CHAPTER – 4

INTERFACE BETWEEN TRIPS AND CBD

4.1 Objects of TRIPS Agreement

The Trade Related Aspects of Intellectual property Rights Agreement is Annex 1C of the Marrakesh Agreement establishing the World Trade Organization (WTO) signed in Marrakesh, Morocco on 15 April 1994. The launch of Uruguay Round of Trade Negotiation in the context of the GATT lead to new initiatives by countries and actors seeking the strengthening of IPR framework. There was significant pressure from corporate lobbies in the United States but the progression of the idea of inserting an IPR agenda in the Trade Negotiation Round also owed to the fact that there was a broad consequence of interests among big business in many countries around the world.\(^1\) In principle the WTO – TRIPS requirements should move them in the direction of becoming competitive.\(^2\) So that TRIPS mandates its Members to provide more extensive protection of intellectual property in the name of minimum standards of protection\(^3\) prior to TRIPS the Paris Convention of 1883 provides the international framework for intellectual property but it did not dictate a uniform standard of Intellectual Property Protection.

The TRIPS Agreement has the potential to contextualize intellectual property within the realm of general public international law which gave its progressive universal adoption. The whole WTO-GATT architecture is based upon the intention of the international community to create a breeder constitutional basis to regulate international trade. For example, it has moved from the creation of negative obligation to the shaping of positive obligations while GATT 1949 was based upon the ban on discrimination against foreign goods. The TRIPS obviously entitled, nature and scope of obligations starts with a general statement giving effect to the obligations contained in the text.\(^4\) However, Members may implement

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3. Art 1.1 of TRIPS Agreement.
more extensive protection than is required in the agreement provided such protection does not contravene the provisions of the Agreement. Moreover, the legal value of TRIPS Agreement’s preamble within the contest of the WTO legal system sets forth the tone for the interpretation of the rest of the provisions of the Treaty. It has been stated in the Shrimpcase that the Preamble of the WTO Agreement does not only inform the GATT 1994 but also all other covered agreements. Thus, it shows the extensive application of TRIPS agreement in other international arrangements. So it is very clearly understood that the heart of the agreement is the prescription of standards concerning the availability, scope and use of the intellectual property rights. By standardizing protection, the agreement seeks to manage the units of conflict and competition between national laws directly. In addition to these objects, it tries to harmonize all domestic laws in respect to the subject matters of intellectual property rights, particularly the patents.

4.2. Obligation in Respect of Patent

As for as, patent is concerned, there is a general obligation under the TRIPS Agreement to comply with the substantive provisions of Paris Convention. In addition, the Agreement requires that the 20 years term of protection for patent to be available for all inventions, whether of products or process, in all fields of technology. The criteria of patentability, that are laid down in this Article are that the invention, whether involving a product or a process, must:

- be new
- involve an inventive step and
- be capable of industrial application.

Where the patent is of a “product”, it allows the owner the exclusive rights to make, use, offer for sale, sell or import the product. Where the subject-matter of the patent is a ‘process’, it grants the owner the exclusive rights to use offer for

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6 Shrimp case 51 USPQ (BNA) 413 PTO Bel. App. (1941)
7 Ibid. Art 27.
8 Ibid.
9 Ibid. Art. 28. 1
sale, sell or import products made from these processes. Inventions may be excluded from patentability if their commercial exploitation is prohibited for reasons of public order or morality, otherwise, the permitted exclusions are for diagnostic, therapeutic and surgical methods and for plants and animals and essentially biological processes for the production of plants or animals other than microbiological processes. Plant varieties however must be protectable either by patents or by a sui generis system. Thus it is very clear that TRIPS agreement encouraged the owners of patent to exploit his invention in all fields of technology without any kind of barriers imposed either by international arrangement or national system. Also, it is understood that TRIPS Agreement did not define the term “invention” but it listed the non-patentable subject –matters.

4.3. Extensive Ambit of Article 27 of TRIPS Agreement

One of the important facts to be noted about the TRIPS Agreement is that it essentially reproduces the Western concept of Intellectual Property Protection and, in particular, it reinforce the presumption that patent protection should be available over a wide scope of material. The following discussions relates to those Articles of the agreement which are seen as specifically of relevance to the protection of genetic material. In fact, it is not intended to provide an exhaustive discussion but the question is whether the inventor of new GMOs entitle patent within the ambit of TRIPS Agreement.

Article 27.1 requires member states to provide patent protection for all types of inventions irrespective of the field of technology in place of manufacture provided the invention can be shown to be novel, inventive step and capable of industrial application as the researcher has already discussed. Implicitly, this provision establishes a presumption of patentability in that Member States are expected provide patent protection for all types of inventive activity. This openly mirrors of the practice of the US and some other developed countries. Article 27 raises number of general issues with regard to the patentability of genetic material real presumption of patentability i.e. a patent should be granted unless there is good

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10 Ibid.
12 Christopher Heath (Ed), Industrial Property in the Biomedical Age Challenges for Asia; 1st Ed, Kluwar Law International, New York, 2003, at p. 84.
reason to grant. This means that any doubt is exercised in favour of the patent applicant. The rationale for this presumption is the possibility of redress through the courts.

The second is that in common with the patent law practice of developed countries, the Agreement does not contain a definition of an invention, it simply stipulate that any material which can fall within the patent law. These concepts are applied in a very flexible manner with the emphasis on inclusion not exclusion. However as will be discussed below the categories of excluded material are carefully defined. This is important for those countries, which do not want adopt an open ended policy with regard to the patentability of genetic material but which would prefer to apply a more closed policy via the utilization of clearer definition of protectable material.

The third is that the TRIPS Agreement contains on specific statement with regard to the patentability of genetic material *per se*. As can be seen Article 27(2) and (3) state that certain categories of genetic material may be excluded but the general presumption within the Agreement is that categories of excluded material notwithstanding genetic material should be treated as inherently patentable. As will be shown the general presumption of patentability has meant that granting offices invariably operate on an inclusionary rather than exclusionary policy. This means that the concept of a patentable invention involving genetic material is broadly interpreted with the granting criteria flexibly defined, whereas the categories of excluded material are given a narrow interpretation. The only qualifying factor for determining if an invention exists is whether it can be shown to be novel, inventive and capable of industrial application. The apparent sole definition of invention recognized for patent law purpose is that which itself provides, there is no recognition of or reference to any external definition of invention. The dividing line for patent law is between protectable and non-protectable material. The former comprises any material which meets the granting criteria. The later however can be divided into two categories viz.,

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(1) The Material which cannot meet granting criteria and therefore is not an invention,

(2) The Material which could meet the granting criteria but is excluded from patent protection.

On this basis, the concept of invention appears purely defined by the availability of patent system. This means that an invention for the purposes of patent law is simply something which the patent law recognizes as an invention.

In fact, the lack of a specific definition of invention means that, “the sole determining factor is whether the material meets the granting criteria that it would appear is the sole basis of determining an invention.”

Obviously discussing, Art. 27 makes no mention of the exclusion of discoveries from patent protection, the only criteria for determining protect ability are the requirements that the invention be novel, inventive and capable of industrial application. These terms are not defined within the TRIPS Agreement; it is left up to national granting offices to determine an appropriate standard for their national purposes. It is important to note that the definitions which are given within national patent laws are legal definitions for the purposes of patent law, a discovery is latent information for which a use has yet to be found. Once a new is found then provided that use is novel and inventive, the discovered material as utilized in that novel and inventive manner may be patentable. But there is an argument that a process for producing a new drug involving genetic material should be patentable and indeed that the new drug itself probably should be patentable. The question which invariably arises is whether the isolated genetic material itself should be covered by the patent. It is at this point that the issue of legal language becomes critical as it could be argued that the moment at which a discovery becomes a patentable subject-matter or invention occurs when it is described as an invention in the patent specification. Thus, based on the Chakrabarty’s legacy, it is clearly understood that it is possible to patent discovery (Biotechnology inventions) provided the granting criterias are met. Thus it is very clear that according to

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14 In Chakrabarty’s case US Supreme Court opined that, “any invention under the sun made by human being is patentable.”
TRIPS Agreement, all kinds of inventions in the field of biotechnology are patentable.

At the same time Article 27.2 and 27.3 of TRIPS create important subject-matter exceptions to the broad rule of Article 27.1. Article 27.2 permits Member countries to exclude from patentability of any inventions the prevention within public order or morality including the protection of human, animal or plant life or health or the avoidance of serious prejudice to the environment. Article 27.3 further permits Member countries to exclude two specific classes of subject-matter from patentability which are. (i) diagnostic, therapeutic and surgical methods for treatment of humans and animals and (2) plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. As open ended as the Art 27.2 exception initially sounds, it is in fact two important limiting conditions. First, the exception applies only if a prohibition against the commercial exploitation of the invention is necessary to protect ordre public or morality. Second, the exception applies only if the exclusion from patentability will likewise contribute to the protection of ordre public or morality by contrast, the two exclusions from patentability permitted by Article 27.3 are subject to no such limiting condition. For that reason the two exclusions found in Article 27.3 will be the principal focus of this Article.

It is important to note that neither of the subject-matter exclusions permitted under Article 27.3 extends to product patents at the genetic or microbiological level of research. Article 27.3(a) merely, permits the inclusion of all “commercially valuable” diagnostic therapeutic and surgical methods of medical and veterinary treatment but Article 27.3(b) permits the exclusion of “microbiological” products and any associated biological processes for producing the same namely any commercially valuable and essentially biological processes for the production of plants and animals, whereas Article 27.3(a) permits the exclusion of all genetic methods medical and veterinary treatment. Article 27.3(b)

15 Ibid. Art 27.2
16 Ibid. Art 27.3.
17 Ibid. Art 27.3(a)
18 Ibid. Art 27.3 (b).
is the provision that will apparently have a more significant adverse impact on the patenting of downstream genetic product at least in the microbiological level, though arguable not at the microbiological or the micro-biological level.\textsuperscript{19} Thus, the liberal interpretation of TRIPS agreement proved that biotechnology inventions are under the umbrella of TRIPS Agreement.

Furthermore, Article 27 contains contentious provisions that underpin the new multilateral trade system. A literal interpretation of these provisions identifies four possible options of implementation, which are as follows:

(i) Member states can allow patents on any invention in biotechnology by not excluding plants, animals and biological provisions.

(ii) Member states may exclude from patentability of plants, animals and biological processes but not exclude “New Plant Varieties.”

(iii) Member states may choose not to patent new plant varieties but can grant sui generis protection.

(iv) Member states can also choose to grant double protection system of not excluding new plant varieties from patentability and simultaneously enjoying sui generis protection.

It therefore, appears that TRIPS obliges member states to provide some kind of IP protection on almost all life forms. Although TRIPS Agreement allows countries to exclude life forms such as plants, animals from patentability, a closer look at Article 27.3(b) reveals that all countries must provide patent protection on microorganisms, non-biological and microbiological processes. It also generally and clearly says “invention in all field of technology” can also obtain patent, which cannot easily exclude life forms which are produced with the help of genetic engineering.

Moreover, presently the rapid development of Genetically Modified Organisms is closely related to TRIPS Agreement. This is an inclination to treat the TRIPS as promoting the adoption of GMO into the food system because the

Agreement requires member state to protect patent in each states. Biotechnology applies to food or pharmaceuticals therefore it has been subject to patents. According to TRIPS Agreement’s stipulation there is a question of whether natural resource can be the subject of patent because biotechnology is regarded as an innovation but as a mere discovery of substances found in nature. Obviously the biotechnology has found a way to use the isolated substances found in natural resources. Hence, it can be said as an invention because of various factors found in Chakrabarty’s decision. In addition, developed countries are exploiting huge quantities of natural resources with the help of patentable biotechnology. It is also true that TRIPS Agreement allowed states to exploit natural resources for promoting trade and commerce so that developed countries are fully depending upon the developing countries because of having plenty of biodiversity. On the other hand, developing countries according to CBD have to protect and conserve all kinds of biological resources and the environment of both human and animal beings. Thus, it is true that the TRIPS Agreement encourages countries to give monopoly over life forms through patent system.

4.4 Principal objects of Convention on Biological Diversity

The Rio de Janeiro Convention on Biological Diversity represents one of the initial efforts of the international legal system to unite economic and environmental issues in a relatively balanced way within single legal instrument. In fact the biodiversity convention is one of the most ambitious attempt in any legal system to integrate environmental goals with a wide range of economic sectors. There are two important criterias focused by the CBD in a different dimensions, one is, the 1980’s the rapid development of genetic engineering showed that biological resources which had been previously deemed worthless and had an economic use and constituted potential source of revenue for countries of origin. The second one is that, the 1980’s also witnessed the rapid development and mainstreaming of the notion of ‘sustainable development’.

The CBD based on the Rio Summit is the attempt to conserve depleting earth’s biological wealth from uncontrolled exploitation and destruction of

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biological resources including genetic resources. The CBD has three main objectives namely:

(1) Conservation of biodiversity,

(2) Sustainable use of its components and

(3) The equitable share of benefits that arise from their use.

The Preamble of the CBD starts out by recognizing the intrinsic value of biological diversity and of the ecological genetic, social, economic, scientific educational, cultural, recreational and aesthetic value of biological diversity and its components the intrinsic values of biodiversity means that all components of biodiversity should be conserved due to their inherent right to exist.21

The Preamble of the CBD recognizes that biological diversity should be conserved “for evolution and for maintaining life sustaining systems in the biosphere.”22 The CBD further notes that the fundamental requirement for the conservation of biological diversity is the “in situ’ conservation of ecosystem23 and natural habitats and the maintenance and recovery of viable population of species in their natural surroundings”. The biodiversity convention applies to ‘in situ’ and ‘ex situ’ genetic resources acquired in accordance with the convention but not those taken and deposited in gene banks prior to the convention. Ex situ conservation measures are called principally to complement ‘in situ’ conservation.24 Recognizing the sovereign rights of states over their natural resources, the authority to determine access to genetic resources rests with national governments and is subject to national legislation.25 However, it is accepted that each party to the biodiversity convention must endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other parties and must not impose restrictions that run counter to the objectives of biodiversity convention.26 Where access to genetic resource is granted it has to be

23 Art 8 of Convention on Biological Diversity.
24 Ibid. Art. 9.
25 Ibid. Art. 15. 1.
26 Ibid. Art 15.2.
on mutually agreed terms and be subject to prior informed consent of the party providing the resources unless otherwise determined by the party. 27

Moreover, genetic resources provided by any party to the biodiversity convention are only those resources that are provided by parties which are countries of origin of those resources or by the parties which have acquired the genetic resources in accordance with the convention. 28 For those parties providing access to genetic resources the benefits include possibility of participation in scientific research based on the genetic resources supplied, 29 of sharing results of research and development and benefits arising from commercial and other utilization of genetic resources on mutually agreed terms, 30 of participation in “biotechnological research activities” based on those activities based on those genetic resources. 31 Also, more particularly the priority access on a fair and equitable basis to the results and benefits arising from biotechnologies based upon those genetic resources on mutually agreed terms. 32 The subsequent parts of the CBD very clearly focuses the intellectual property subject-matters particularly patent protection in relation with genetic resources.

4.5. Interface between TRIPS and CBD

The Rio de Janeiro Convention of Biological Diversity aims to set up an international framework for the preservation and utilization of the world’s biological resources. The CBD is the result of prolonged international pressure to respond to the destruction of unequal profits from, the biodiversity of the Southern Hemisphere. After years of debate, the United Nations agreed upon the CBD in 1992. It came into force in 1993 and now 188 states have ratified it.

There exists a well-established principle of international law that, States have sovereign right over their territory including the natural resources contained therein. Before the CBD codified this principle, most states defined it in their

27 Ibid. Art 15.4 and 15.5
28 Ibid. Art. 15.3.
29 Ibid. Art. 15.6.
30 Ibid. Art 15.7.
31 Ibid. Art 19.1.
32 Ibid Art 19.2.
Interface between TRIPS & CBD

constitutions, typically stating that the ‘state owns all flora and fauna’ and that all other natural resources with the exception agricultural lands shall not be alienated.

If States allow IPRs over flora and fauna, this may result in a form of alienation, because IPRs by their nature are exclusively the monopoly rights that prevent others from producing the patented flora and fauna. Before the CBD’s adoption, many questioned whether biological resources were under the regime of the “heritage of mankind” or whether states lacked the ability to exercise over sovereignty ever biological resources and subject genetic resources to private property rights. The shift to the ideas purported by the CBD came from an increasing commercial interest in biological and genetic resources and a desire to subject, such resources to private property claims namely intellectual property. Much of the movement came in the form of plant breeder’s rights and patents, which give their owners an exclusive right to control any commercial use of these resources. Thus, it is very clearly understood that the CBD is also not against accessing genetic materials for private commercial purpose but it focus conservation of biological resources.

Almost the global pressure to privatize biological resources the CBD stands as an important watershed in international efforts to promote biodiversity conservation. For instance the conventions binds signatories to a number of basic principles regarding how by whom and for whose benefit biodiversity must be conserved. Finally, Para 5 of Art. 16 asserts that “IPR must not conflict with the conservation and sustainable use of biodiversity”. Therefore, the CBD not only gives rights to provider states but also regulates the transfer and interacts between the provider and the recipient states. It is the task of each state and the international community as a whole to interpret the afore mentioned CBD principles in a manner harmonious with Article 27 of TRIPS. So the researcher wants to discuss the interface between TRIPS agreement and CBD in respect of access to genetical materials and conservation of biological diversity.

Intellectual Property Laws typically viewed only to devices of industrial and cultural progress have also been receiving attention as tools for achieving the breeder goals of conserving biodiversity while promoting sustainable development. The conservation of biological diversity and the protection of IPRs are connected in several aspects. Attention has been crystallized around the CBD and its relationship in the WTO TRIPS Agreement.

4.5.1. Conservation Requirement of CBD

It is significant to note that conservation of biological diversity is a common heritage of human kind. The CBD creates several references to the needs of indigenous and for local communities. It creates new rules relating to access to genetic resources and the sharing of benefits. The CBD also has provisions in respect of technology transfer and financial resources to developing countries. The Researcher would like to emphasis on the four key issues between CBD and TRIPS Agreement, which are as following:

(1) The sharing of benefits and payment of royalties and fees for the use of technology transfer and the recognition of this knowledge in the patent system.

(2) The extent to which genetic material and life forms should be patented and the issue of “farmers rights as against the rights of breeders of plant varieties”.

(3) Technology transfer in respect of biotechnology for conservation and sustainable use of biological diversity to countries that provides access to genetic resources i.e., the basic principle of CBD. But under TRIPS the technology is protected.

(4) Control of technology that can damage the environment, for instance environmentalists say that GMO technology has the potential to adversely harm the environment.

Thus, it is rather important that the CBD and TRIPS Agreement are concerned, the imperatives of both these instruments are similar for the human development in the conserved biodiversity. Giving patent to the inventor gives
considerable benefit to the society and conserving biodiversity also gives more and more benefits to the society.

4.5.2. Effects of Access

The changes of patentability pertaining to genetic resources originated with developments in biotechnology. This positively encouraged the developed countries to concentrate over this subject matter, more particularly access to genetic material for their private ownership. In respect of patent protection over biotechnology inventions the TRIPS agreement does not create a single universal patent system. More so, access to a rich variety of genetic resources is essential for plant breeding and food security and more particularly pharmaceutical products in all parts of the world. Applying patents to genetic resources taken from the biodiversity causes some predicted and unexpected consequences. But TRIPS agreement encouraged access to genetic material for patent purpose. On the other hand, the environmental system should be maintained in accordance with the requirements contemplated in various international instruments. The multinational corporations are energetically exploiting huge quantities of genetic resources for their economic purposes comes under Article 27 of TRIPS Agreement. At the same time CBD imposed some obligations upon the way in which the genetic materials are accessed for patent purposes but CBD also does not prevent accessibility of genetic materials for the interest of the society.

Furthermore, it is noted that patent is a form of property rights mechanism that has been created to ensure that investment in human capital will be rewarded. Such patents create economic incentives to innovate and which ultimately benefits the society as a whole. The basis of the theory behind huge investments in human capital applies to the problem of biodiversity, conservation too. This is because investments in stocks of diverse resources generate not only tangible goods and services but also the intangible one. Thus, the exploitation of genetic materials from various species leads to lot of problems. The loss of one or more species in an ecosystem may adversely affect the ecosystem’s ability to recycle nutrients, generate soil, maintain the equality of the atmosphere and fresh water control flooding, provide food from the sea and control pests that attack crops or carry
disease. The researcher would like to discuss such matters in the subsequent chapter very elaborately.

4.5.3. General Obligations

While WTO member states incorporate TRIPS within their national laws access to genetic resources from which genetically engineered products are developed is becoming one of the critical areas of debate between industrialized and developing countries.\(^{35}\) In many developing countries the relationship between TRIPS and the CBD is one of the opposing principles. On one side stands the principle of economic growth purposed by the TRIPS Agreement. On the other side is principle of sustainable development served by the CBD. Industrialized countries justify globalizing and harmonizing patents because such rights will strengthen the supply of innovation to the market. They strongly argue that economic growth will result from improving, dynamic efficiency through stronger patents. Pushing market towards the “high technology (particularly biotechnology) fix” however stands in stark contrast to the kind of economy advocated by many committed environmentalists who believe that states should subject development to environmental costs and implications.\(^{36}\) Most of the conflicts between CBD and TRIPS is spurred by moral and rhetorical assumptions. One assumption claims that the patent regime i.e. a Western form of IPR, which is totally unsuitable to the majority of the societies in the South, that have accepted TRIPS by acceding to the WTO. Another assumption asserts that private rights are completely alien to indigenous communities because the vast majority of their farmers who manage biodiversity at the local level are accustomed to collective rights.

The CBD intends to strengthen developing countries capacities to conserve and use biological diversity on a long-term basis by reserving all rights over their resources.

Conversely, TRIPS Agreement intends to provide private property rights over products and processes whether biodiversity based or not. The pressure of


certain non-state actor interests namely those of multinational companies have overwhelmingly helped to achieve TRIPS intended results.

While describing these apparent points of conflict, it is important to remember that contracting parties to the CBD have an obligation to cooperate and ensure that ‘patents’ are supportive of and do not run counter to the CBD’s objectives. Moreover, provision of CBD states that it’s provisions will not affect countries’ rights and obligations to any existing international agreement except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This harmonization process is mainly subject to national legislation and international law and stands as a basis for countering the runaway march of the patent regimes.

When a conflict exists between two treaties dealing with the same subject–matter the applicable rule is ‘\textit{lex posterior derogate lex anterior}’,\textsuperscript{39} which, Article 30 of the Vienna Convention on the Law of Treaties enshrines. In this connection, the TRIPS will prevail since it came into force after the CBD. However if evaluated under prima facie evidence and by a stricto sense, legal point of view, the subject-matter of CBD and TRIPS basically differ, therefore state should fully and simultaneously implement both of them.\textsuperscript{40} For instance, although both Article 27 of TRIPS and some of the provisions of the CBD deal with the utilization of biological resources they do so the achieve two different objectives that are not necessarily mutually exclusive.

Although TRIPS subject-matter does not suffer from an identity problem per se, some provisions regulate the same object and have the same purpose as CBD provisions. In order to fully apply and universally ratify both treaties, certain provisions contained in both treaties need to come into harmonization.\textsuperscript{41}


\textsuperscript{38} Art 22 of CBD.

\textsuperscript{39} This means that the later law prevails over the first which is mentioned in Art 30 of the Vienna convention on the law of treaties.

\textsuperscript{40} Jonathan Curci; \textit{The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property}, 1st Ed. Walter kluwar, Newyork, 2010, at p.55.

\textsuperscript{41} \textit{Ibid.}
The private property regime i.e., patent on biological diversity established by TRIPS may undermine the implementation of the benefit sharing provision of CBD that require the knowledge or material holders’ PIC\textsuperscript{42} for the use of genetic resources. The aim of TRIPS to homogenize national patent regimes may jeopardize a country’s freedom to choose the way it wants to deal with the use and protection of its biodiversity.

In spite of the fundamental contradictions that seems to exist between CBD and TRIPS, legally speaking inconsistencies between patents applied to life forms under TRIPS and the obligation of CBD are multifaceted. The inconsistencies particularly reveal themselves in the following fields, the access to and fair and equitable sharing of benefits from the utilization of genetic resources.

Para 19 of the Doha Ministerial Declaration calls on the council for TRIPS in its review of Art.27.3(b) and Art 71.1 of the TRIPS Agreement to consider the relationship between the TRIPS and CBD in order to settle the issue. The recent works within TRIPS council has focused particularly on whether and how disclosure requirement in respect of biological resources could contribute to building a more coherent and supportive relationship between the two instruments. The issue of the disclosure of the origin and sources of genetic resources and the question of PIC are closely related Article 15 of CBD, in recognition of the sovereign rights of states over their genetic resources requires that access to genetic resources be subject to PIC.

4.5.4 Impacts of TRIPS on Transfer of Technology

Whether or not TRIPS will promote the transfer of technology is highly controversial, on the one hand, the rigorous implementation of the CBD provisions on Technology Transfer can be negatively challenged by the TRIPS agreement regime’s ability to hinder the transfer of environmentally harmful techniques on the other hand, TRIPS may also create extraordinary incentive for innovation.

The rigid intellectual property regimes without derogation can seriously hinder the environmentally sound technologies transfer among states particularly

\textsuperscript{42} Prior Informed Consents.
from industrialized countries to developing countries. Indeed, transfer of appropriate technology is a key tool for achieving the goals fixed to the CBD.\textsuperscript{43} The CBD refers to technologies that are, “relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment The CBD also requires parties to transfer technology to developing countries on “fair and most favourable terms”, including concessional and preferential terms, in which there is mutual agreement.\textsuperscript{44} This provision means that where a developing country should have facilitated access to technology that makes use of these resources. Obviously, this objective needs corresponding national and international patent law and sound and fair competition policy which are supportive of and do not run counter to the CBD objectives.

Another possible impact of patent protection on living matters lies in the development of environmentally harmful technologies. This concern mainly focuses on the technologies essentially based on the modification of plant, animal and microorganism, genomics with the aim to embody a special characteristic. One such, example is developing herbicide resistance or the predisposition to avoid certain diseases in order to attain a commercial advantage. Regarding transgenic plants and animals specified environmental risks are particularly harmful to human health. These risks can concretize into irreversible harms for the global ecosystem and human welfare after their entry into the environment and market. This holds particularly true for technologies that produce “terminator seeds”, “sterile seeds” that require the application of a chemical “switch” before performing certain characteristics like flowering. In this context national and international bodies should more closely define the patentability exceptions under Article 27.2 of TRIPS Agreement as they are the only readily available defences against the patent invention threatening biodiversity. TRIPS Agreement has also insisted to avoid environmentally harmful inventions from, patentability but it allows the member

\textsuperscript{43} Art 16 of CBD and Art 7 of TRIPS Agreement.

\textsuperscript{44} Ibid., Art 8.
states to include patentable subject-matter based on their own policy frame work.\footnote{Ibid.} This will certainly affect uniformity in respect of patentability criteria.

### 4.5.5. Impact of TRIPS and Biopiracy

The alleged inconsistencies between TRIPS and the CBD reside at the schematic cross road between the opposing perspectives of North and South. The debate over patent on biological resources and international trade is embedded in a broad context with so many intertwined aspects and competing interests. The private property regime established by TRIPS may underline the implementation of the benefit sharing provisions of CBD that require the material holder’s prior informed consent for the genetic resources.

TRIPS Agreement does not require the transparency of PIC and is therefore inconsistent with the CBD in that regard. Without such a PIC obligation in TRIPS entities from countries (generally industrialized ones) that use genetic resources in innovative processes will limit their efforts to seek and exploit benefit sharing with the countries of origin (generally developing countries).

The aim of TRIPS to harmonize national patent regime may jeopardize a country’s freedom to choose the way, it wants to deal with the use and protection of biodiversity and the related matters. This issue blatantly arises when firms appropriate genes from a State that manipulates and sells the genetically modified products rather than from the State that patents the original products. Following the imposition of patents on life forms and related knowledge communities of developing countries have risen against this kind of piracy of indigenous and local community knowledge.

The well-known phenomenon of bio-imperialism or biopiracy defines the way in which industrialized countries ‘conquered,’ and accused developing countries of pursuing, “intellectual piracy” and after the adoption of TRIPS, developing countries accused industrialized countries of biopiracy. Developing countries coined this term as part of a counter attack strategy to describe the misappropriation of genetic resources by private entities in the North. Through
TRIPS, the South has an obligation to grant patents without any compensation to the local communities that preserved and bred biological resources.

It is very likely that biotechnology research relies upon natural biodiversity to the same extent as it does general agricultural research. Moreover, the stock of germplasm relied upon by society for the maintenance of its agricultural system may be seen as a continuously eroding asset. For all those reasons the argument arises that patent can prevent countries from realizing the full and practical meaning of the CBD, the Articles regarding national sovereignty over their natural resources and the rights of their local and indigenous communities are highly focused. This prevention frustrates the ultimate goal of fairly distributing the benefits arising from the use of genetic resources situated in the contracting parties’ territories. So it is apparent that patent on biotechnology creates lot of transborder disputes, this can be reconciled by the help of both these international instruments namely TRIPS and CBD.

4.5.6. CBD and TRIPS Emerging Issues

In proportion of the 1999 Ministerial conference on TRIPS focused on the environmental risks of introducing genetically modified organisms under Article 27 of TRIPS Agreement. Environmental risks involved in biotechnology are becoming well-known in recent times. Herbicide tolerant soybean represents about 27 percent of total area under soybean, while genetically modified maize was assumed to represent about 25% of the total area in 1998. The fear about transgenic crops affecting the wild biodiversity is no more a matter of speculation. Bt. cotton killed lots of monarch butterflies and other human and environment friendly insects.

Moreover, the risks in biotechnology includes the risk of antibiotic marker genes causing allergy in the human body and increase in instability in the transgenic lines, containing CaMV 358 promoter. The researcher feels that

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48 Ibid.
release of such transgenic lines which contains this promoter is not justified in the light of the findings and caused severe environmental hazard GMO crops may be more vulnerable to certain pests and their non-GMO varieties too. Transgenic varieties will in some circumstances need additional pesticide treatments to achieve maximum yield sand targeting non-target beneficial insect and microorganism and etc.

More significantly, the potential “transnational harm” caused by genetic engineering via genetic pollution and through an accelerated decline of biological diversity on a global scale. Thus, legal control over biodiversity is an issue of serious international consequence. Moreover industrialized countries realizing the potential gains flowing from new technologies driven by private industries promote the integration of stronger patent in multilateral and bilateral treaties that ultimately conflict with interest of developing countries. Most developing countries join as parties, to these treaties despite the benefit sharing problem, arising from the international exploitation of genetic material / resources. At the same time, however developing countries accused industrialized States of watering down the patentability requirements of biotechnology within their own national jurisdictions effectively accommodating corporate interests without precise and careful consideration of the intrinsically complex and multifaceted issues or the consequences involved. The granting of patent to modify unauthorized appropriations of plant and animal genetic resources frustrates providing countries trying to implement the concepts and principles provided by the CBD or control over their genetic resources. The CBD is far more favourable to conservation of biodiversity and preservation of rights for developing countries, while TRIPS is far more aggressive about facilitating biological patentability and promoting private ownership and exploitation of such resources too.

So it is very clear that the permission given by the TRIPS Agreement to obtain patent over biotech invention are creating lot of environmental and health issues day by day. Thus, conservation under CBD is concerned it should ensure a standard level of environmental protection includes health of human and animal

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49 *Supra note 40.*
beings. TRIPS opened the gate way to commercialize all kinds of life forms which are genetically engineered, and at the same time a question arises is whether this will cause adverse impacts upon the biodiversity and can the CBD make an balance under the doctrine of sustainable development.

**4.5.7. GENERAL DIFFERENCE BETWEEN CBD AND TRIPS**

<table>
<thead>
<tr>
<th>TRIPS</th>
<th>CBD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. TRIPS conferred lot of “rights” to the industry to carry out and extend their business throughout the world without any impediments.</td>
<td>1. CBD imposed lot of “obligations” to conserve biodiversity of the countries.</td>
</tr>
<tr>
<td>2. TRIPS encouraged commercial exploitation as an obligation</td>
<td>2. CBD encouraged conserving and protecting the biodiversity from unmindful exploitation for commercial purposes.</td>
</tr>
<tr>
<td>3. It encourages technology transfer for commercial exploitation.</td>
<td>3. It encourages technology transfer for protecting and conserve biological diversity</td>
</tr>
<tr>
<td>4. It is for economic development.</td>
<td>4. It is for environmental development such as sustainable development.</td>
</tr>
<tr>
<td>5. Profit is monetary interest</td>
<td>5. Profit is conservation</td>
</tr>
<tr>
<td>6. It destroys tradition and creating new culture</td>
<td>6. It preserves tradition and promotes culture and community rights.</td>
</tr>
<tr>
<td>7. It is ensuring private interest by way of granting private rights</td>
<td>7. It is ensuring public interest by imposing obligations</td>
</tr>
<tr>
<td>8. It encourages commodifications of life forms</td>
<td>8. It encourages conservation of life forms</td>
</tr>
<tr>
<td>9. It is inducing economic interest for present generation.</td>
<td>9. It is promoting potential economy for future generation.</td>
</tr>
<tr>
<td>10. Development is the primary agenda</td>
<td>10. Conservation is the primary agenda.</td>
</tr>
</tbody>
</table>
11. Members are binding to exploit and extract resources.

12. Enforcement mechanism is more effective.

13. It encourages corporate control over genetic material.

11. Members are binding to conserve and preserve resources.

12. Enforcement mechanism is less effective.

13. It encourages state control over genetic resources.

### 4.6. New Developments in EC Directives

With regard to the patenting of biotechnology invention in Europe, the main legislative framework is provided by Directive 98/44/EC of the European Parliament.\(^{50}\) The EC Directive on the legal protection of biotechnology invention is more than just a normative framework for patenting biological substances. After an uphill struggle against fierce opposition to “patents on life”, the Directive signifies a breakthrough yearlong statement having regard to the Directive the Administrative council adopted the revised guidelines for examination in the EPO in 1999.

The Member states of the European Union were obliged to bring the provisions of the Biotech Directive into force in each of their countries before 30\(^{th}\) July 2000. However as of November 2004, there are some countries failed to do this. Even though, the EPO, which is the “Main Patent Granting Body” was not bound by the provision of the Biotech Directive since it is not the moon-council of the EPO, amended the Rules of the EPC to include a new chapter on biotechnological inventions.\(^{51}\) Because of which, a number of Articles of the Biotech Directive were explicitly incorporated into the EPC.

European patent will not be granted in respect of biotechnological inventions, which in particular concern the following:\(^{52}\)

(a) Processes for cloning human being.

(b) Processes for modifying the germ line, genetic identity of human being.

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51 Rules 23(b) and 23 (a) of EPC.

52 Rule 23(d) and Art. 53(a) of the EPC.
(c) Uses of human embryos for industrial or commercial purposes.

(d) Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefits to man or animals and animals resulting from such processes.

(e) A process for the production of plants or animals is essentially biological, if it consists entirely of natural phenomena such as crossing or selection.\textsuperscript{53}

The concept of plant variety is defined by the EC Regulation.\textsuperscript{54}

4.6.1. Basic Principles

The Directive establishes the principles that biotechnology inventions are amendable to patent protection.\textsuperscript{55} For the purpose of this Directive, inventions which are new, which involve an inventive step and which are susceptible to industrial application shall be patentable even if they concern a product consisting of containing biological material or a process by means of which biological material is produced, processed or used. This clause reflects well established principles in line with the International Law of Treaties. The three criterias of new, inventive step and susceptible of industrial application are globally accepted conditions for the patentability of inventions that ensure the differentiation between patentable inventions. These parameters are said to be ensure the delimitation between patentable inventions and non-patentable discoveries. But Art 3(1) of the Directive provides nothing spectacular, it simply recognizes that biotechnology inventions subject to the same standards as any other invention even it consists of biological material.

Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confided to a particular plant or animal varieties. This is similar to that of the EPC provision.\textsuperscript{56} Which says, “European patent shall not be granted in respect of plant or animal varieties or essentially biological for the production of plants or animals”. This provision shall not apply to microbiological process or the product there of which shows that EC Directive

\textsuperscript{53} Ibid. Art 2(2).
\textsuperscript{54} Art 5 of Regulation (EC) No. 210094.
\textsuperscript{55} Ibid. Art 3(1).
\textsuperscript{56} Art 53(b) of the EPC.
are not against granting patent over life forms, which are genetically engineered.

One Biological material which is isolated from the natural environment or produced
by means of a technical process may be the subject of an invention even if it
previously occurred in nature.\textsuperscript{57} This provision and synthetic production of
naturally occurring substances is a vital importance. Opponents of the legal
protection of biotechnology inventions hold the view that no material occurring in
nature could be subject to patents. Article 3(2) of the Directives clearly rejects the
philosophy that, “the Directive’s approach has seen as a logical consequence of
patent laws basically neutral orientation. According to generally recognized
principles, it is not the function of patent law to give a stamp of approval to any
direction taken by research a to authorize the marketing of products generated by
such research.”

More so, in its Article 5 of the Directive gives operable contours to the
patentability of the human body,\textsuperscript{58} but the next part simply reiterates the non-
patentability of mere discoveries, This shows the advance march of EC Directives
in respect of patenting over life forms including human body parts, comparing with
TRIPS Agreement, which are as follows;

(1) The human body at the various stages of its formation and development and
the simple discovery of one of its elements, including the sequence or
partial sequence of a gene, cannot constitute patentable inventions.\textsuperscript{59} But
the following paragraph clarifies that sequences of a human gene and other
elements isolated from the human body or otherwise produced through a
technical process can enjoy patent protection regardless of structural
identity between the isolated element and its natural equivalent.

(2) An element isolated from the human body or otherwise produced by means
of a technical process including the sequence or partial sequence of a gene
may constitute a patentable invention even if the structure of that element is
identical to that of a natural element.\textsuperscript{60} It looks like that Art 5(1) simply

\textsuperscript{57} Ibid. Art 3(2).

\textsuperscript{58} Herdegenm, Matthias. "Patents on Parts of the Human Body." The Journal of World Intellectual Property

\textsuperscript{59} Ibid. Art. 5(1).

\textsuperscript{60} Ibid. Art 5(2).
reiterates the non-patentability at mere discoveries with respect to the human body responding to sensitivities in the public at large and fulfils an atmospheric function. But it is important to read the first two paragraphs of Article 5 together – If disguises as responds to the fundamental fear that allowing patents on life would lead to the undue restriction of individual rights and would entail the risk of incalculable and excessive dependence. In short, no doubt they are providing patent protection to the human body parts too which is isolated. Furthermore, the Article 5(1) has a understood as expressing the respect of human dignity mentioned in the 10th recital which reads as follows:

(3) “Patient law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person..., it is important to assert the principle that the human body at any stage in its formation or development including germ, cells and the simple discovery of one of its element or one of its products, including the sequence or partial sequence of a human gene can not be patented, these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented.61”

The EC Directive does not specifically oblige the Member states to grant patents on substances i.e. DNA sequences Article 5(2) of the Directive is explicit only in allowing patents on sequences of a gene or other elements identical to parts of the human body. It follows however, from the purpose of establishing a common framework and the Preamble of the Directive that such elements may not be excluded from patentability.

It should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application is not excluded from patentability. The primary justification for the patentability of biotechnological material from the human body comes from the field of medicine. Numerous serious illnesses can only be found effectively if approaches are used which involve genetic

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61 Recital 16 of EC Directive.
engineering. In particular, medicine derived from elements isolated from the human body have proved to be especially effective in the long term treatment of serious and terminal illnesses. For example, production of insulin by microorganisms is one of the milestones of genetic engineering. Ninety percent of all patients suffering from diabetics are now being treated with the recombinant drug which is well tolerated to a higher degree and safer than the insulin obtained from animal sources which was also used.

But it is to be noted that the elements are of products of nature which cannot be patentable and the monopoly granted to a person on these elements will definitely prevent the others from using. It permitted to use only by providing certain costs. The issue is not using those elements for medicinal purposes but regarding of granting property rights to these elements. But the countries are arguing that all these research activities are really making many breakthroughs, in the field of medicine so that granting monopoly over all these biological materials are not contrary to TRIPS Agreement, because TRIPS Agreement encourages countries to obtain patent in all fields of technology. It very clearly indicates that property rights and corporate control over all these biological materials through patent protection is considerably supporting by the TRIPS Agreement for the better development in the field of pharmaceutical innovations.

Thus, the researcher finds that, EC Directives has really gone a long step ahead of the TRIPS Agreement in defining, explaining, expanding, and granting patent for all kinds of life forms including human body parts. EC Directives are comparatively more inclusive than TRIPS Agreement in above regards. Both the TRIPS Agreement and EC Directives are enlisted non-patentable subject matters but the later is more clear and precise, because the former is silent about the patentability of plants, animals and human body parts. After these discussions it is obvious that now the TRIPS member states are ready and equipped in respect of granting patent over all kinds of life forms which are genetically produced or genetical engineering is applied for new forms.

The following chapter discusses, the impacts of patent on life forms to the biodiversity, including human environment, agriculture and the health of animal
and human beings. As a result of commodification of life forms as ‘commercial assets,’ the society is getting remarkable benefits and also facing huge adverse consequences. Thus, the researcher would like to focus all the adverse consequences happened, happening and will happen in the biodiversity.