Chapter 8

Conclusion and Recommendations

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8.1 Suggestions

a) Trade Related Aspects of Intellectual Property Rights

b) Protection of Plant Varieties and Farmers' Rights Act, 2001

c) Indian Patent Act

8.2 Harmonizing Intellectual Property Rights & Biodiversity

8.3 Recommendations

8.4 Conclusion

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Intellectual Property Rights (IPRs) have assumed central importance throughout the world in the recent past. Intellectual property is the creative work of the human mind. The main motivation for its protection is to encourage creative activities. The contribution of intellectual property to industrial and economic development of a country cannot be exaggerated. The prosperity achieved by developed nations is the result of exploitation of their intellectual property. The protection of intellectual property is also responsible for the transfer of technology from developed countries to the developing countries. Since the role of intellectual property is *sine qua non* in the industrial and economic development of a country, it becomes therefore inevitable to protect it. Yet, at the same time, this branch of law is necessitated and aims to promote and protect the interest of an individual to secure a fair value for his intellectual effort or investment or capital or labour. However, the recent provisions in TRIPs and the subsequent judgments by the various courts have expanded the scope of patentability beyond human imagination and have brought all living organisms like plants, animals including human beings under the ambit of Intellectual Property Rights.

The granting of patents on life forms have awakened the world to the horrific implications of IPRs on life forms and biotechnologies

and have increasingly brought demands for severe curbs on this runway, out-of-control juggernaut. This new emerging IPR regime has caused a serious threat to biodiversity itself. Establishing property rights over living beings has also raised serious issues on environment. Life forms are part of public domain. Subjecting the ecological and cultural heritage of indigenous communities to the legal regime of commercial monopoly rights will place them in serious jeopardy.[1] Granting patents on life forms may lead to an extinction of several species of flora and fauna, ultimately causing imbalance in the environment. The review committee on the constitution of India has also suggested that the fundamental right of "right to life" guaranteed under article 21 of the constitution of India also includes "right to live in a healthy environment". Any attempt to cause an imbalance in the environment may amount to an infringement of this fundamental right.

Considering the impact of intellectual property rights on biodiversity, many developing countries including India have made an attempt to enact legislations to check the onslaught of IPRs on biodiversity. However, due to the short sightedness of the country's politicians who act under the pressures of the profit-hungry MNCs that have always placed profits before people, the present legislations are not enough to protect biodiversity.

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[1] *M D Zafar Mahfooz Nomani, "Laws and flaws relating to conservation of biological diversity: A kaleidoscopic view", 2, The Company Law Journal, 2000 at pp 17-22*

Intellectual property is integral to the progress of humankind and an indispensable element in the economic development in a global environment and so it is essential that its utilization also assures protection of basic human values. Benefits of intellectual property should transcend evenly to creators and users without distinction or discrimination of any kind and the deployment of resources should be directed in such a manner so as to ensure equal opportunity among nations to enjoy the fruits of knowledge based progress. To prevent piracy and to protect our knowledge system there is an urgent need of its documentation. There is also a need to institute a mechanism for sharing the benefits arising out of commercial exploitation of biological resources using such Traditional Knowledge. This chapter makes some fundamental recommendations to bridge the gap between these two diverse necessities.

8.1 Suggestions

a) Trade Related Intellectual Property Rights

The TRIPs Agreement should provide that Members shall require that an applicant for a patent relating to biological material or to Traditional Knowledge shall provide, as a condition to acquiring patent rights:

1. Disclosure of the source and country of origin of the biological resource and of the Traditional Knowledge used in the invention;

2. Evidence of prior informed consent through approval of authorities under the relevant national regimes;

3. Evidence of fair and equitable benefit sharing under the relevant national regimes.

Such measures are fully in line with the provisions of the Convention on Biological Diversity and its recommendations on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilisation. An amendment of the TRIPs Agreement to include such provisions would prevent systemic conflicts with the CBD arising from the implementation of TRIPs.

From a practical standpoint, it would be more cost-effective to establish an internationally accepted solution as suggested above to prevent bio-piracy than to divert national resources to expensive judicial processes for the revocation of patents that include illegal genetic resources (as experienced, for instance, by the Govt. of India in challenging patents abroad over its genetic resources). Developing countries, in particular, do not have the resources to follow each and every patent issue outside their territories on the use of their resources.

Besides, this would also address the crucial problem of coherence between two binding international agreements. Consequently, the proposed amendment would have the clear benefit of providing a predictable environment for governments,

investors, traditional communities and researchers. Research and development in biotechnology in developing countries would thus be encouraged, which would be in line with the objectives of the TRIPs Agreement to promote technological innovation and the transfer and dissemination of technology.

The proposed requirements would also represent an important step towards ensuring, although only to a limited extent, protection of traditional knowledge from unauthorized patenting by third parties without the prior informed consent of the traditional communities that hold the involved knowledge. Traditional communities have faced threat of misappropriation of their knowledge arising from increasing evidence of bio-piracy and the grant of bad patents. One of the major concerns in the global community today refers to the patenting of new biotechnological inventions based on the biological resources and associated traditional knowledge, without any share of the benefits arising out of commercial use to the communities who conserved and developed such resources and knowledge.

The incorporation of the proposed requirements in the TRIPs Agreement, however, would only provide defensive protection for traditional communities from misappropriation of their knowledge, associated or not to genetic resources through unauthorized patenting. Consequently, it might be necessary for the TRIPs Council to give further considerations to proposals regarding an international framework to provide positive protection of traditional knowledge, which would recognize

protection of traditional knowledge at the national and regional levels. These proposals are: (i) local protection to the rights of TK holders through national level *'sui generis'* regimes including customary laws as well as others and its effective enforcement *inter alia* through systems such as positive comity of protection systems for TK (ii) protection of traditional knowledge through registers of TK database in order to avoid misappropriation (iii) a procedure whereby the use of TK from one country is allowed, particularly for seeking IPR protection or commercialization, only after the competent national authority of the country or origin gives a certificate (international certificate regime) that source of origin is disclosed and prior informed consent, including acceptance of benefit sharing conditions, obtained (iv) an internationally agreed instrument that recognizes such national level protection. To ensure a more equitable sharing of benefits arising out of the use of biodiversity, the following proposals can be adopted:

1) Charging collection fees- At the time of collection, the community or country can charge appropriate fees.
2) Paying for the past and present- by pricing traditional knowledge, which already has current commercial value. The current market value could be assessed, their origins determined, and appropriate compensation paid to local communities or countries.
3) Fixed royalties- A certain percentage of profits can be committed as royalty payments to the country/community of origin of the material.

4) Rewards- by rewarding farmers through fairs competitions, which would help determine the value of their innovations and ideas relevant to biodiversity and provide incentives to farmers who maintain high diversity in their fields.

5) Financial support- Insurance companies can underwrite the premium obligation for traditional communities who maintain bio-diverse farming systems. National credit systems can be extended to them.

6) Development and resource regeneration inputs- Communities who have excelled in biodiversity conservation, development and knowledge, could be given special inputs of appropriate development projects and programmes for regenerating natural resources.

7) Exemption from the application of IPRs- This could be in the form of a system of automatic licensing rights, without royalty payments, to Third World countries for all patents of materials derived from their biodiversity.

Article 27.1 of the Dunkel Draft on TRIPs lays down that patent rights shall be enjoyable without discrimination as to whether the products are imported or locally produced. This may give rise to the controversy that importation is to be regarded as working of the patent in all circumstances. This has to be amended to harmonise it with article 5 of the Paris Convention that lays down that if a patentee fails to work a patent, or works a patent insufficiently and he has no legitimate reasons for the failure to work or insufficient working, it is open to the host country to grant a compulsory licence.

Article 31 (b) of the Dunkel Draft that allows compulsory licensing in the event of national emergencies, should be extended to article 8.1 of the Draft that lays down provisions relating to formulation of national laws and regulations to protect public health, nutrition and public interests.

Article 27.3 (b) that allows patenting of microorganisms should be amended to exclude naturally occurring genes, including those that are trivially modified.

Furthermore, the following changes must be negotiated during the next review of TRIPs. India must play a strong and enabling role in this process and help to coordinate the efforts of developing countries to secure basic rights for their citizens.

1. The review of Article 27.3(b) must be one of a *substantive* nature, not merely of implementation. We need to revisit the provisions and correct the fundamental inequities contained in them, not just make a chart of which country has implemented what.

2. A clause for Disclosure will have to be introduced in TRIPs. Members should revise Article 27.3 (b) and/or Article 29 of the TRIPs Agreement, so that the source of patented material has to be disclosed. This would prevent biopiracy. The requirements for patent applications should be revised to help prevent misappropriation of knowledge regarding genetic

resources and to ensure consistency with access and benefit sharing regimes of the CBD.

3. A substantive review of Article 27.3(b) should be completed and the review should seek to harmonise the TRIPs Agreement with the CBD and the International Undertaking on Plant Genetic Resources where rights of farmers and communities are recognised.

4. The period for implementation of Article 27.3(b) should logically be extended till after a substantive review is completed.

5. The exceptions to patentability under Article 27.3(b) should be expanded. At a minimum, members must have the discretion not to grant plant and animal patents that the current language of Article 27.3(b) allows. The discretion to refuse patents over life is essential to give Members who are also CBD Parties the flexibility they need to experiment with approaches for implementing CBD.

6. The flexibility that the GATT allowed in defining *'sui generis'* systems for the protection of new plant varieties should be retained. Members should have the right to determine their own *'sui generis'* system. UPOV which is a platform for regulating *'sui generis'* systems like Plant Breeders' Rights in industrial countries and of which no developing country is a member, is not mentioned in the TRIPs agreement. The

current effort to make UPOV the only "effective" *'sui generis'* platform acceptable under TRIPs is unjustified and must be abandoned.

India has already drafted a *'sui generis'* legislation called the Plant Variety Protection and Farmers' Rights Act. This is not in line with UPOV. Gene Campaign has drafted an alternative treaty to UPOV called the Convention of Farmers and Breeders (CoFaB). The UN Human Development Report has termed CoFaB a far superior option for developing countries than the restrictive UPOV. CoFaB or something similar should form the basis for a *'sui generis'* platform for developing countries, not UPOV.

7. A "sustainability review" provided under Article 71.1 of the TRIPs Agreement should be undertaken straightaway to assess the impact of TRIPs on the capacity of developing countries to engage in sustainable growth and development. The TRIPs review should ensure that implementation of the TRIPs Agreement supports its objectives, as set out in its Preamble and Article 7, as well as the broader objective of the WTO to promote trade "in accordance with the objective of sustainable development". In the event that the TRIPs Agreement fails to meet these objectives, or is found to be inconsistent with the successful implementation of international agreements, such as the CBD, WTO Members should amend it, as permitted by Article 71.1 and Article X of the WTO Agreement. As required in Article 16(5) of the CBD,

Parties must cooperate to ensure that IPRs are supportive of, and "do not run counter" to, the objectives of the CBD.

8. A cessation must be put on unilateral pressure and challenges at the WTO dispute settlement system. WTO Members should agree to a cessation on any challenges against developing countries until the reviews under Articles 27.3(b) and 71.1 are complete, and any extended transitional periods are over. Further, WTO Members should refrain from exercising unilateral pressure that aims to have developing countries implement intellectual property regimes that offer a higher level of intellectual property protection than required by the TRIPs Agreement. The EU has been having bilateral consultations with countries like Jordan and Pakistan and recommending that they accept UPOV 1991. This is unfair and undesirable.

9. CBD objectives must be taken into consideration in the WTO dispute settlement process. In the event of a conflict, the TRIPs Agreement must not interfere with a Party's legitimate implementation of its CBD obligations.

10. And finally, the human rights concerns that have been raised with respect to TRIPs, should be taken on board. The TRIPs agreement should be modified so that it does not violate the rights of ordinary citizens.

b) Protection of Plant Varieties And Farmers' Rights Act, 2001

There are some provisions in the Law that need to be changed and amended. The use of farmer's varieties to breed new varieties should be paid for. Revenue should flow into a National Gene Fund. Despite its good intentions of protecting the interests of the farming community, the formulation of this section [46 (2) d], is likely to create problems in implementation because of poor, even incomplete, drafting. The Gene Fund should be the recipient of all revenues payable to the farming community under various heads. Farming communities should collectively, rather than individually, access this money, except in clear cases where an identifiable farmer's variety has been used. Farmers should have the right to decide how this money that they have earned will be spent. The use of the money should not be restricted to conservation or for maintaining ex-situ collections. The method for fixing and realising benefit sharing should be made simpler and easier to implement. One approach could be a system of lump-sum payments, based for example on projected volume of seed sale.

In providing a liability clause in the section on Farmers' Rights, the farmer in principle is protected against the supply of spurious and/or poor quality seed leading to crop failures. At present too much is left to the discretion of the Plant Variety Authority which will fix the compensation. This will lead to arbitrary decisions and should be amended. If it is proved that

the breeder has made false claims and the farmer has suffered a crop failure, then compensation should be awarded amounting to at least twice the projected harvest value of the crop. Compensation should be large enough to be a deterrent. In addition, a jail term should be provided if the breeder repeats the offence.

The legislation has also attempted to address a concern voiced by several quarters, that when the new system of PBRs is imposed for the first time, there will probably be many cases of unknowing infringement of Breeders' Rights. Section 43 specifies that the farmer cannot be prosecuted for infringement of rights specified in the Act if he can prove in court that he was unaware of the existence of such a right.

This is well intended, but badly drafted, and has to be made more specific. Nothing is said about what will constitute a violation of Breeders' Right. This is especially critical since the Act would allow the farmer to sell generic seed of the variety protected by Breeders' Right. And what would constitute proof in a court of law that the farmer was unaware of the existence of such a right? In all likelihood this will boil down to a 'your word against mine' situation and be very difficult to prove.

Breeders' Rights over the varieties they have developed are more than adequately protected by the draft legislation. On registration, the Breeder has rights of commercialization for the registered variety either in his/ her own person or through

anyone designated. These rights include the right to produce, sell, market, distribute, import or export a variety, in short, full control over formal marketing. The strong protection granted to a plant breeder over his/her variety is seen in the section dealing with infringement of Breeders' Rights where punishment in the form of substantial fines and jail terms has been prescribed for those who infringe the rights of the registered breeder.

Violation of Breeders' rights can be construed at several levels. It applies to the variety itself as also to its packaging. Infringement will be established if the packaging is the same or even similar, such that the package could appear to be that of the Breeder. Legally, a similar looking package will be considered "Passing Off" and so actionable. Any one other than the Breeder naturally cannot use the registered name or denomination. The use of the same or similar name in any way, by action or even suggestion, will constitute a violation and will be punishable. Penalties are prescribed for applying false denomination and for selling varieties to which false denomination is applied.

Breeders' Rights have been strengthened to the extent that if there is mere suspicion of violation or infringement, the onus of proving innocence is on the alleged violator. In any prosecution for falsely using a denomination, the burden is reversed and it is incumbent on the alleged violator to prove that the consent of the Breeder was obtained. This needs to be toned down. The normal course in law is for the accuser to furnish proof for the accusation and so it must remain in this case too.

Penalties can range from 50,000 to one million rupees, as well as a jail term ranging from three months to two years, depending on the severity of the damage caused. If the violator is actually selling, offering for sale or merely in the possession of a registered variety belonging to someone else, the punishment is somewhat worse. The penalty remains the same, but the jail term applicable will not be less than six months, going up to two years. If the offence is repeated, the minimum jail term prescribed is one year, extending to three years and the fine starting at 1 million rupees, can go up to two million.

There is much that can be improved in the Act. The drafting and language are poor and need improvement. A separate fast track for the clearance of EDVs, which will often be GM varieties, raises questions. EDVs should be dealt with in the same way as other conventionally bred varieties, providing the same opportunities for their examination and opposition, as has been provided for the registration of other varieties.

On the whole, the Act advocates very strong Breeders' Rights but equal weightage should be given to Farmers' Rights.

c) Indian Patent Act

The second amendment to the Indian Patent Act, 1970 brought about a lot of changes in 2002. Since the amendments made in 2002 were neither sufficient to protect the interest of our country nor did the profit-hungry multi-nationals find them suitable, a

third amendment was inevitable. In 2005, further amendments were carried out in the Patents Act, 1970, which is known as the Patent Amendment Act, 2005. The common man, environmentalists and legal professionals, all had high hopes from the government. But the government failed to protect the country's interest once again. This new Amendment Act, 2005 is like old wine in a new bottle. The cosmetic changes made in the Act are nowhere beneficial to our country and especially our biodiversity but will be helpful only to multi-nationals. Not a single provision has been made in this amended Act which can protect the rich biological heritage of the country. In this chapter, the amendments are analysed within the purview of TRIPs. While carrying out the third Amendment in 2005, India could have taken the following steps –

Abuse of Intellectual Property Rights should be recognised as a ground for revoking the patent. If as Article 61 of TRIPs agreement has provided, criminal procedures and penalties can be applied in cases of infringement of intellectual property rights, there is no reason why an abuse should not be penalised. Threat of penal consequences through proper procedure would alert the patentees to be careful in their pricing strategies even when they are the sole producers.

Compulsory Licence

Article 31 of the TRIPs agreement dealing with compulsory licensing (CL) does not place any restriction on the grounds under which a CL can be given. The Patents Act, 1970 had a

clear strategy – to eliminate the monopoly of the transnational corporations (TNCs) and remove the bottlenecks in the previous regime which prevented the indigenous firms from producing patented drugs. And it was done through a very simple process of abolishing product patents in drugs. But in the product patent regime being introduced in India, the indigenous firms will not be able to produce a patented drug even if they develop the processes of manufacturing, unless they get a CL. Hence it is of fundamental importance to have a simple and easy to administer and implement CL system. The TRIPs agreement does not prohibit this.

The basic problem with the amended Act is that it lacks any positive strategy. Attempts should be made to take advantage of the flexibilities that the TRIPs agreement provides. The wording of the grounds for granting CL in section 84 is not amenable to easy interpretation and is not operationally useful and the procedure specified is cumbersome. It should be made simple and easy to understand. The procedure is open-ended without any time limit imposed at any stage.

To make effective use of CL, it is important to have independent and efficient non-patentees with adequate space of operations. And to do so in a product patent regime, it is important to ensure that CL is granted not once in a while but on a regular basis. The TRIPs agreement does not prohibit this and hence there is no reason why for preventing monopolies this should not be attempted.

There is enough justification to carry out further amendments to simplify the general provisions of CL in the Act to enlarge its use. As we have mentioned above, it is possible to frame the grounds for CL in such a way that licences can be granted without delay within a specified time. Consideration of the appeals also can be made simpler and faster by constructing suitable grounds and formulating proper guidelines. The judicial review can be replaced by a simple administrative review to make it a less time consuming affair.

In the more immediate context, the effectiveness of CL can also be improved by framing proper rules. While framing these rules, some of the administrative steps that can be taken are as follows:

Rather than adopting a case by case approach, the central government may notify the list of medicines eligible for CL in public health crises. The list should be prepared in consultation with health experts and may be revised from time to time. Any relevant new drug should be added to the list. The list may be prepared bearing in mind the specific situation in the country, such as the disease pattern, the need for drugs and the present availability. It is well known that a majority of the Indian people living in rural areas and in urban slums have little or no access to modern drugs. Medicines necessary to take care of the health needs of these people should be included in the list.

The inclusion of any drug in the list cannot be a ground for opposition and appeal. There is nothing in the TRIPs agreement

or the amended Act to suggest that it should be so. Guidelines may be issued for the royalty to be paid to the patent holders in case of CL. For any drug in the public health list, the controller may immediately after receiving an application, grant the CL, fixing a royalty rate using the royalty guidelines. Any opposition or appeal against the grant of a CL in this case can only relate to the royalty rate fixed. The opposition to the rate fixed should not hold up the use of CL. While this is being adjudicated, the non-patentee could begin to use the patent on the basis of an undertaking that the royalty rate finally decided will be paid in full. The case by case consideration of the royalty rates payable and the opportunity to oppose and appeal against the royalty rate fixed will satisfy the Article 31 clauses (a), (i) and (j) of TRIPs relating to consideration of individual merits and review of the CL decision. For other drugs too, a simple time bound procedure may be formulated for considering and deciding on CL applications. The maximum time permissible at each stage may be specified. The royalty guidelines may be used to reduce uncertainty and speed up decisions.

There must a provision in the Act to facilitate compulsory licensing even before the mandatory 3-yr period since MNC pharmaceuticals often refuse to deal with requests for compulsory licenses or demand high royalties, which will curb the abuse of patent rights by patentees. A penal provision can also be introduced for such abuse.

With respect to exporting drugs to a country, which makes a request for a generic drug, the amendment no longer requires the importing country to issue a compulsory license. However, one question that arises is whether the procedure for the grant of the compulsory license for the domestic market (under section 84 (6) discussed above) will also be the same for compulsory licenses for export. It is quite possible to argue the procedure both ways, thus potentially delaying urgent new drugs that a developing or least developing country may require.

Other areas

There are also other areas where the legislation could have made suitable provisions to protect the country's interest –

While amending the Patents Act, 1970, India has not taken full advantage of the flexibilities that the TRIPs agreement provides. While deciding on the inventions eligible for patents, the terms 'new' and 'inventive' should be defined to exclude lower level innovations such as new dosage forms or new formulations from the grant of patents. This will restrict the number of patents. Article 30 of the TRIPs agreement provides for limited exceptions to patent rights. This should be used to permit non-patentees in India to produce and export patented medicines to least developed countries, which they cannot produce themselves. This would be beneficial to both India and these countries.

At present, to meet the inventive step criteria the patentee will either have to show that the invention includes a technical advance or has economic significance, or both.

The provision should have required the applicant to comply with both requirements for an inventive step, namely existing knowledge and having economic significance and delete the term or both. Economic significance alone, cannot determine the inventive step of a patentable invention.

The amendment defines Pharmaceutical substance as any new entity involving one or more inventive steps. This provision is too broad and allows all types of pharmaceutical substances. The term 'chemical' ought to have been inserted so as to read 'any new chemical entity'.

The act permits generic manufacturers to continue producing generic version of new drugs, which are in the mailbox, by paying the patent holder a reasonable royalty, and if the generic producer has made a significant investment provided they were producing and marketing the generic version prior to 1st January 2005.

The words 'significant' and 'reasonable' are very vague and could have been more clearly defined. The reasonable royalty rate should have been fixed as a particular percentage, the norm being 4 %. For example in South Africa, Glaxo Smith Kline demanded a royalty of 25 % before the courts intervened.

Genetic Engineering

Though life forms are patentable under TRIPs there is no specific provision in any Indian Act to prevent the abuse or misuse of

genetically modified organisms. As soon as possible, governments, in cooperation with scientific experts and non-governmental organizations, should develop and adopt an international, legally binding protocol to control genetic engineering and the release of genetically engineered organisms into the environment.

Such a protocol must address the risks of genetically engineered organisms to the environment, human health and the economies of less developed countries, as the philosophy of sustainable development demands.

Until such strict regulations are in place covering the transfer, handling and use of genetically engineered organisms, there must be a worldwide cessation on their release to the environment.

Patent protection for genetically engineered plants and the means of producing them is often obtained in countries that are not members of the Organization of Economic Cooperation and Development (non-OECD states) by transnational corporations which have their headquarters in OECD states – a form of genetic colonialism. Patent protection often covers crops which are particularly important in developing countries such as cotton, sorghum, cassava, millet, banana and rye. Such patents will ensure that northern countries can control and profit from their use and secure import monopolies by preventing local production.

8.2 Harmonizing Intellectual Property Rights and Biodiversity

The ultimate analysis of the ongoing discussions is that the patenting of commodities found in the rich biodiversity of the tropics is the area where WTO has to reconsider and rework thereon. A full review of TRIPs agreement must be undertaken and India, along with other developing countries, must present its case of exclusion of so-called invention of Traditional Knowledge based on Indian traditional heritage from the existing ambit of patenting once and for all. It would be the best possible way to ensure the safety and to counter the bio-piracy of the products and processes of the developing countries by governmental and non-governmental dominant enterprises in the western countries.

The entire study is focused on two major and important issues for the sustainment and development of mankind namely biodiversity and intellectual property rights. The former being a God's gift to all who live on the earth cannot be exclusively used by man but has to be shared equally amongst all living organisms. The latter being the sole creation of mankind ideally must be used for the development and sustainment of mankind only but can man be so selfish that whatever is invented or discovered by him is kept for the benefit of him only and whatever is given by Nature is shared amongst all living creatures?

The importance of Intellectual Property Rights cannot be questioned as they can add fuel to the development and betterment of human life but this study poses the question whether the rights in the form of Intellectual Property can be extended to biodiversity including life forms for which man has either no role or a very limited role.

The study deals with various Acts, Statutes, Conventions, both national and international, on Intellectual Property Rights and biodiversity. The effects of these Acts, Statutes, Conventions on biodiversity have been discussed at length in all legal, social and economic perspectives.

The researcher concludes his study with the following findings –

1. The original idea of an invention in the mechanical domain was to grant protection to an inventor who had created an indigenous new device. However, today the scope of granting Intellectual Property Rights is not confined to mere technological inventions or inanimate objects but has been extended to plants, biological material and living organisms, thus making what was once God's creation into an individual's commercial venture.

2. It is perceived that inventions take place only in the backdrop of Intellectual Property Rights but the most important and useful inventions from the earliest times like fire and the wheel were without IPR protection. Even Newton's theory of

gravity which has provided a platform for satellites and space technology was without IPR protection.

3. The importance of IPRs in the field of medicine and telecommunication cannot be denied. Because of IPR protection scientists and researchers were encouraged to develop a newer and better technology which ultimately changed the entire human life. The researchers and scientists must be adequately rewarded for their untiring and laborious efforts.

4. Biodiversity is one of the bigger wealths of the earth but it has not got its due recognition and importance. Biodiversity plays a very critical role in the day-to-day existence of entire humankind. Unfortunately, human activity, especially in the last few decades, has ended up causing large-scale loss of biodiversity.

5. Since the great majority of the world's species remain unexplored for their potential, there is no doubt that further revolutionary discoveries such as cures for various kinds of cancer, are in store. But we will be able to tap this potential only if we are able to save these species in the first place.

6. The fact that today seeds can be patented and plant varieties protected is hitting farmers hard because of the exorbitant royalties being demanded by plant breeders. An effective *'sui*

generis' system must be developed keeping in mind the specific requirements of the country.

7. Knowledge, innovation and biodiversity have evolved through community rights and community responsibility - and the recognition of community rights is a precondition for the protection of biodiversity and the protection of people's rights.

8. Knowledge and resources flow freely from poor countries to rich countries. In the poorest countries a double loss occurs - through the theft of their intellectual and biological wealth, and then through royalty payments for what has been derived from their innovations and biodiversity.

9. Traditional Knowledge is being usurped by developed countries. Biopiracy cases concerning Traditional Knowledge of products like neem, karela, turmeric, etc. keep occurring. If IPR systems are not changed to prevent bio-piracy, over time we will be paying royalties for what belongs to us and is necessary for everyday survival.

10. Community held and utilized biodiversity knowledge systems must be accorded legal recognition as the 'common property' owned by the communities concerned.

11. Genetic modification can threaten human health or harm the environment. On the other hand, they also have the potential to alleviate mass hunger and increase the shelf life of products.

12. With patents now being granted on life forms, issues such as ownership of genetic material, safety of genetically modified organisms and potential misuse of genetic information require serious consideration.

13. With patents bieng granted to cloning methods if these methods are applied to humans, people will also be treated as 'invention' and the 'intellectual property' of the scientists involved.

14. A balance has to be struck between protecting biodiversity and protecting intellectual property. For this purpose necessary amendments need to be made in the existing laws not only at the national level but also at the international level. These laws must be formulated keeping in mind the specific requirements of each country though in a wider global perspective.

8.3 Recommendations

Intellectual Property is integral to the progress of humankind and an indispensable element in the economic development in a global environment and so it is essential that its utilization also assures protection of basic human values. Benefits of intellectual property should transcend evenly to creators and users without distinction or discrimination of any kind and the deployment of resources should be directed in such a manner so as to ensure equal opportunity among nations to enjoy the fruits of knowledge based progress.

Some suggestions are given below in order to preserve the rich biodiversity of the earth and at the same time encourage inventors by protecting their intellectual property.

1. The expansion of IPRs into the realm of biological material should be restricted.

2. Traditional farmers should be allowed to continue to save and exchange seeds that they have harvested.

3. To protect Traditional Knowledge and prevent its piracy, it must be documented at the earliest and it must be recognised as the property of the respective communities.

4. A proper mechanism for sharing the benefits arising out of commercial exploitation of biological resources using Traditional Knowledge must be instituted.

5. The TRIPs agreement should provide that a member country should require any one wanting to make an application for a patent relating to biological material or Traditional Knowledge to disclose the source and country of origin and evidence of prior informed consent of the relevant national regimes.

6. A substantive review of TRIPs must be completed and it should seek to harmonise the TRIPs with the CBD.

7. The Indian Patent Act must be amended to make abuse of Intellectual Property Rights a ground for revoking the patent.

8. An international, legally binding protocol must be developed and adopted to control the release of genetically engineered mechanisms into the environment.

8.4 Conclusion

If IPR laws in India are carefully formulated and implemented, India could be an ideal center for activities of research and development and clinical studies, with patent protection. Both domestic and global contract research organisations are viewing India as the hotbed for clinical research. Proficiency in English and skilled manpower, and availability of huge patient volunteers is going to set the pace for unprecedented opportunities for domestic manufacturers.

India has a vast domestic market as well as a vast reservoir of technical, managerial and entrepreneurial skills. It is in our long-term interest to have an intellectual property protection system that recognizes both, the need for encouraging and rewarding innovation, as well as our key public interest concerns. It must be remembered that as more and more countries adopt international norms and standards for the protection of intellectual property rights, the export of products from India to those countries in violation of intellectual property rights will not be permissible. The reason is that the world today

has become a "global village" particularly as a result of the advances in science and technology- through informatics, telecommunications, mass transportation, etc. Globalisation in human activities is a natural consequence. We should be a part of this globalisation and not adopt an isolationist stance. It will be advisable for us to adopt internationally accepted norms and standards for the protection of intellectual property rights while including provisions that are necessary to protect biodiversity.
But in participating in a global partnership as comprehensive as covered by the Dunkel Draft, we have to examine the short, intermediate and long term aspects from the viewpoint of different sectors and the advantages and disadvantages in these different time horizons. No one can deny that it is good to be part of the international body, but that has to be for the benefit of the common man and not for the profit-hungry commercial corporations or under pressure from developed countries. No doubt one cannot have everything in one's favour, but overall there must be a clear indication that the losses will not be such as to constitute colonization once again. Globalization must involve a deep consideration of issues relating to social justice and equity. Each country will, no doubt, have to give up some elements of its national sovereignty to function as part of the world community. But the developing world should not be the one that is expected to pay a major price.

Science and technology are a shared heritage of all humankind. Our past in this area is a result of equal participation of all, and our future lies in joint endeavour of diverse people throughout

the globe. In the present day situation, the fact remains that creation, mastery and utilization of science and technology are basically what distinguish the Third World from the developed nations. Modern technology breaks all barriers to development and offers the best and perhaps the most affordable hope for transforming underdeveloped nations into vibrant economical developed countries. It is also not surprising to find national development policies revolve around measures for strengthening technical knowledge based indigenously or acquiring it from abroad. The recent global trend in IPRs has made it necessary to bring the disparities within the IPR law to the minimum to develop an atmosphere of understanding and friendliness among the nations. This is perhaps the beginning towards the establishment of a global system of IPR that also protects biodiversity.