that need to be addressed. To illustrate a few: under the new law, a maker of generics can apply to copy a patented drug, but only after it has been marketed for three years. The generic's maker however must pay a "reasonable" royalty. The new law does not define what can be considered to be "reasonable". This can result into unwarranted complications and needless litigation. Further, the
amendments have sparked fears that with the new law, prices on patented breakthrough drugs would most likely rise to nearly the level in the United States, while prices on more commonly used drugs would most likely rise only moderately. The Indian government has said it would step in if price rises were excessive but has not said how that would be determined. In fact, the new law bars the government from over-riding any patent for at least three years - a provision not required under the TRIPS Agreement. Further, the new law states that the Controller of Patents has a series of wide-ranging discretionary powers to determine all kind of criteria like "reasonable affordability," "reasonable pricing," and "reasonable royalty." As Subbaraman Ramkrishna, senior director for corporate affairs at Pfizer India Ltd. noted, the word "reasonable" appears 42 times in the bill, giving the impression that royalty rates would be imposed subjectively. Lastly, with the removal of Section 5 of the law, it is not clear if chemical processes continue to be defined to include biochemical, biotechnical and microbiological processes.

**Conclusion**

The amendments made to the patent law by India have been ostensibly to comply with its WTO obligations on intellectual property, the amended law represents a compromise between opposing interests. This compromise has resulted in a complicated and confused law with potential negative consequences that could have been avoided. The new law at times seems to exceed the requirements of the Agreement on TRIPS, or has provisions unique to India, and at other times, appears to be in conflict with the TRIPS Agreement. It is also believed that India, ironically, has swung from one extreme to another, moving from 1970 law that was clearly anti-patent to a law that is pro-patent applicant but not necessarily pro-innovation. At a time when there is increasing skepticism around the world over the patent-system as it has evolved so far, particularly in the U.S.25, it remains to be seen whether the hybrid Indian patent-system stands the true test of time.

"The works of founders of states, law givers, tyrant destroyers and heroes cover but narrow spaces, and endure but for a little time, while the work of the inventor though of less pomp is felt everywhere and lasts forever".
III. DESIGN ACT OF 2000 (with Design Rules, 2001)

"Design" means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by any industrial process or means, whether manual, mechanical.

The Designs Act, 2000 which came into effect from May 11, 2001 replacing the earlier Designs Act, 1911.

1. International classification based upon Locarno classification has been adopted wherein the classification is based on articles - the subject matter of design. Under the previous law a 'Design' was classified on the basis of the material of which the article was made.

2. Under new law, a Design registration can now be obtained for new or original features of shape, configuration pattern, ornamentation or composition of lines or colours as applied to an article, whether in 2 or 3 dimensions or both

3. A concept of "absolute novelty" has been introduced whereby a 'novelty' would now be judged based on prior publication of an article not only in India but also in other countries. Under the previous law, the position was ambiguous.

4. A Design registration has been brought within the domain of the public records right from the date it is physically placed on the Register. Any member of public can take inspection of the records and obtain a certified copy of the entry. In the previous Act, there was a 2-year confidential period - post registration - which prohibited taking inspection/certified copy of any entry in the records.

5. A Design registration would be valid for 10 years (from the date of registration which is also the date of application) renewable for a further period of 5 years

6. Under the previous law the validation period was 5 years which was extendable for 2 terms of 5 years each.

7. A Design registration can be restored within a year from its last date of expiry. Under the previous law, no provision relating to restoration upon expiration of the Design registration was provided.

8. Cancellation of a Design registration under the new law is possible only before the Controller and there are a couple of additional grounds which have been recognized:

9. The subject matter of Design not registerable under the Act
• The subject matter does not qualify as a 'Design' under the Act.

• The subject matter does not qualify as a 'Design' under the Act

Under the previous Act, the cancellation was provided for before the Controller within 12 months from registration on limited grounds and in the High Court within 12 months or thereafter.

**Design Amendment Rules 2008**

Pursuant to section 353 of the Building Act 2004, the Minister for Building and Construction makes the following rules:

**Title**

• These rules are the Licensed Building Practitioners Amendment Rules 2008.

**Commencement**

• These rules come into force on 1 November 2008.

**Principal rules amended**

• These rules amend the Licensed Building Practitioners Rules 2007.

**Schedule 1 amended**

- Schedule 1 is amended by omitting competency 1 from the licensing classes of site 1, site 2, site 3, and carpentry and substituting the following competency: "Competency 1: Demonstrate knowledge of the regulatory environment of the building construction industry"

- Schedule 1 is amended by omitting competency 2 from the licensing class of carpentry and substituting the following competency: "Competency 2: Demonstrate knowledge of current building and trade practice"

- Schedule 1 is amended by adding the licensing classes competencies like roofing, external Plastering, bricklaying and Block laying.

**IV. Trade Marks Act, 1999**

A trade mark is a visual symbol, applied to articles of commerce, in the form of mark or a device or a label which is capable of distinguishing the goods or services of one person from those of others and indicates some kind of trade connection between the goods or services and the person using the mark. A person who sells his goods under a particular trademark acquires a sort of limited exclusive right to the use of the mark in relation to those goods. By registration of trade mark, such right is protected under the Trade Marks Act 1999.
Salient Features of the Trademark Act 1999 are as follows:

- It provides registration of trademarks for services besides goods.
- Imitation of well-known trademarks not permitted to be registered as it enlarges the grounds for refusal of registration. The provisions relating to defensive registration no more exist in the new Act.
- Enlargement of factors to be taken care of while defining a well-known trademark.
- It provides a single register with simplified procedure for registration with equal rights deleting the system of maintaining registration of trademark in Part A and Part B with different legal rights.
- Enlargement of the scope of permitted use and simplification of the procedure for registration of registered user.
- It also provides for registration of “collective marks” owned by association, etc.
- Establishment of appellate board known as “Intellectual Property Appellate Board” for speedy disposal of appeals and rectification of applications. Which at present lie before the High Court.
- Final authority pertaining to registration of certification trademark transferred to the Registrar instead of the central government.
- Punishment enhanced on par with the present Copyright Act, 1957 for the offences relating to trademarks to prevent the sale of spurious goods.
- Application of convention country to include other countries that are members of group or Union of countries and inter – governmental organization extended.
- Use of some one else’s trademark as part of corporate name or name of business concern prohibited.
- The definition of “Trademark” amended incorporating in it “Collective mark” or “certification trade mark”.
- It made provisions for filling single application for registration of trademarks and increased the period of registration and renewal from 7 to 10 years.
- Trademarks/ offences made cognizable and jurisdiction of Courts enlarged to bring the law on par with copyright law.
- Enlargement of the powers of court to grant ex parte injunction in certain cases if the circumstances so warrant.
V. Geographical Indications of Goods (Registration & Protection) Act, 1999

Geographical Indications of Goods (Registration & Protection) Rules, 2002

India, as a member of the World Trade Organization (WTO), enacted the Geographical Indications of Goods (Registration & Protection) Act, 1999 has come into force with effect from 15th September 2003.

- Geographical Indications of Goods (Registration & Protection) Act, 1999
- Geographical Indications of Goods (Registration & Protection) Rules, 2002
- Operationalisation of Geographical Indications of Goods (Registration & Protection) Act, 1999

Geographical Indications of Goods (Registration & Protection) Rules, 2002 provides for the principal place of business in India as the place where the business in the goods bearing a geographical indication, is carried on at one place then that particular place.

Object of the Geographical Indications of Goods (Registration and Protection) Act, 1999 is to provide for the registration and better protection of geographical indications relating to goods in India. Examples of geographical indications are Basmati rice, Darjeeling tea, Kanchipuram silk sari, etc.

The Geographical Indications of Goods (Registration and Protection) Act, 1999 contains penal provision for violation of various provisions relating to GIs given below

- Falsifying and falsely applying GIs to goods.
- Selling goods to which false GIs is applied.
- Falsely representing a GIs as registered.
- Improperly describing a place of business as connected with the GIs registry.
- Falsification of entries in the register.
VI. SEMI – CONDUCTOR INTEGRATED CIRCUITS LAYOUT DESIGN ACT: 2001

A semiconductor integrated circuit is a product having transistors and other circuitry elements, which are inseparably formed on a semiconductor material or an insulating material or inside the semiconductor material and designed to perform an electronic circuitry function. In India, the Semiconductor Integrated Circuits Layout-Design Act, 2000 (hereinafter known as the "Act"), along with the Semiconductor Integrated Circuits-Layout Design Rules, 2001, is the prevailing law. Registering the layout-design under the Act gives the rights holder the exclusive right to the layout-design and to obtain relief in respect of infringement.

Layout-designs are prohibited from registration under the Act if they are as follows:

- Not original;
- Have been commercially exploited anywhere in India or in a Convention country i.e. any country that the Government of India notifies in the Official Gazette for the fulfillment of a treaty, convention or an arrangement with any country outside India and which affords to citizens of India similar privileges as are granted to its own citizens;
- Not inherently distinctive;
- Not inherently capable of being distinguishable from any other registered layout-design.

Any person who is claiming to be the creator of a layout-design and who is interested in registering it has to apply in writing to the Registrar. A registered layout-design is infringed by a person who, not being the registered proprietor of the layout-design or a registered user thereof,

- Does any act of reproducing, whether by incorporating in a semiconductor integrated circuit or otherwise, a registered layout-design in its entirety or any part thereof; or
- Does any act of importing or selling or otherwise distributing for commercial purposes a registered layout-design or a semiconductor integrated circuit incorporating such registered layout-design or an article incorporating such a semiconductor integrated circuit containing such registered layout-design for the use of which such person is not entitled.

VII. INDIA’S PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT

The objectives of the Act are as follows:

To provide for the establishment of an effective system for protection of plant varieties. To provide for the rights of farmers and plant breeders. To stimulate investment for research and
development and to facilitate growth of the seed industry, To ensure availability of high quality seeds and planting materials of improved varieties to farmers.

**Salient features of the Act**

**Authority:** The Central Government shall establish an Authority to be known as the Protection of Plant Varieties and Farmers’ Rights Authority. It shall consist of a chairperson and fifteen members as representatives of different concerned ministries and departments, seed industry, farmers organizations, tribal communities and State-level women’s organization, etc.

**Eligibility:** For a variety to be eligible for registration, it must conform to the criteria of novelty, distinctiveness, uniformity and stability (NDUS), as described below [Section 15 (1)–(3)]. For the purposes of the Act, a new variety shall be deemed to be: Provided that a trial of a new variety which has not been sold or otherwise disposed off shall not affect the right to protection. Provided further that the fact that on the date of filing the application for registration, the propagating or harvested material of such variety has become a matter of common knowledge other than through the aforesaid manner shall not affect the criteria of novelty for such variety.

- **Distinct**, if it is clearly distinguishable by at least one essential characteristic from any other variety whose existence is a matter of common knowledge in any country at the time of filing of the application.
- **Uniform**, if subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its essential characteristics.
- **Stable**, if its essential characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle. The variety will be subjected to such distinctiveness, uniformity and stability tests as shall be prescribed.

**VIII. COMPETITION ACT, 2002**

India’s anti-trust law is embodied in the Competition Act, 2002 (amended by the Competition Amendment Act, 2007) and became fully operational from 1 June 2011 when the provisions regulating mergers and acquisitions were notified. While competition advocacy was notified in 2003, the provisions regulating anti-competitive agreements and abuse of dominance were notified with effect from 20 May 2009.
Both the Competition Commission of India (CCI) (which administers the law) and the Competition Appellate Tribunal (CAT) are operational.

Objectives of the act

- Establish a Commission to prevent practices having adverse effect on competition
- Promote and sustain competition in markets
- Protect the interests of consumers
- Ensure freedom of trade in the Indian markets

Ambit

- Regulates anti-competitive agreements – ex post facto; operational
- Regulates abuse of dominant position – ex post facto; operational
- Regulates combinations – ex ante; operational
- Repeals MRTP, 1969
- Has extra-territorial reach
- Covers both goods and provision of services

IX. BIOLOGICAL DIVERSITY ACT

The Act covers conservation, use of biological resources and associated knowledge occurring in India for commercial or research purposes or for the purposes of bio-survey and bio-utilization. It provides a framework for access to biological resources and sharing the benefits arising out of such access and use. The Act also includes in its ambit the transfer of research results and application for intellectual property rights (IPRs) relating to Indian biological resources.

The Act covers foreigners, non-resident Indians, body corporate, association or organization that is either not incorporated in India or incorporated in India with non-Indian participation in its share capital or management. These individuals or entities require the approval of the National Biodiversity Authority when they use biological resources and associated knowledge occurring in India for commercial or research purposes or for the purposes of bio-survey or bio-utilization.

Indians and Indian institutions do not require the approval of the National Biodiversity Authority when they engage in the above mentioned activities. However they would need to inform the State Biodiversity Boards prior to undertaking such activities. However, any
commercial application related to use of biological resources should be approved by the Authority.

**Included Excluded by the Biological Diversity Act**

The Act excludes Indian biological resources that are normally traded as commodities. Such exemption holds only so far the biological resources are used as commodities and for no other purpose. The Act also excludes traditional uses of Indian biological resources and associated knowledge and when they are used in collaborative research projects between Indian and foreign institutions with the approval of the central government.

The National Biodiversity Authority shall give approval, based on agreement with State Biodiversity Boards (SBBs), only after establishing mutually agreed terms and an equitable benefit sharing agreement between the users of the biological resources and associated knowledge and concerned local bodies and benefit claimers.

**The consequences of lack of compliance with the Biological Diversity Act**

In cases where an approval of the National Biodiversity Authority is required for the use of Indian biological resources and associated knowledge and such approval is not obtained, the punishment can extend to five years imprisonment or a fine of ten lakh rupees or both.

In cases where the State Biodiversity Board needs to be intimated about the use of Indian biological resources and associated knowledge and this is not done, the punishment can extent to three years imprisonment or a fine of five lakh rupees or both. Any offence under the Act is cognizable and non-bailable.