Chapter IV
TRIPS, CBD and IPR Protection in India

4. Introduction

Realm of the intellectual property rights especially matters related to the protection of Biodiversity associated traditional knowledge have been marred by the overlapping of the provisions in various prevalent conventions. Perhaps, the highest levels of divergence in this regard are related to the TRIPS agreement under the auspicious of WTO and the CBD under auspicious of United Nations.

The growing interaction and interdependence between local cultures and modern science in the sphere of biodiversity conservation and utilisation have raised both ethical and commercial questions. The pertinent issues are embodied in both the Convention on Biodiversity (CBD), which seeks to conserve biodiversity and protect community rights, and the World Trade Organisation (WTO) agreement on Trade Related Aspects of Intellectual Property Rights (known as the TRIPS agreement), which emphasise private property rights over community rights. As already discussed earlier, there are substantive conflicts between the goals of TRIPS and those of the CBD, reflecting the lack of international consensus on these difficult questions of rights and equity. An examination of such grey areas in the specific context of developing countries like India is being attempted in this chapter.

4.1 TRIPS and Developing Countries

The TRIPS Agreement that was enforced in 1994 is widely described as a regime of "hyperownership," (Safrin 2004: 641) capable of radically reshaping intellectual property law, especially with regard to genetic resources and biodiversity. Prior to the 1994 adoption of TRIPS as part of the Uruguay Round of the GATT multilateral trade negotiations, intellectual property was not covered by the GATT agreement. Instead, each country had its own national intellectual property laws, with a few international conventions like the Berne Convention and the International
Union for the Protection of New Varieties of Plants (UPOV) serving as a common backdrop. Traditionally, intellectual property was a domestic, rather than an international issue; states were free to set their own level of protection based on their particular circumstances. TRIPS changed all that by establishing universal and uniform standards for intellectual property law. To generalise, the United States, the European Union and Japan had expansive intellectual property regimes that provided strong protections to individual inventors for a broad array of inventions. Developing countries, by contrast, granted fewer protections to a more narrow class of inventions, and many refused to recognise intellectual property claims to medicines, foods and other essential items. India, for example did not permit patenting of pharmaceuticals or living organisms. TRIPS, by contrast, imposed a one-size-fits-all approach that created mandatory minimum standards regardless of the state's domestic situation. (Bratspies 2006-2007: 324-325)

International IP law has largely been created and promulgated by developed countries. When taken from the perspective of developing nations, the formation, evolution, and current status of international IP laws are extraordinarily different. Michael Finger (1999) describes the prevailing attitude reflected in the TRIPS agreement: it is about the knowledge that exists in developed countries, about developing countries' access to that knowledge, and particularly about developing countries paying for that access. Finger further states that international IP laws have largely overlooked the "knowledge that exists or might be created in developing countries"; when it has been addressed, it is to protect 'traditional knowledge' against misappropriation by industrial country interests" and police "'bio-piracy' on the part of the industrial country interests."

Some scholars believe that TRIPS agreement reflects superior social and political attitude of Europe which desire to extend to all non-Europeans. Some other believe that it kind of power struggle between European countries "to secure national economic interests against other European countries in colonial territories." Because decolonisation paved way for developing countries to participate in the international legal framework and became involved with international IP laws. When this
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occurred, there was a brief scramble to ensure the continuity of IP laws in order to protect foreign interests in those developing countries.

Many scholars view intellectual property rights as a "means for all the European countries to control competition from former colonies as global rights became an entrenched feature of international economic relations." To ensure this continuity and accession to international treaties, developing countries were allowed a lower set of obligations under international treaties. This lower bar for compliance also meant a lower level of power within the international intellectual property framework, and many of the changes made in the twentieth century reflected this trade off. Although occasionally, developing countries together could make some impact on the international legal framework, the power of developing countries within the international organisations was weaker than developed countries.

Negotiations for the TRIPS agreement were an exhaustive process, and in the end both developed and developing countries compromised. Nonetheless, TRIPS radically changed the face of international IP law. The TRIPS agreement provided "minimum standards for legal recognition of intellectual property rights" that were basically the standard levels already in place in most developed countries. In 1996, one scholar thinks that if TRIPS is successful across the breathtaking sweep of signatory countries, it will be "one of the most effective vehicles of Western imperialism in history. (Loew 2006: 178-180)

Indeed, TRIPS was intended to standardise these differences in intellectual property protection between the nations of the global north and the global south. Because the United States, the European Union, and, to a lesser extent, Japan wield tremendous influence in the WTO, their voices drew the most attention in the process of drafting the TRIPS agreement. These nations were, in turn, influenced by the commercial interests of their corporate citizens. In fact, the TRIPS agreement was drafted and introduced in the Uruguay Round of GATT by an American industry coalition, the Intellectual Property Committee (IPC), which conducted what it called "missionary work" to sell the idea to the international community. (Bratspies 2006-2007: 325)
The WTO negotiations succeeded in reshaping international trade because the process bundled previously unrelated areas into a single take-it-or-leave-it package. To participate in the global economy, states had to agree to abide by all the agreements that make up the WTO. Among the mass of terms were new intellectual property standards. By linking specified levels of intellectual property protection to previously unrelated trade issues, such as labour and environment, the TRIPS negotiation forced developing countries to sign on to higher standards of intellectual property than their state of development would otherwise have dictated. These intellectual property standards are having profound effects. (Salazar-Xirinachs 2000: 381)

From the standpoint of economic development and technology transfer, a United Nations Development Program ("UNDP") report stated that "countries at low levels of human technological capability cannot benefit significantly from TRIPS . . . Developing countries are not likely to be even at least as well off under TRIPS as they would be outside it." While some critics, such as the UNDP, call for TRIPS's abolition, others argue that it is workable for developing countries if interpreted appropriately. Everyone agrees that the short-term consequences will be massive resource transfers from developing countries to owners of intellectual property. The World Bank has estimated that TRIPS should yield an annual nineteen billion dollars for the United States, whereas South Korea would sustain the largest loss - fifteen billion dollars. (Salazar-Xirinachs 2000: 381)

Many scholars have commented on these marked asymmetries in the development of intellectual property norms and principles captured by the TRIPS agreement. Nowhere is that asymmetry as sharply delineated as it is in the treatment of the claims of indigenous peoples to a property interest in their traditional knowledge and biological resources. This asymmetry stems in large part from one of the most significant changes in intellectual property rights through TRIPS - the expansion of the kinds of things that will be patentable. (Heald 2003: 249)
In particular, TRIPS Article 27, entitled "Patentable Subject Matter," requires marked changes to the domestic patent law of many states. Under Article 27.1, states must ensure that patents "shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." The most controversial portion of the TRIPS agreement, at least from the indigenous rights perspective, has been Article 27.3’s requirement that states include plants and animals within the inventions eligible for patenting or develop a sui generis plan for protecting these inventions. (Bratspies 2006-2007: 326)

Arguably there is room within TRIPS agreement to reshape implementation in a manner that protects traditional knowledge. (Chon 2006: 2821) Article 7 identifies the objectives of the entire TRIPS agreement as to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." This language, together with Article 8, which provides that member states may adopt measures necessary to protect public health and to promote the public interest in "sectors of vital importance to their socio-economic and technological development," was included in the final TRIPS agreement at the behest of developing countries. These provisions have become something of a rallying cry for groups attempting to blunt the force of Article 27.3. (Bratspies 2006-2007: 326-327)

Recently, there has been some modest success in this campaign. In Paragraph 19 of the Doha Round Ministerial Declaration, for example, negotiators reaffirmed that Article 27.3(b) needs to be reconsidered in light of the Article 7 and 8 objectives, with regard to traditional knowledge. (Sun 2003: 101-104) The Declaration emphasised that this is to be accomplished in the context of protecting the rights of developing states and the environment, with reference to CBD. Nonetheless, the focus to date has been predominantly on protecting producers by expanding protections rather than on balancing interests. (Sun 2003: 104-105)
According to the WTO, "intellectual property rights are the rights given to people over the creations of their minds." Yet the way TRIPS is structured against indigenous groups to claim any intellectual property rights over the unmediated products of their traditional knowledge. As a result, indigenous and traditional knowledge is consigned to the global commons. This produces a striking imbalance - the "creations of the mind" of modern science are considered property and eligible for the full panoply of TRIPS protections, while the "creations of the mind" of indigenous peoples are not. (Bratspies 2006-2007: 327)

When goods and services are made possible by combining traditional knowledge with western science, the contributor of the western scientific thinking is entitled to patent protection - a recognition of his or her property interest in creations of the mind - under TRIPS, the contributor of traditional knowledge is entitled to nothing. At its worst, TRIPS legitimises the transfer of exclusive ownership and control of biological resources and traditional knowledge from indigenous innovators to western ones, with no recognition, reward or protection for the contributions of the indigenous innovators. (Kadidal 1993: 223)

Thus, in the definitional moment itself, TRIPS excludes indigenous innovation about biological diversity from what will be property in this new globalised legal world. This treatment stands as a sharp contrast to the patent rights that biotechnology routinely generates, and that TRIPS requires be recognised. By defining property to exclude the resources of indigenous peoples while including what is developed from those resources, this vision of property reconstructs the cycle of dependency that was at the heart of colonialism. TRIPS has to date proven itself resistant to accommodating and protecting indigenous works within the hyper-owned world it has created. While the Doha Declaration recognised this problem of inequitable recognition of property rights, the Minister's state-based perspective suggests that the fundamental problem of inequity with regard to indigenous rights is unlikely to be resolved in the near future. (Bratspies 2006-2007: 328)
Despite many countries’ reservations over TRIPS, the past decade witnessed a strengthening of intellectual property rights legislation in developing countries. Although dissent over the role of intellectual property rights continues, strengthened intellectual property regimes appear to be the wave of the future, due in part to national commitments under TRIPS. (Lesser 1998:197)

Despite optimistic predictions that TRIPS would lead to increased technological transfer and economic stimulation in developing countries, experience has shown that TRIPS tends to promote the importation of biotechnological products, not processes, into developing countries. Large pharmaceutical corporations from developed countries often apply for patents in developing countries but will not physically establish production facilities or research labs inside host countries. Many large biotechnological firms expressly precondition granting patent licenses on a host country's promise not to establish research facilities domestically. While these business practices may provide limited protection to large biotechnology firms, they inhibit the overall transfer of scientific knowledge and technology envisioned under Articles 66 and 67. Many agreements between foreign biotechnological firms and host countries charge excessive royalties or force developing countries' firms to purchase inputs from the patent holder exclusively. This likewise imposes additional costs on the developing world that may inhibit local development and increase prices of crucial biotechnological products, such as pharmaceuticals and certain crops. (Mark Ritchie 1996:439-440)

Not surprisingly, many developing countries remain reluctant to strengthen their intellectual property rights protections for a variety of reasons. First, increased prices for life-saving pharmaceuticals and other products have prompted many countries to thwart the patent provisions of the United States and the European Union by producing essential medicines locally. Moreover, TRIPS-compliance often imposes huge burdens on developing economies. To comply formally with the TRIPS Agreement, countries must establish industrial property registries, develop enforcement mechanisms, combat piracy, and prosecute criminals. (Coenraad J. Visser 2004:208)
In sum, the TRIPS Agreement made many promises for facilitating the equitable transfer of technology to developing countries. Although strengthened intellectual property protection enabled a handful of developing countries to obtain greater FDI than before the TRIPS Agreement, the overall impact of TRIPS on technology transfer has been dismal. Despite the predictions of many economists and scholars alike that increased intellectual property protection will result in technological development both domestically and abroad, the fruits of this transfer have yet to provide any substantial gains for most developing countries. Consequently, the net effect of Articles 66 and 67 has resulted in little effective technology transfer and benefits-sharing to developing countries. (Maskus 2000: 239)

4.2 Indian Patent System

The administration and protection of intellectual property rights in India is divided between the Department of Industrial Policy and Promotion in the Ministry of Commerce and Industry, which is responsible for
industrial property through the Controller General of Patents, Designs and Trade Marks; the Ministry of Human Resource Development, which supervises copyright protection; and the Ministries of Agriculture and Communication and Information Technology, which administer the protection of plant varieties and semiconductors and integrated circuits, respectively. India is a member of most of the key international conventions and agreements on intellectual property rights.

**History of Indian Patent System**

1856 The act vi of 1856 on protection of inventions based on the British patent law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.

1859 The act modified as act xv; patent monopolies called exclusive privileges (making, selling and using inventions in India and authorising others to do so for 14 years from date of filing specification).

1872 The patents & designs protection act.

1883 The protection of inventions act.

1888 Consolidated as the inventions & designs act.

1911 The Indian patents & designs act.


2002 The patents (amendment) act 2002 came into force from 20th May 2003

2005 The patents (amendment) act 2005 effective from 1st January 2005

Source: http://ipindia.nic.in/ipr/patent/patents.htm
4.2.1. Colonial History of Indian Patent System

The history of patents in India dates back to British colonial rule primarily to maintain India as a market for British. In order to facilitate this process, first patent came into being with the enactment of the exclusive privileges Act on 3rd March 1856 modelled on the same line as British Patent Act of 1852. After several amendments and modifications, the Indian Patent & Designs Act, 1911 was passed consolidating to both patents and designs. (Chandrashekaran 1998: 28)

4.2.2 Post-Independent Patent System

Immediately after independence, India realised that existing patent system is acting inimically to her infant stage of development and decided to reform it to satisfy the national interest. The central government decided to set up a committee to study and suggest a suitable patent system for the country that would promote her industrial growth and self-reliance. Committee of Dr. Bakshi Tek Chand examined the Indian Patent & Designs Act, 1911 and submitted a report to the government. Central government drafted a bill consisting of the recommendations and suggestions of the committee and introduced it in parliament in 1953. But the bill was rejected by the parliament due to lack of detail to promote growth based on the national interest. So a second committee was constituted under Justice N Rajagopala Ayyangar to review the Indian patent laws in 1957. The committee submitted its report in 1959 and parliament constituted a joint committee to make recommendations on the report. Based on this report, Indian Patents Act, 1970 was enacted in the parliament on 27th February 1970. (Seth 2001: 20-21)

4.2.3 Indian Patent Act, 1970

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. Patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. The Act tries to strike a balance between the rights of the patent holder and his obligation to the society.
Not Patent will be granted in respect of an invention relating to Atomic Energy within Sec. 20(1) of the Atomic Energy Act, 1962. Only methods or process of manufacture is patentable in respect of substances that can be used as food, medicine or Drug or any substances produced by chemical processes but product per se is not allowable under sec. 5 of the Act. The Act contains provisions for compulsory working of a patent. Working of a patent means manufacturing the product in India. The patentee cannot hold the patent in India and import the product from another country, thereby compelling the Indian consumer to pay an excessive price. 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 (Garima Gupta & Avih Rastogi 2002).

The main objective behind this policy was to enable a developing country like India to benefit from inventions from other countries by ensuring the availability of the same products at cheaper prices produced by a different process. Such access was required because invention in drugs and food were life saving in nature and India is a country with 50 million people below poverty line who otherwise could not afford them. This is especially true in the case of drugs patented abroad, which is very costly. The term of patent starts from the date of filing the complete specifications and this date is entered in the Register of Patents. The term of patent in respect of food, Drug and medicine will be 5 years from the date of sealing or 7 years from the date of patent, whichever is shorter. In respect of any other inventions the period will be 14 years from the date of patent. It is the sole responsibility of the patentee to pay renewal fees from the beginning of 3rd year or pay in advance to avoid the patents from getting lapsed. (Chandrashekaran 1998: 31-39)

Chapter II of the Indian Patent Act, 1970 explains inventions that are not patentable would make it very difficult for most traditional knowledge to be protected. Section 3 (e) states: "a substance obtained by a
mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance." This provision would apparently require the applicant to demonstrate that the mixture yielded unexpected results. Section 5 of the Indian Patent Act, 1970 states that inventions: "intended for use, or capable of being used, as food or as medicine or drug," no patent can be granted for the substance itself, but claims for the method or process of manufacture would be allowed. By dispensing with product patents, the law gave particular incentives to finding efficient methods of manufacture. It also left generic drug manufacturers with many possibilities. At the same time, it aggravated western pharmaceutical companies. As an unintended consequence for Traditional Medicine (TM), new methods of manufacture may be difficult to formulate. This would effectively require melding TM with science. While China has invested substantial sums to integrate scientific methods with TM, India has not. (Eiland 2007: 60-61)

4.3 Revision of Patent Law

In order to fulfil the TRIPS obligations the president of India on December 31, 1994, promulgated the patents (Amendment) Ordinance to amend the Patent Act of 1970 and provide for an exclusive marketing right. The ordinance become effective on January 1, 1995 and India notified the Council for TRIPS as required under article 63(2) of TRIPS. However, the ordinance lapsed on March 26, 1995 since registration of this kind ceases to apply at the expiration of six weeks from the re-assembly of Parliament. The patent Bill of 1995, which was intended to give permanent legislative effect to the provisions of the ordinance, was passed by the Lok Sabha in March 1995, but lapsed in the Rajya Sabha. Therefore the patents Bill lapsed with the dissolution of the 10th Lok Sabha on that date in November 1995. The Indian sentiment over the introduction of exclusive marketing rights also accounted for the lapsing of the bill.¹

¹ “Changes to India's Patents Act and Access to Affordable Generic Medicines after January 1 2005,” at http://healthgap.org/press_releases/04/121404_HGAP_FS_INdia_patent.pdf#search=%22India%20patents%20act%22
As India delayed to make transitional system to comply with TRIPS, USA and European Union requested the Dispute Settlement Body of (DSB) of the WTO to examine whether India had defaulted in its TRIPS obligation. Indian argument in the DSB was that there is an effective mechanism exists in India as required by TRIPS. India also argued that as a developing it could delay the process under Article 65(2) for a period of 4 years. The panel ruled that India was in default of its obligation because the administrative notification could not be considered as in compliance with the requirements in TRIPS. The panel also held that India was obliged under 70(A) to have a transitional system in place immediately and not after four years. The appellate body upheld this ruling. Thus, India was forced to amend the Indian Patent Act 1970 to avoid facing trade sanctions and the first amendment act was passed in December 1999. (Raghavan 2001:1-2)

The TRIPS agreement has raised a furore in India and some vociferous opponents of the TRIPS agreement have suggested to give up its membership of the WTO. While this is an option which exists in theory, given the growing importance of international trade to India, the fact that the WTO is and will remain the most important institution to make and enforce rules of international trade and the difficulties faced by important non members like China and Russia in gaining entry into the WTO. India could not consider leaving the WTO without adequate and serious reason. On the other hand, if India is to remain in the WTO compliance with the TRIPS agreement has to be real, credible and defensible before any future dispute settlement panel of WTO. (Watal 1997: 2461)

In order to meet 10 April 1999 deadline for amendments to the Patents Act, to provide Exclusive Marketing Rights and receive product patent applications, the President promulgated the Patent (Amendment) Ordinance on 8 January 1999. Both houses of Parliament later passed this amendment. The amendment made it possible for firms and individuals to apply for product patents in India in the area of food, chemicals and pharmaceuticals. The applications are to go into a ‘mailbox’ and would be
examined for the grant of a patent when India finally allows product patents in these areas. The amendments also provided for the grant of Exclusive Marketing Rights for a product in the area of food, chemicals and pharmaceuticals provided they had obtained a product patent and a marketing license in a country that was a member of the Paris Convention. (Raghavan 2001: 1-2)

4.3.1 The Patents (Amendment) Act, 2002 & 2005

As already mentioned in the previous chapter, Indian Patent Act, 1970 was amended twice, first during 2002 and later during 2005 in compliance of the obligations under TRIPS. The Patents (Amendment) Act, 2002 extended the period of protection granted for all product and process patents to 20 years from the date of filing (Section 53); previously, protection was for five years for process patents for food or medicine and 14 years for other cases. Other key changes introduced by the 2002 Act include a more detailed framework for the granting of compulsory licences and deletion of the sections dealing with "licences of right". The Patents (Amendment) Act, 2005, by deleting Section 5 of the Act, which excluded product patents for food, medicine or drug or products using chemical processes, ended the ten-year transition available to India and other developing countries under the TRIPS Agreement. The regime for exclusive marketing rights, introduced under the 1999 amendment was also revoked.

Under the current Patents Act, which became effective on 1 January 2005, patent protection may be granted to any invention relating to either a product or process that is new, involves an inventive step, and is capable of industrial application (Article 2(1)(j)). The Act also sets out products or processes that are not recognised as inventions and are therefore not patentable. Patents of addition for an improvement to a patented product can be granted to the holder of the original patent for the same period as the validity of the original patent. Applications for patents may be submitted by nationals of any country, to the Controller General of Patents, Designs, Trademarks and Geographical Indications. Under the 2005 amendment, applications will only be examined by the Patent Office
if requested by the applicant or by another interested party within 48 months, failing which the application is deemed to have been withdrawn. The Act also provides for pre- and post-grant opposition under Chapter V.

The patent rights accrue from the date of publication of the patent application, which is within one month after completion of 18 months of its filing or at an earlier date, if requested by the applicant. On average, it takes between 10 and 60 months to grant a patent depending on the information provided by the applicant. However, the applicant is not entitled to institute any infringement proceedings until the patent has been granted. For patents relating to pharmaceuticals filed before 1 January 2005 (the "Mailbox"), the rights of the patentee accrue from the date of grant of the patent, but the period of protection remains 20 years from the date of filing. Moreover, the patent holder may not institute infringement proceedings against manufacturers already producing the patented product when the patent is granted; in such cases, the patent holder is entitled to receive reasonable royalties. The law does not define "reasonable", which depends on the circumstances of each case, like royalty payment under Article 31 (h) of the TRIPS Agreement. The law also does not define the authority for determining the royalty. However, according to the authorities, although some 8,000 applications were made through the Mailbox facility, there have been no demands for royalty payments from patent holders. It is not clear how many patents have been granted under this facility.
## Miscellaneous information relating to patent during the period from 1998-99 to 2007-2008

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### Applications filed from residents and non residents through various routes for last 18 years

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The number of applications for patents filed in 2007-2008 was 35,218 compared to 28,940 applications in 2006-2007 representing an increase of about 22% in the filing. 11 applications were filed as patent of addition. The number of applications for patents which originated in India were 6,040 contributing approximately 17% of the total number of applications filed during the year. Out of the said applications, which originated in India Maharashtra accounted for the maximum number, followed by Karnataka, Delhi, Andhra Pradesh, West Bengal and Gujarat. The State / Union Territory wise break up figure is as shown in brackets: Maharashtra (1936), Karnataka (814), Delhi (812), Andhra Pradesh (414), West Bengal (303), Gujarat (286), Uttar Pradesh (161), Kerala (123), Haryana (123), Jharkhand (85), Madhya Pradesh (50), Punjab, (44), Rajasthan (36), Chandigarh (33), Uttarakhand (25), Bihar (21), Assam (16), Chhattisgarh, (15), Himachal Pradesh (15) etc.

Number of patents granted during last years from 2003-2004 to 2007-2008 under various fields of inventions

Total number of patents granted during the year was 15,261 out of which 3,173 were granted to Indians. The Number of Patents In force was 29,688 as on the 31st March 2008 of these, 7,966 patents comprised Indians. From the total grants 3,230 patents granted on applications relating to Mechanical, 4,071 to Chemicals, 2,052 to Computer/Electronics 1,469 to Drug or Medicines, 1,078 to Electrical, 88 to Food etc.  

Compulsory licences can be granted under Chapter XVI of the Patents Act. Under Section 84 any person interested in working a patent can, after the expiry of three years from the date of grant of the patent, apply to the Controller for grant of a compulsory licence. The grounds for such a compulsory licence may include: that the reasonable requirements of the public with respect to the patented invention have not been satisfied; the patented invention is not available at a reasonably affordable price; or that it is not worked in India. The Controller may issue a licence upon terms and conditions outlined in the Act. Two years after a compulsory licence has been granted, the Central Government or any other interested person may request the Controller to revoke the patent on the grounds that it has not been worked or that the reasonable requirements of the public

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have not been met, or that it is not available to the public at a reasonable price. The Controller would normally make a decision within one year of it being presented. No compulsory licences have been granted under this provision. The Central Government may also, if necessary, such as in the case of a national emergency, provide for issue of a compulsory licence for a patented product through a notification in the Official Gazette (Section 92) and may use a patented invention for government purposes (Section 100). Following the amendment to the TRIPS Agreement in December 2005 to include the decision on patents and public health, a new section 92A was inserted in the Act to permit compulsory licences for exports of patented pharmaceutical products in certain exceptional circumstances. This provision has not been used to date.

India also permits parallel imports, the definition of which was changed in 2005 from "importation of patented products by any person from a person who is duly authorised by the patentee" to "importation of patented products by any person from a person who is duly authorised by the law". False representation of any article sold in India as being patented in India or for which an application has been made are punishable by a fine of up to Rs 100,000. Contravention of secrecy provisions relating to certain inventions or falsification of any information relating to the Patents Register is punishable by a fine or imprisonment of up to two years. Appeals can be made to the Appellate Board established under Section 83 of the Trade Marks Act, 1999. However, pending establishment of the Appellate Board, appeals are to the High Courts.

The Patents (Amendment) Act 2005 introduces product patents for medicines for the first time in 35 years. The Amendment omits section 5 of the 1970 Act. This removes the stricture against patenting medicines. In the case of Traditional Medicine, section 3(d) still applies. Traditional Medicine will continue to be difficult to patent in India. The Amendment lists what are not inventions: 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 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.³

The principal Act of 1970 has a similar provision, but it does not specifically consider an invention to be a new use of a known substance that results in enhancement of the 'known efficacy.' While case law will have to be developed, this appears to be favorable to patenting some Traditional Medicine. However, given that the US has a huge pharmaceutical market, there have been instances where Indian Traditional Medicine has been patented in America. (Eiland 2007: 61)

The changes at Glance

<table>
<thead>
<tr>
<th>Indian Patent Act, 1970</th>
<th>TRIPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only process not product patents in food, medicines and chemicals</td>
<td>Process and Product patents in almost all fields of technology</td>
</tr>
<tr>
<td>Term of Patents-14 years, 5-7 in chemicals and drugs</td>
<td>Terms of patents 20 years</td>
</tr>
<tr>
<td>Compulsory Licensing</td>
<td>Limited Compulsory Licensing</td>
</tr>
<tr>
<td>Several areas excluded from patents</td>
<td>Almost all fields of technology patentable</td>
</tr>
<tr>
<td>Government allowed using patented invention to prevent security</td>
<td>Very limited scope of governments</td>
</tr>
</tbody>
</table>


4.3.1.1 Trade Marks

Trade marks are protected under the Trade Marks Act, 1999 and the Trade Marks Rules, 2002 (in force since September 2003), which repealed the Trade and Merchandise Marks Act, 1958. The changes introduced by the Act, include: protection to well known marks, as well as service and collective marks; extension of the period of protection from seven to ten years; establishment of an Appellate Board; and increased penalties for infringement of trade marks.

Recent Trends in Trade Marks Applications

<table>
<thead>
<tr>
<th>Year</th>
<th>Filed</th>
<th>Examined</th>
<th>Registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-03</td>
<td>94120</td>
<td>249003</td>
<td>11190</td>
</tr>
<tr>
<td>2003-04</td>
<td>92251</td>
<td>89958</td>
<td>39762</td>
</tr>
<tr>
<td>2004-05</td>
<td>78996</td>
<td>72091</td>
<td>45015</td>
</tr>
<tr>
<td>2005-06</td>
<td>85699</td>
<td>77500</td>
<td>184325</td>
</tr>
<tr>
<td>2006-07</td>
<td>103419</td>
<td>85185</td>
<td>109361</td>
</tr>
<tr>
<td>2007-08</td>
<td>123514</td>
<td>63605</td>
<td>100857</td>
</tr>
</tbody>
</table>

Breakup of Trademarks Registered during last five years

1. Total number of Registered Trade Marks as of 31st March, 2008 6,53,078
2. Total Number of Registered Trade Marks in last 5 years 4,79,320

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Year</th>
<th>Numbers of Trade Marks Registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2003-2004</td>
<td>39762</td>
</tr>
<tr>
<td>2</td>
<td>2004-2005</td>
<td>45015</td>
</tr>
<tr>
<td>3</td>
<td>2005-2006</td>
<td>184325</td>
</tr>
<tr>
<td>4</td>
<td>2006-2007</td>
<td>109361</td>
</tr>
<tr>
<td>5</td>
<td>2007-2008</td>
<td>100857</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>479320</td>
</tr>
</tbody>
</table>

Trade marks must be filed in writing at one of the offices of the Trade Marks Registry. Following examination to determine whether the trade mark is distinctive and does not conflict with an existing or pending trade mark, the Registry publishes the trade mark in the Trade Marks Journal. Opposition to the trade mark can be made within three months of publication (extendable by one month) to which the applicant must respond within two months. Following a decision to register the trade mark a certificate of registration is issued. The trade mark is registered for ten years, renewable for further periods of ten years on payment of the prescribed fee. If the registered mark is not used for a continuous period of five years and three months from the date it was registered, or if the renewal fee is not paid within the prescribed period, it can be removed from the registry on grounds of non-use. Appeals against a decision by the Registrar may be made to the High Court pending establishment of the Appellate Board.

Under the Act, registration of a trade mark gives the owner "the exclusive right to the use of the trade mark in relation to the goods or services and to obtain relief in respect of infringement of the trade mark" (Chapter IV, 28(1)). Registration is not compulsory, but the owner cannot bring a legal case against an infringer if the mark is not registered. The law also enables a suit for passing off to be filed for the use of any trade mark that is identical or deceptively similar to the plaintiff's trade mark, whether registered or unregistered. The Trade Marks Act, 1999, preserves common law rights in respect of an unregistered trade mark. Penalties for falsification of trade marks and selling or providing goods that infringe trade marks include a prison term of at least six months, extendable to three years, and a fine of between Rs 50,000 and Rs 200,000. Second or subsequent convictions may lead to imprisonment of between one and three years and a fine of between Rs 100,000 and Rs 200,000. Falsely representing a trade mark as registered may lead to imprisonment of up to three years and/or a fine. Other penalties include imprisonment of up to two years and/or a fine for improper description of a place of business as connected with the Trade Marks Office and for falsification of entries in the Register.
4.3.1.2 Industrial Designs

Legislation governing industrial designs in India is the Designs Act, 2000 and the Designs Rules, 2001. Under the Act, designs may be registered by the Controller General of Patents, Designs and Trade Marks, provided that: they are new or original; have not been disclosed to the public in India or another country by publication prior to the filing or priority application date; they are significantly distinguishable from known designs or combinations of known designs; and they do not comprise or contain scandalous or obscene matter. Following registration, the design is published in the Gazette of India and made publicly available in a Register of Designs.

Industrial designs are protected for ten years, extendable by five years, upon payment of the appropriate fee. A design may be cancelled at any time by the Controller General if it is determined that it does not fulfil the requirements for registration defined in the Act. Three design registrations have been cancelled since 2002. Appeals against a decision by the Controller General may be made to the High Court within three months of the decision. Four appeals have been made to the High Court since 2002 and are pending. The sale, import or imitation of any article in which the design is registered without the consent of the registered owner is punishable by a fine of up to Rs 25,000 (to be paid to the registered owner) or any other damages incurred of up to Rs 50,000 if the owner begins legal proceedings. The Act does not contain criminal penalty provisions.

The number of applications filed for registration of designs during the year was 6402 showing about 16% increase in comparison to the previous year’s total of 5521. The applicants in India filed 3873 applications while the remaining 2529 applications were originated abroad.4

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## Trend of Applications Filed and Registered by Origin

<table>
<thead>
<tr>
<th>Year</th>
<th>Filed</th>
<th>Registered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Indian</td>
<td>Foreign</td>
</tr>
<tr>
<td>2003-04</td>
<td>2619</td>
<td>738</td>
</tr>
<tr>
<td>2004-05</td>
<td>3093</td>
<td>924</td>
</tr>
<tr>
<td>2005-06</td>
<td>3407</td>
<td>1542</td>
</tr>
<tr>
<td>2006-07</td>
<td>3584</td>
<td>1937</td>
</tr>
<tr>
<td>2007-08</td>
<td>3873</td>
<td>2529</td>
</tr>
</tbody>
</table>

4.3.1.3 Copyright

Copyright is protected under the Copyright Act, 1957, most recently amended in 1999. Protection is granted to: original literary, dramatic, musical and artistic works; cinematographic films; and sound recordings. The term of protection is the lifetime of the author plus 60 years for literary, dramatic, musical and artistic works; and 60 years after the year of publication for anonymous and pseudonymous works, photographs, cinematographic films, sound recordings, and works owned by the Government or by a public undertaking or an international organisation. Broadcast reproduction rights are for 25 years from year of broadcast, and performer’s rights are for 50 years from the date of performance.

Compulsory licences may be issued for works withheld from the public or for unpublished "Indian works", where the author is dead or unknown. In such cases applications may be made to the Copyright Board, which after holding an inquiry, may direct the Registrar of Copyright to issue the licence under specified terms and conditions. The Central Government may also, if it deems it to be in the national interest, require the heirs or executors of a work whose author is no longer alive, to publish the work. Applications for licences to publish a translation of a literary or dramatic work in any language may be made to the Copyright Board seven years after publication of the work (three years if the translation is required for teaching, scholarship or research). Parallel imports are not permitted by the law.

Both civil and criminal remedies are available for infringement of copyright. Under Section 63, the penalties can be imprisonment for between six months and three years and/or a fine of between Rs 50,000 and Rs 200,000. Repeat offences are punishable by imprisonment of one to three years and/or a fine of Rs 100,000 to Rs 200,000. Any person who knowingly makes use of an infringing copy of a computer program is punishable by imprisonment of seven days to three years and/or a fine of Rs 50,000 to Rs 200,000. The penalty for making or possessing plates for making infringing copies of protected works is imprisonment of up to two years and/or a fine. Publication of a sound recording or a video
film in contravention of the Act is liable to imprisonment of up to three years and a fine.

4.3.1.4 Geographical Indications

Geographical indications are protected under the Geographical Indications of Goods (Registration and Protection) Act, 1999 and the Geographical Indications of Goods (Registration and Protection) Rules, 2002. The Geographical Indications Registry was established on 15 September 2003.

Applications for registration of a geographical indication must be made in writing to the Registrar of Geographical Indications who is the Controller General of Patents, Designs and Trade Marks. Geographical indications can be registered for any or all goods in a territory of a country or a region or locality in that territory (Section 8). Once the application is accepted, the Registrar issues an advertisement of application. If there is no opposition to the registration within three months, the GI will be registered. If the application is not accepted by the Registrar, the grounds for the refusal must be given in writing. Registration of trade marks containing geographical indications may be invalidated by the Registrar of Trade Marks (section 25). Decisions by the Registrar may be appealed to the Appellate Board within three months from the date of notification of the Registrar's decision.

The Geographical Indications Registry is a statutory organisation set up for the administration of the Geographical Indications of Goods (Registration and Protection) Act, 1999, which was brought into force on 15th September 2003. The Registry is situated at Chennai. The Registry has started receiving applications for registration since 15th September 2003 and since then the Registry has received a total number of 121 (One Hundred and Twenty One) applications in the reporting financial year. 61 (Sixty One) Geographical Indications (GIs) have been registered up to 30th March 2008. List of registered GIs (Products), which inter-alia, include, Darjeeling Tea, Pochampally Ikat, Chanderi Sarees, Kota Doria, Kancheepuram silk, Mysore Agarbathi, Mysore silk, Madurai Sungudi,
Kullu Shawl, etc. (List Annexed). During the reporting year a total number of 31 (Thirty One) registration certificates have been issued.

**Registered Geographical Indications (Products)**

*From The Year 2003 - 2008*

<table>
<thead>
<tr>
<th>Product</th>
<th>No. of GI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tea &amp; Coffee</td>
<td>4</td>
</tr>
<tr>
<td>Agricultural Products</td>
<td>5</td>
</tr>
<tr>
<td>Horticulture</td>
<td>6</td>
</tr>
<tr>
<td>Handicrafts</td>
<td>10</td>
</tr>
<tr>
<td>Textiles</td>
<td>13</td>
</tr>
<tr>
<td>Others</td>
<td>23</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>61</strong></td>
</tr>
</tbody>
</table>


Protection for the owner of the geographical indication and any authorised user is ten years, but may be renewed by the Registrar for a further period of ten years. Currently, 28 geographical indications are registered in India. Additional protection may be provided by the Central Government to certain goods or classes of goods by notification in the Official Gazette. Registration guarantees exclusive use of the geographical
indication by the owner or authorised user and protection in case of infringement. Infringement is defined under the Act as: use of the geographical indication to indicate or suggest that the goods originate in a geographical area other than the true place of origin in a misleading manner; use that constitutes an act of unfair competition, including passing off; and use of a geographical indication to falsely indicate that the goods are those to which the registered GI relates. The penalty for falsifying or falsely applying geographical indications or selling goods under false geographical indications is imprisonment for six months to three years, and a fine of Rs 50,000 to Rs 200,000. Repeat offences are subject to a prison term between one and three years and a fine of Rs 100,000 to Rs 200,000.

The Geographical Indication Registry has received two requests under Section 50 of the Act for the opinion of the Registrar, which has to be obtained before conducting search and seizure; a suit was filed for infringement in the Delhi High Court by the registered proprietor of the GI; the matter ended in a compromise.

4.3.1.5 Semiconductor Integrated Circuits Layout-Designs

The Semiconductor Integrated Circuits Layout-Design Act was passed in September 2000. There have been no changes to this legislation since the previous Review. Applications should be made in writing to the Registrar and filed at the office of the Semiconductors Integrated Circuits Layout-Design Registry, although it appears that the Registry is not yet functional. Upon accepting the application, the Registrar must publish an advertisement within 14 days. Opposition to registration must be made within three months of publication of the advertisement and the applicant is given two months to respond. A registration certificate will be issued to the applicant. Registration is for ten years from the date of filing the application or from first commercial exploitation in India or elsewhere, whichever is earlier. Decisions by the Registrar may be appealed to the Layout-Design Appellate Board.

Infringement is defined as unauthorised reproduction, whether by incorporating in a semiconductor integrated circuit or otherwise, a registered layout-design or any part of it, or unauthorised import, sale, or
distribution for commercial purposes of a registered layout-design or a semiconductor integrated circuit incorporating a semiconductor integrated circuit with a registered layout-design. However, reproduction is permitted for scientific evaluation, analysis, research or teaching. In addition, if a person creates another original layout-design on the basis of scientific evaluation or analysis of a registered layout-design, that person has the right to reproduce, sell or incorporate this layout-design in a semiconductor, while if a person independently develops a layout-design that is identical to a registered one, that person may use it as desired without infringing. The penalty for infringement of a layout-design is imprisonment for up to three years and/or a fine of Rs 50,000 to Rs 1 million. There is no specific legislation regulating the protection of trade secrets or enforcement measures/penalties for violations of trade secrets. However, aggrieved parties can seek action through the Civil Courts.

4.3.2 Enforcement

Enforcement of intellectual property rights in India is carried out by the police for domestic cases and by the police and customs for imports and exports. Domestic enforcement, especially for copyright violations, appears to have been stepped up, notably through the setting up of a Copyright Enforcement Advisory Council (CEAC). The CEAC, headed by the Secretary (Higher Education) in the Government of India, has 28 other members including the head of Police from some states as well as senior officers of related departments like Customs; it meets twice a year. In addition special IPR cells have been set up, currently in 18 states, and nodal officers appointed to coordinate enforcement activities with industry. Industry associations and copyright societies are also involved in supplementing and sometimes guiding the efforts of the enforcement agencies. A police officer (not below the rank of a sub-inspector) has ex officio powers to seize goods suspected of infringing copyright.

Under the Customs Act, Customs may seize and hold goods "for a reasonable period", including for suspected violations of intellectual property rights, following which, the goods must be released or a court injunction obtained to start infringement proceedings. Under Section 53 of
the Copyright Act 1957, the Registrar of Copyright has the power to order that copies of an infringing work cannot be imported and order a physical search of any ship, dock or premises. An amendment to this provision, to transfer the power of banning import of any infringing copy to the Commissioner of Customs, is currently under consideration.

Enforcement by the police has been stepped up through increased raids since 2004. As a result some 6,290 cases were filed in 2004 with the National Crime Records Bureau (1,211 cases in 2000). According to information provided by the National Crime Records Bureau (NCRB), 2,108 cases were registered under the Copyright Act between January and June 2005. This resulted in the arrest of over 2,000 alleged offenders and over Rs 93 million in seized material. Similarly, data made available by the IMI, an industry group, reveals over 2,100 raids and 2,255 arrests in 2005/06 in music-related copyright violations. The police also have ex officio powers under the Trade Marks Act, 1999, which permits any police officer not below the rank of deputy superintendent of police or equivalent, to search and seize without warrant the goods, die, block, machine, plate, and other instruments or goods suspected of infringing intellectual property. However, the police officer must obtain the opinion of the Registrar before any search and seizure. No data were provided to the Secretariat on enforcement with regard to other IPR violations, nor on the number of IPR infringement cases that have been settled through the courts.

The Government has stepped up training to increase awareness of IPR enforcement. The Intellectual Property Institute (IPI) provides training to government officials (including from the IP offices and from other government agencies), the private sector, including management in companies, creators of IPRs, and academics, and to "potential users from the public at large". A scheme of the copyrights division (the intellectual property education, research and public outreach scheme) aims to create an IP culture and awareness at colleges and universities through grants for seminars, training, and discussions on IP, especially copyright. Activities are also carried out in conjunction with industry organisations.
Despite these efforts, however, according to NASSCOM, which represents India's software suppliers, it appears that much remains to be done to improve IPR enforcement. While the reported number of police raids appears to have increased in recent years, it is unclear whether these are a sufficient deterrent to further violations of IPR, given that there is very little information on the number of cases resulting in prosecutions through the justice system or civil or criminal penalties. The authorities state that the courts are well aware of the gravity of the problems and the legal provisions of the various IP laws and regularly pronounce sound enforceable judgments. Moreover, there is a growing realisation of the need to sensitise the judiciary on the role of IPR and the impact of IP violations on the economic climate, and creativity and innovation, including through seminars for the judiciary.\(^5\)

However, VK Gupta (2006) views that the new global IPR regimes have affected several policy domains including the domain of international relations and the domain of international cooperation in science and technology. These cooperative programmes are likely to build a strong scientific and technological base in the country. India could continue to leverage its strengths to become a leader in knowledge creation and use. There is a great potential in new knowledge-based activities, which could be complemented with an intense and proactive programme of cooperation in science and technology with advanced countries. Shashi Kumar (2006) is of the view that if India wants to harvest the benefits out of IPR, she has to cater knowledge intensive infrastructure in the country.

### 4.4 Biotechnology versus Biodiversity

Perhaps, one of the most contentious areas in the negotiations under WTO and CBD is on the matters related to the protection of biodiversity associated traditional knowledge. As a matter of fact, protections of such resources have been confronting a severe crisis primarily due to the provisions for patenting of life forms enforced by the TRIPS Agreement. These provisions have found a place in the TRIPS Agreement primarily due

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to revolutionary breakthrough in the biotechnology industry under monopoly control of multinational companies based in United States and Europe. It has been rightly argued that the challenges posed by biotech multinational companies have redefined the very notion of security.

The rapid growth of the biotechnology industry over the past two decades led many countries to recognise the vast economic potential of their genetic resources and indigenous knowledge. (Ajay Sharma 1995) With increasing demand for new biotechnological products, the global community is struggling to strike a balance between the interests of host countries, who seek remuneration for supplying genetic resources and traditional knowledge, and biotechnological inventors, who are pressing for free access, open markets, and stronger intellectual property rights protection.

**Biotechnology R & D intensity, 2006**

Biotechnology R&D as a percent of industry value added

<table>
<thead>
<tr>
<th>Country</th>
<th>Biotech R&amp;D firms</th>
<th>Dedicated biotech firms</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>0.31%</td>
<td>0.28%</td>
</tr>
<tr>
<td>Switzerland (2004)</td>
<td>0.27%</td>
<td>0.22%</td>
</tr>
<tr>
<td>Ireland (2005)</td>
<td>0.24%</td>
<td>0.21%</td>
</tr>
<tr>
<td>Belgium (2007)</td>
<td>0.19%</td>
<td>0.18%</td>
</tr>
<tr>
<td>France (2005)</td>
<td>0.26%</td>
<td>0.26%</td>
</tr>
<tr>
<td>Canada (2005)</td>
<td>0.20%</td>
<td>0.20%</td>
</tr>
<tr>
<td>Finland (2007)</td>
<td>0.09%</td>
<td>0.10%</td>
</tr>
<tr>
<td>Korea (2005)</td>
<td>0.05%</td>
<td>0.05%</td>
</tr>
<tr>
<td>Norway (2005)</td>
<td>0.04%</td>
<td>0.04%</td>
</tr>
<tr>
<td>Germany (2007)</td>
<td>0.07%</td>
<td>0.06%</td>
</tr>
<tr>
<td>Czech Republic (2007)</td>
<td>0.05%</td>
<td>0.05%</td>
</tr>
<tr>
<td>Spain</td>
<td>0.03%</td>
<td>0.03%</td>
</tr>
<tr>
<td>Slovenia (1)</td>
<td>0.02%</td>
<td>0.02%</td>
</tr>
<tr>
<td>Italy</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Slovak Republic</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Portugal (2005)</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
<tr>
<td>South Africa</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Poland (2007)</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
</tbody>
</table>


Industrialised countries, seeking to maintain incentives for new innovations through a strong intellectual property rights regime, viewed
many developing countries' wishes to assert sovereign control over their resources as barriers to free trade. (Ajay Sharma 1995: 15-17) In contrast, many developing countries viewed intellectual property rights as a tool for industrialised countries and multinational corporations to gain free access to their resources without sharing in the benefits derived from these resources. (Lesser 1998) Consequently, developing countries began to assert their sovereign right to control the resources within their territorial jurisdictions.

Pharmaceutical corporations and Agribusiness increasingly rely upon these resources to engineer new drugs and genetically modified crops for sale in the international market. Developing countries, home to over eighty percent of the world's biodiversity, (Joseph Straus 2000:142) have become hotbeds for bio-prospectors searching for the next big breakthrough in medicine or agriculture. As a result of the high stakes involved in this multi-billion dollar industry, the global community, in seeking to facilitate the equitable sharing of benefits, is struggling to strike a balance between the interests of biological suppliers and biotechnological inventors.

The Convention on Biological Diversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) mirror the conflicting views of industrialised and developing countries concerning intellectual property rights. Industrialised countries view the CBD with a suspicious eye, as it precariously balances the sovereign rights of states with intellectual property protections. In turn, developing countries often viewed TRIPS as a tool for affording multinational corporations access to their resources without sharing in the benefits derived from them.

The conflict over intellectual property rights is partially the result of an unequal distribution in the location and wealth of the world's global biodiversity. (Ajay Sharma 1995) As a general rule, the richness in biodiverse natural resources is inversely related to latitude. Thus, the majority of the world's biological wealth is concentrated in the temperate regions of the globe. (Ashish Kothari 1994: 67-72) Estimates indicate that nearly eighty percent of the raw genetic inputs used in biotechnology are from tropical developing countries. (Joseph Straus 2000:142) The uneven
distribution of the earth's biological resources, coupled with the superior
technology, economic leverage, and scientific knowledge of developed
countries, has resulted in serious inequities in the global biotechnology trade.

4.4.1 CBD and Developing Countries

The CBD represents a global framework aimed at protecting
biodiversity. Although this agreement is largely an international treaty
aimed at promoting the sustainable use of environmental resources, it also
possesses important economic aspects that impact the application of
intellectual property rights on the inputs of the biotechnological industry.
The CBD approaches conservation based on the theory that what is
perceived as having economic value tends to be used more efficiently, thus
promoting the sustainable use of depletable resources. (Lesser 1998)

For many decades Developed Countries have combated the
counterfeiting of their products abroad. They have called “pirates” all the
foreign enterprises, no matter whether big or small, who reverse engineered
and copied their intellectual creations in order to form their own industrial
capacity and skills and decrease the technological gap dividing developed and
Developing Countries. But ironically enough, the biodiversity and traditional
knowledge (TK) issue seems to reverse the roles in the game. Almost all
industrialised countries do not have Peru’s plant varieties or anything like the
Indian neem tree, not to mention any shamanic knowledge associated to those
natural resources. (Gustavo Ghidini & Emanuela Arezzo 2006)

The problem of biodiversity and TK stems from the circumstance
that foreign researchers and scientists, backed by their own governments,
take such resources without permission, and without granting any truly
equitable sharing of benefits flowing from production of biodiversity-based
drugs to the indigenous people, nor to their governments. Indeed, not only
local natural resources and knowledge generate huge amount of profits to
the exclusive benefit of such companies but also, as Professor Boyle has
pointed out, they often go back to their country of origin embedded in
strong patents that impede the very local communities, who have long
studied and cherished them, to keep using their own heritage and scientific
culture. (Gustavo Ghidini & Emanuela Arezzo 2006)
The best way of protecting those communities in a way consonant to the principles expressed by the Convention on Biological Diversity is to grant them some form of entitlement to protect their tangible and intangible knowledge against its misappropriation. In 1992, the United Nations Conference on Environment and Development convened in Rio de Janeiro created the CBD. Generally, the CBD "established sovereign national rights over biological resources and committed member countries to conserve them, develop them sustainably, and share the benefits resulting from their use."

Over the centuries, many samples of unique genetic resources have been taken from their original country of origin to collections in industrialised nations. Many unique biological resources have yet to be catalogued or even discovered. These resources, which are concentrated in developing countries of high biodiversity, remain in demand as sources of leads for new products, or for scientific collections. (Sarah A. Laird & Kerry ten Kate 2002) This demand has led many biodiversity rich developing countries to exercise their rights over biological resources established by the CBD by enacting national laws and rules to protect their resources. (Michael A. Gollin 1999) The extension of developing countries' laws to require informed consent and benefit-sharing as preconditions to access to biological resources has resulted in contractual arrangements between biodiversity source countries and biotechnology and pharmaceutical corporations seeking access to the biological resources. These agreements are variously referred to as either biodiversity prospecting agreements or access and benefit sharing agreements.

While national legislation relating to biological resources and biodiversity prospecting agreements is intended to protect countries' rights to their biological resources, it has also added new legal complexities. Intellectual property experts have not been extensively involved in the establishment of such rules, with the result that they are of limited practicality.

While some biodiversity prospecting agreements may be fairly straightforward, many provide negotiated royalty payments in exchange for access and sample collection, and other agreements involve complex negotiations regarding the sharing and value of locally acquired and/or pre-existing indigenous knowledge regarding a developing country's biological
resources. (Charles V. Barber et al., 2002: 371-74) Source countries may place a high value on these contracts in monetary, environmental, and political terms. Thus, legal representation that can adequately and appropriately handle the intellectual property issues that arise in the context of biodiversity prospecting agreements is crucial.

The concerns of developed and developing countries resulted in various concessions that are reflected throughout the text of the CBD. In Article 16, for example, the CBD consistently acknowledges the importance of intellectual property rights and stipulates that these rights be honored. Nevertheless, Article 16 places conditions on adherence to intellectual property rights by requiring mandatory technology transfer and benefits-sharing obligations when necessary to meet the goals of the CBD. The end result was an international agreement that arguably fell short of meeting the expectations of both developed and developing countries because of its compromised and often ambiguous language. (Maskus 2000:225)

Despite the shortcomings of the CBD, the agreement marked a crucial starting point for addressing the concerns of intellectual property rights and the trade of biotechnological products. By acknowledging the importance of intellectual property rights and the goal of equitably sharing the benefits derived from utilising the genetic materials of developing countries, the CBD came close to striking a balance between the divergent views of the developed and developing world.

4.4.2 TRIPS versus CBD: Conflict or Cooperation

There are few laws and regulations in force at present that have been explicitly enacted to govern access to genetic resources or to clarify the questions related to private versus community rights. Most countries face significant new challenges regarding administrative competencies and jurisdictions for regulating access to genetic resources, particularly given the partially conflicting directives of the major international treaties. Although CBD predates TRIPS, it is not clear which treaty takes precedence when conflicts occur; TRIPS has enforcement and penalty provisions, CBD does not, but both treaties have equal nominal authority. Thus the dearth of legal, institutional, and scientific capacity to deal with
these complex biodiversity, trade, and property rights issues is exacerbated by the lack of clarity within the international policy framework.

<table>
<thead>
<tr>
<th>CBD vs. TRIPS</th>
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| **Main CBD issues** | Conservation of biodiversity  
Sustainable use of its components  
Fair and equitable sharing of benefits on derived products  
Protection of traditional access to genetic resources and technology |
| **Main TRIPS issues** | Reduce distortion and impediments to international trade  
Promote effective and adequate protection of intellectual property rights (IPR), including for plant varieties and other genetic innovations  
Ensure that measures and procedures to enforce IPR do not themselves become barriers to legitimate trade |
| **Potential Conflicts** | TRIPS asserts IPR protection on life forms; CBD asserts national sovereignty and right to prohibit such protection  
CBD promotes equitably shared benefits from use of biological resources and protection of traditional knowledge; TRIPS promotes private appropriation of benefits with no mechanism for acknowledging role of traditional knowledge from which industrial applications may derive |
| **Potential Resolutions** | Article 1 of TRIPS provides some flexibility, allowing domestic law to exceed minimum protection standards—a provision that could allow member nations to enact legislation to protect traditional knowledge  
Article 27.2 of TRIPS allows for the exclusion from patentability based on public order or morality  
Article 27.3b of TRIPS allows for the development of unique IPR protection systems for plants, animals, and essentially biological processes, creating an opportunity to develop alternative IPR regimes appropriate to the needs and conditions of traditional communities |

Source: Data Compiled from TRIPS agreement and CBD

There are differences in rationale, origins and overall framework of the CBD and the TRIPS Agreement. TRIPS is a commercial treaty with
commercial objectives that largely benefit strong private firms. On the other hand, the establishment of the CBD was prompted mainly by the growing concern over the rapid worldwide loss of biodiversity, a recognition of the important role of traditional knowledge and the rights of local communities that develop and hold the knowledge, and the need to regulate access to and the sharing of benefits deriving from the conservation and sustainable use of biodiversity.

Article 16(5) of the CBD, in fact, recognises that IPR can have a negative effect on the implementation of the CBD provisions, and thus, urges Parties to cooperate to ensure that IPR are supportive and do not run counter to the CBD objectives. The discussions raised under the TRIPS Council have dealt with the relationship with the CBD, as well as the review of Article 27.3(b). (Gervais 2003:228-30) Nonetheless, developing countries argue that they feel consistently exploited because of structural imbalance between countries rich in biological diversity and those strong in technological and legal instruments.\(^6\) They contend the CBD is intended to conserve and use biological diversity of developing countries on a long-term basis, while TRIPS is intended to provide private property rights over products and processes. According to the developing countries’ standpoint, TRIPS Agreement influences the provisions of the pre-existing CBD in the access to genetic resources, the fair and equitable sharing of benefits from the utilisation of genetic resources, and the respect for traditional knowledge held by the indigenous communities.\(^7\)

Based on the principle of national sovereignty enshrined in the CBD, countries have the right to regulate access of foreigners to biological resources and knowledge, and to determine benefit sharing arrangements. TRIPS enables persons or institutions to patent a country’s biological resources (or knowledge relating to such resources) in countries outside the country of origin of the resources or knowledge. In this manner, TRIPS


\(^7\) Ibid.
facilitates the conditions for misappropriation of ownership or rights over living organisms, knowledge and processes on the use of biodiversity takes place. The sovereignty of developing countries over their resources, and over their right to exploit or use their resources, as well as to determine access and benefit sharing arrangements, is compromised.

Developing countries argue that CBD Article 15.1 recognises the sovereign rights of States over their national resources and that national governments might determine access to genetic resources. Also, under CBD Articles 14.4 and 14.5, the CBD simply submits access to genetic resources to the "prior informed consent" of the party on mutually agreed terms aimed at sharing the benefits arising from the utilisation of such resources. However, on the contrary, it is said that biological resources should be subject to private intellectual property rights under TRIPS Articles 21 and 27. Thus, developing countries assert that the conflict arises, while national sovereignty in the CBD implies that countries have the right to prohibit patents on life forms, and TRIPS requires provisions of intellectual property rights on life forms.\(^8\)

A key aspect of the CBD is that it recognises the sovereign rights of states over their biodiversity and knowledge, and thus gives the state rights to regulate access, and this in turn enables the state to enforce its rights on arrangements for sharing benefits. Access, where granted, shall be on mutually agreed terms (Article 15.4), shall be subject to prior informed consent (Article 15.5), countries providing the resources should fully participate in the scientific research (Article 15.6) and, most importantly, each country shall take legislative, administrative or policy measures with the aim of “sharing in a fair and equitable way the results of research and development, and the benefits arising from the commercial and other utilisation of genetic resources with the contracting party providing such resources. Such sharing shall be upon mutually agreed terms”.

Under TRIPS, there is no provision for the patent holder on claims involving biological resources or related knowledge to share benefits with the state or communities in countries of origin. In fact, there is little that a

\(^8\) Ibid.
country of origin can do to enforce its benefit-sharing rights (recognised in CBD) if a person or corporation were to obtain a patent in another country based on the biological resource or related knowledge of the country of origin. While a legal challenge can be launched, such legal cases are prohibitively expensive. Even if a state has the resources to legally challenge a patent in another country, it may not have the resources to track down and challenge every patent that it believes to be a case of bio-piracy against it, nor is there a guarantee of success. Thus, if the patent laws, the administration of approvals, or the courts of a particular country operate in a context that is favourable to granting such patents, there is little that can be done by a country of origin to ensure that bio-piracy does not take place, or that if it takes place that it can get a remedy.9

In the preamble of TRIPS, it is recognised that “intellectual property rights are private rights”. Patents confer exclusive rights on its owner to prevent third parties from making, using, offering for sale, selling or importing the patented product, and to prevent third parties from using the patented process (and from using, selling or importing the product obtained from the patented process). In TRIPS, the award of IPR over products or processes confers private ownership over the rights to make, sell or use the product or to use the process (or sell the products of that process). This makes it an offence for others to do so, except with the owner’s permission, which is usually given only on license or payment of royalty.

IPR, therefore, have the effect of preventing the free exchange of knowledge, of products of the knowledge, and their use or production. This system of exclusive and private rights is at odds with the traditional social and economic system in which local communities make use of, and develop and nurture, biodiversity. For example, seeds and knowledge on crop varieties and medicinal plants are usually freely exchanged within the community. Knowledge is not confined or exclusive to individuals but shared and held collectively, and passed on and added to from generation to generation, and also from locality to locality.

9 Ibid.
The CBD has several provisions that acknowledge this and also that aim at protecting community rights, the key provision being Article 8(j). However, the contribution and nature of community knowledge and community rights are not recognised in the TRIPS agreement. Instead, the patent system endorsed by TRIPS favours private individuals and institutions, enabling them to acquire “rights”, including rights over the products or knowledge, whose development was mainly carried out by the local communities. TRIPS and the enactment of patent laws relating to biological materials in some countries have facilitated the misappropriation of the knowledge and resources of indigenous and local communities, and the number of “bio-piracy” cases has been increasing at a rapid rate. This misappropriation is counter to the principles and provisions of the CBD that oblige countries to recognise local community rights and fair benefit sharing. Indeed, one of the main objectives of establishing the CBD was to counter the possibility of misappropriation or “bio-piracy”, whilst one of the effects of TRIPS has been to enable the practice of such misappropriation.

4.4.3 Towards a review of TRIPS and CBD

In the review of TRIPS (which is provided for in Articles 27.3(b)), amendments should be made in Article 27.3(b) to bring the scope of exclusion of biological materials and processes in line with environmental and ethical considerations as well as the need for preventing bio-piracy; and an interpretation can be made that the sui generis option for plant varieties can include the protection of traditional knowledge and local community rights, in line with the CBD.

Amendments can also be made to TRIPS, in the context of the review under Article 71.1, to strengthen the obligations of developed countries to ensure the transfer of technology to developing countries, or to operationalise the implementation of technology transfer. Consideration can also be given to revise TRIPS to allow for exclusion or relaxation of standards of IPR relating to environmentally-sound technologies, and to technologies that relate to the use of biodiversity. This would bring TRIPS more in line with the spirit of the CBD, and with Article 16 provisions, including those dealing with technology transfer on concessional and
preferential terms (para 2) and with the need to ensure that IPR are
supportive of and do not run counter to CBD objectives (para 5).

In a review of the CBD, Article 16 could be amended to remove the
tensions in Article 16, so that the important objectives and principles of
access to and transfer of technology to developing countries are not so
constrained, as with the present CBD, by the references to the need to be
consistent with adequate and effective protection of IPR and international
law. The obligations on technology transfer can also be strengthened and
the implementation made more operational.

It should also be recognised that the present provisions in the CBD
on access to genetic resources now place the onus of implementation on
national policies and legislation. However, measures by national
authorities are insufficient to enable effective implementation of access and
benefit sharing arrangements. For example, in its national legislation, the
state of a country of origin may require as part of its access contract that the
collector cannot patent the product or knowledge (or that such a patent can
be applied for only under certain conditions or benefit-sharing arrangement);
but that state would require the cooperation of patent authorities or Biodiversity Authorities of other states to be able to monitor
or effectively implement that contract. An international protocol would be
required to establish guidelines and standards for access and for fair and
equitable sharing of benefits, as well as to establish international
cooperation to facilitate implementation of the access and benefit-sharing
arrangements. 10

India as a founding member of both CBD and WTO initiated
enactments of domestic laws in order to comply with her international
obligations. The following sections illustrate how India was forced to enact
Biodiversity Act 2002 and completely revamped intellectual property
regimes in the wake of TRIPS agreement.

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10 Third World Network (2001): “Intellectual property rights, TRIPS Agreement and the
CBD,” TWN Statement to the 2nd meeting of the Panel of Experts on Access and
4.5 Traditional knowledge (TK) and Globalisation

The TK that indigenous peoples have developed over the course of the millennia, and which they still hold, has a fundamental role in the conservation and sustainable use of biodiversity. Where these peoples live in equilibrium with nature, harmonised ecosystems still exist. This maintains cultural diversity and their associated knowledge about flora, fauna, and ever-evolving interconnections.

Globalisation is jeopardising the normal development of many indigenous peoples around the world in three main ways. First, it is creating sophisticated legal mechanisms to control the management of vast territories in the name of conservation. Second, globalisation has exponentially increased the chances of acquiring first-hand information about the knowledge that indigenous peoples have of plants, animals, fungi and other living organisms, thus becoming medicinal prospects for pharmaceutical industries. Third, the intrusion of western styles in their traditional cultures and the exploitation of natural resources in their territories—a typical behavior of the western actor—have produced emigrations as well as the consequent subsuming of indigenous peoples as a whole.

This complex combination of factors has enhanced the erosion of TK, which in turn produces additional vulnerability of ecosystems. It has been shown that indigenous knowledge of medicinal plants and food decreases research and production costs by 40% or by $200 million a year. Ten years ago, the global pharmaceutical industry had yearly revenues for over $32,000 million. Traditional knowledge about ecosystems, specifically regarding medicinal plants and animals, has become the "green gold" of transnational corporations, representing increasingly important economic advantages for just a few.

4.5.1 From Bio-prospecting to Bio-piracy?

Bio-prospecting is defined as the "exploration of wild plants and animals for commercially valuable genetic and biochemical resources." Bio-prospecting is a fair enterprise based on certain legal conditions and benefit sharing. Bio-prospecting can help medical and other scientific research by collecting biological samples. Bio-piracy, on the other hand,
occurs when corporations use the folk wisdom of indigenous people to locate and understand the use of medicinal plants and then exploit this knowledge commercially. Bio-piracy refers to the appropriation and monopolisation of a traditional population's knowledge and biological resources, including the smuggling of diverse forms of plants and animals. Bio-piracy results in traditional populations losing control over their resources. (Song 2005: 271)

The term has gained popularity in use only over the past decade. Prior to that, research expeditions occurred regularly with the purpose of finding, collecting, and making use of the rich abundance of biological diversity worldwide with little to no legal repercussions.\(^{11}\)

The expeditions funded by pharmaceutical companies are in no way undertaken for the simple goal of expanding knowledge of the unknown. Nor are they intended to satisfy the researcher's innate desire for learning. The entire purpose of these expeditions is to acquire as much local knowledge of traditional biological applications and collect "genetic samples from plants, animals and humans for later use in product research and development." The controversy stems from the multinational companies accumulating huge benefits while basically forgetting to share any of the profits with the countries providing the resources. (Marden 1999: 279)

A rational definition of 'bio-piracy' would focus on activities relating to access or use of genetic resources in contravention to national regimes based on the CBD. Accordingly, a legitimate claim of 'bio-piracy' will involve unauthorised access to a controlled genetic resource and using that resource in a manner that contravenes the national regime. In practical terms, this means that (a) the activity in question occurred after the CBD came into force (December of 1993), and (b) the acts consist of a party gaining access without the consent of the source country, or in contravention to laws or regulations governing access to or use of genetic resources that the country has established.

This concept of bio-piracy stands in stark contrast to the claims of bio-piracy that are made with ever-increasing frequency by certain groups. For these groups, bio-piracy consists of an innovator gaining access (legitimate or otherwise) to some genetic resource, making an invention, and filing a patent application. Indeed, some groups make lists of 'examples' of bio-piracy that consist merely of patent applications. It is hard to see how the filing of a patent application can, in itself, amount to 'bio-piracy'. The filing of a patent application presumes that something beyond the information relating to the genetic resource has been developed; namely, an invention. By attacking the innovative process itself, including efforts to obtain intellectual property protection for inventions arising out of use of genetic resources, these groups will ultimately prevent or deter parties from even attempting to create benefits that could be shared under the CBD model. Of course, the CBD may require equitable sharing of the benefits from such an invention; if this does not take place, this could then reasonably be termed 'bio-piracy'. However, the wrong does not lie in filing the patent application, but in failing to deal fairly with the parties that helped create the opportunity for innovation.12

4.5.2 Interpreting Patent legislation: A case of bio-piracy

In 1980, the Supreme Court of United States indirectly addressed the question of whether bacteria qualified as patentable subject matter. The Court explained that the relevant consideration was whether the invention was the product of human intervention. This decision paved the way for future applications containing eukaryotic organisms. The PTO adopted the policy of addressing patentability on a case-by-case basis according to the precedent established in Chakrabarty. Chakrabarty, a genetic engineer employed by General Electric, developed a bacterium from the genus Pseudomonas that was capable of breaking down crude oil. It was suggested that the bacterium could be used for treating oil spills. With the organism originally rejected by the PTO as unpatentable subject matter, the issue

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eventually went to the Supreme Court. Ultimately, in a 5-4 ruling, the Court held in favour of Chakrabarty, stating "A live, human-made micro-organism is patentable subject matter under Title 35 USC 101. Respondent's micro-organism constitutes a 'manufacture' or 'composition of matter' within that statute." Just because the subject matter of the patent is a living organism does not bar the subject matter from patent protection. In other words, the Court's holding set the stage for future courts as well as the PTO to give wide scope to their interpretation of patent laws. (Moyer-Henry 2008: 3)

The Supreme Court decision in Chakrabarty was vital to progress in the biotechnology industry. The industry uses an abundance of natural discoveries, particularly living organisms, in most of the new products it develops each year. From pharmaceuticals to agricultural engineering, the active ingredients behind many of the most remarkable inventions are from plants and organisms discovered in the diverse ecosystems of smaller, less developed countries. Company representatives travel to remote locations looking for "undiscovered" traditional medicine that could possibly be commercialised for profit. (Moyer-Henry 2008: 3)

Indeed, in the ten years following Chakrabarty's victory, patents were extended in rapid order to isolated and purified genetic sequences, to man-made plants, and to animals. By the turn of the millennium, raw biological material increasingly moved from an open access or global commons good to a private or government-owned good. (Safrin 2007: 1927-28)

4.6 Summary

The forgoing discussion reveals that many developed countries and most developing countries had opposed the very inclusion of new themes in the Uruguay Round of GATT negotiations. However, the TRIPS Agreement was enforced on the international community at the insistence of the United States. Ever since the agreement came into force, there were huge opposition to most provisions in the TRIPS Agreement all over the world.
A review of the provisions of TRIPS Agreement, which was attempted in this chapter, reveals these provisions have radically altered the very nature, scope and duration of prevalent IPR provisions in national legislations. TRIPS have also introduced universal and uniform standard of protection in a fashion that one size fits all approach. From the standpoint of economic development and technology transfer, the findings of UNDP report that countries at low levels of human technological capability can not benefit significantly from TRIPS Agreement are serious and quite disturbing. The most controversial point of the TRIPS Agreement, at least from indigenous perspective, has been article 27.3 that requires state to include plants and animals within the inventions eligible for patenting or develop a sui generis plan for protecting these inventions.

Perhaps, one of the most contentious areas in the negotiations under WTO and CBD has been on the matters related to the protection of biodiversity and traditional knowledge resources. As a matter of fact, protections of such resources have been confronting a severe crisis primarily due to the provisions for patenting of life forms enforced by the TRIPS Agreement. These provisions have found a place in the TRIPS Agreement primarily due to revolutionary breakthrough in the biotechnology industry under monopoly control of multinational companies based in the United States and Europe. It has been rightly argued that the challenges posed by biotech multinational companies have redefined the very notion of security.

Conversely, many of the provisions in the CBD are found to be in tune with the development aspirations and efforts to protect biodiversity and traditional knowledge resource base of developing countries. The mismatch in this regard is most evident in the article 16 (5) of the CBD and article 27.3(b) of TRIPS. Article 14.4, 14.5 and 15.1 of the CBD reinforce the need for ABS and PIC. In that sense, there are conflictual areas in the TRIPS Agreement and CBD which demand a review of such provisions so that the minimum interests of all stake holders are protected. It would also restrict the tendencies opportunities for manipulation and unfair dealings through bio-piracy and bio-prospecting. A number of cases of bio-piracy
have been reported from developing countries in Asia, Africa and South America, reflective and illustrative of the ambiguities and mutually contradictory prescriptions in the TRIPS and CBD.

An examination of Indian experience in this regard reveals that until the advent of TRIPS Agreement, the IPR protection in the country has served well the interests of the people and society on the one hand and the legitimate interests of the right holders on the other. Implementation of the TRIPS Agreement in India, as in the case of other developing countries, did experience a variety of challenges, the intensity of which was felt high in the realm of protection of indigenous and traditional knowledge as well as biodiversity resources.

As a signatory to TRIPS Agreement, a series of initiatives have been enacted in the country to ensure compliance with the TRIPS. Such initiatives include amendment of Patent Acts and series of Acts related to Biodiversity, Copyright etc. In this regard, the Patents Act, 1970 was amended twice, first during June 2002 and later during April 2005 to comply with the TRIPS obligations. Besides, Trade marks are protected under the Trade Marks Act, 1999 and the Trade Marks Rules, 2002, which repealed the Trade and Merchandise Marks Act, 1958. Legislation governing industrial designs in India is the Designs Act, 2000 and the Designs Rules, 2001. Copyright is protected under the Copyright Act, 1957, most recently amended in 1999. Geographical indications are protected under the Geographical Indications of Goods (Registration and Protection) Act, 1999 and the Geographical Indications of Goods (Registration and Protection) Rules, 2002. The Geographical Indications Registry was established on 15 September 2003. The Parliament passed the Protection of Plant Varieties and Farmers' Rights Act in 2001. The Semiconductor Integrated Circuits Layout-Design Act was passed in September 2000. One of the most important amendments that try to protect the biodiversity associated traditional knowledge was Indian Biodiversity Act, 2002. The immediate concern of such an act was ever increasing biopiracy resulted with the advent of Information and Communication Technology and Biotechnology.
In brief, the dearth of legal, institutional, and scientific capacity to deal with these complex biodiversity, trade, and property rights issues have been exacerbated by the ambiguity in the international regulatory framework. A review of the provisions in the TRIPS Agreement especially Article 27.3 is the essential minimum to prevent bio-piracy. The recognition of the provisions in the CBD especially those related to ABS and PIC will be in the interests of the protection of biodiversity associated traditional knowledge in developing countries.