

Trips: Patenting of Biotechnological Inventions

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Abstract

Granting of intellectual property rights on biological materials could be very contentious issue from cultural, legal, ethical and religious points of view. This could be even more complicated, once it acquires an international dimension. The Agreement on Trade Related Intellectual Property Rights (TRIPs) is the latest international arrangement under which, a complex structure for international protection of intellectual property rights has been created. However, while it embodies some provisions of previous international documents on intellectual property rights, it reflects a unique and unprecedented scheme of protection of intellectual property rights, which also highlights a tension between developed and developing countries especially over the patentability of biological inventions. The provisions of TRIPs make it difficult for developing countries to deny such protection. However, it is possible for them to limit the scope of such protection by relying on exceptions provided by TRIPs and also by relying on the distinction between invention and discovery. These strategies would allow developing countries to exercise some discretion in defining the scope of patentable biotechnologies.

Keywords: Intellectual Property, Biotechnology, Invention, Patent, TRIPS.

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Introduction

Patenting of life forms has perplexed many patent offices around the globe. The long-standing uncertainty whether or not life forms can be patented, has brought to the fore a complex web of issues. The debate arose in this area due to the recent advancement in the field of biotechnology. Biotechnology involves either directly or indirectly, living beings as the subject matter of its experiment. The recent technological advancements succeeded in introducing genetic changes in organisms with specific ends. The outcome of this technology was living organisms exhibiting novel qualities. This culminated in claims for patent protection for these biotechnological inventions with 'novel qualities', which are living organisms.

It was once believed that patenting of living organism, in any form, is unjustified. In the United States, the belief before 1930s was that plants and animals were products of nature and as such were not to be subjected to patent protection [1]. The US Plant Patent Act enacted in 1930, can be rightly termed as the beginning of patenting of living beings. After half a century of this Act, in *Diamond v. Chakraborty*, in the US, patenting of microorganisms gained its legal recognition in 1980 [2]. In this case, the US Supreme Court held that a man-made microorganism, which has been genetically engineered in the laboratory, was patentable. For a considerable period, the interpretations

provided by the US Patent Office(USPTO) and its courts did not receive any acceptance in the European continent. It is only on July 6,1998, the European Parliament and of the Council of European Union adopted a Directive on the Legal Protection of Biotechnological Inventions [3]. On the other hand, developing countries, which were facing severe problems of poverty and development, had not accorded any importance to this area until recently.

The agreement on Trade Related Intellectual Property Rights (TRIPS) was concluded when the W.T.O. Agreement replacing GATT was formally signed at Marrakesh on 15th April 1994, in order to reduce distortions and impediments to international trade and taking into account the need to promote effective and adequate protection of intellectual property rights [4]. This agreement is aimed to recognize the public policy objectives of national systems for the protection of intellectual property including developmental and technological objectives, also the special needs of the least developed country members, in respect of maximum flexibility in the domestic implementation of laws as well as in order to enable them to create a sound and viable technological base [5]. The TRIPS agreement is to achieve the objectives that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of

producers and users of technological knowledge and, in a manner, conducive to social and economic welfare, and to the balance of rights and obligations [6]. In order to achieve the above objectives, members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in the sectors vital to their socio-economic and technological development, while formulating or amending their laws, provided that such measures are consistent with the provisions of this Agreement [7]. TRIPS agreement became operative from 1st January 1995 with the formation of the World Trade Organization (WTO) replacing GATT. It came into force from 1st January 1996, one year after the entry into force of the WTO. Section 5 of the TRIPS deals with Patents. Main provision relating to patentability of biotechnological inventions under the TRIPS agreement is the Article 27 that we examine the implication of TRIPS patent regime on the biotechnology industries. It further analyses the scope of limiting the patent protection within the TRIPS Agreement in the light of the TRIPS mandate for such patents. This article also discusses the impact and interface between the Convention of Biological Diversity and TRIPS Agreement.

1. Biotechnology

Biotechnology, despite its long history, has not been properly defined. 'Bios' means life in Greek and hence; generally biotechnology is the

term used to connote technology that uses living entities like animals, plants and microorganisms or causing changes in them. Many attempts have been made to define the term biotechnology. Organization of Economic Cooperation and Development (OECD) defines 'biotechnology' as the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services [8]. The Office of Technology Assessment of the United States Congress (OTA) defined biotechnology as "the collection of industrial processes that involve the use of biological systems." [9] In a broader sense, it is defined as the use of biological materials such as living organisms or parts thereof to produce a useful product [10]. From the historical experiences, it can be generally concluded that due to the rapid growth of science and technology, a comprehensive definition of the term biotechnology cannot be permanently arrived at.

2. Development of Biotechnology

Biotechnology is often described as the third technological revolution of the century after nuclear and information technology [11]. Friedrich Miescher around 1870, discovered that the basic constituents of cell nucleus were nucleoproteins [12]. Biotechnology evolved to its present form in the 19th century. Presently, the importance in this field of science occurred as a result of the recent developments in the

Trips: Patenting of Biotechnological Inventions

area of 'genetic engineering'. The rapid evolution of biotechnology has opened the way to immense possibilities in various areas such as medicine, pharmacy, food, agriculture, environment and so on. In other words, biotechnology today is multidisciplinary in nature involving chemistry, molecular biology, biochemistry, chemical engineering, genetic microbiology and immunology etc [13].

The structure of DNA was discovered by Watson and Crick in 1953, which led to the introduction of the *recombinant DNA (rDNA)* technology[14]. The DNA is a molecule composed of small sugar molecule, a phosphate group [15] and four kinds of nitrogen bases namely adenine, thymine, guanine and cytosine. The phosphate and sugars form two long chains, with one nitrogen base, getting attached to each sugar molecule. The two chains are held together like a ladder. The nucleotide chains twist around each other forming a "double helix".

The debate on patenting life forms, came to the fore due to the advent of many latest improvement in the field of biotechnology like the *recombinant DNA* technology, somatic cell hybridization, the monoclonal antibodies technology, gene technology etc. These techniques are enumerated to understand the modern technology.

3. Legal Issues of Life Patenting

Patenting of life forms because of its inherent complexities and technicalities raise few serious

legal issues. National legislations of most of the countries do not provide *per se* for patenting of life forms. If most of the national legislations are analyzed, irrespective of the basic policy differences, we can find a common stand against patenting of life forms.

The modern biotechnology proved possible the creation of new life forms through genetic engineering. Through these genetic manipulations, creation of new and higher forms of life was achieved and presently it has reached to transgenic mammals. Patent laws also traveled along with this scientific revolution and the jurisprudence in this area of patenting life forms developed due to the judicial interpretations broadening the patentability norms.

3.1 Inventions and Discovery

The general criterion for patenting is that the invention should be novel and it should comprise an inventive step and is to be industrially applicable. An invention is novel, if it has not been disclosed to the public either in writing or orally by use or otherwise before the date of filing or the priority date. If an invention-seeking patent is known to the public by a prior publication, novelty is lost [16]. When it comes to inventions in the field of biotechnology, naturally occurring substances, microorganisms or other biological materials face special problems. One such basic

theoretical issue relates to the concept of invention and discovery. In identifying what is an invention and what is not, for the purpose of providing intellectual property protection, it is usual to distinguish an invention and discovery. The patent laws of most of the countries exclude discoveries from patent protection. The patent laws of some countries use the terms invention and discovery, synonymously [17]. The problem with respect to biotechnological patenting is, to what extent the traditional concept of invention covers inventions in the field of biotechnology for intellectual property protection?

The common definition of discovery includes the products of nature [18] because invention in the field of biotechnology, directly or indirectly, relates to the living forms, which are products of nature. Hence, the distinction between inventions for which protection is available and discoveries, which cannot be protected, seems a problem for biotechnological products.

The issue of inventiveness of discovery gets a new dimension when it comes to patenting living subject matter. It is always an issue because most of the biotechnological inventions amount to the identification of naturally occurring living materials.

In *Continental Soya Company Ltd v. J.K. Shart Milling Co Ltd*, [19] the question that arose before the Supreme Court of Canada was

whether claims to naturally occurring enzymes were valid. The court held that if there exists an inventiveness in these discoveries then they can be allowed patent rights, concluding that there exists a difference between discovery and invention [20].

In *Genetech Inc's* patent, [21] the Court of Appeal in England had to consider the patentability of DNA sequences [22]. The Court unanimously rejected the patent claims by adhering to the literal interpretation of para (a) of sub section 1(2) of English Patent Act, 1972, which states that a discovery, in itself, is not to be regarded as invention. The attempt by National Institute of Health (NIH) to file a patent for human genes also received wide criticism [23].

3.2 Problem of 'Disclosure'

Any microorganism to be patented needs to be "sufficiently disclosed". Any life form, whether any non-naturally occurring non-human multicellular living organisms or any biological process leading to the creation of animals or plants, needs to be sufficiently described so that a skilled person can understand the inventive factor behind the invention. This is sometimes impossible in case of microorganisms. Article 112 of U.S. patent law states that the patent application should adequately describe the three components namely (a) the invention (b) the manner and process of making and using the

Trips: Patenting of Biotechnological Inventions

invention and (c) the best mode contemplated for carrying out the invention [24]. Article 29 of TRIPS Agreement states that:

“ Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.” [25]

3.3 Depositing Problem

Both European and the US patent regulations have made it mandatory to deposit the sample of the microorganism in the authorized institution. Rule 28 of the EPC, for example, outlines the requirements of European patent applications relating to microorganisms. It provides that:

(1) if an invention concerns a microbiological process or the product thereof and involves the use of a microorganism which is not available to the public and which cannot be described in the European patent applications in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 if:

(a) a culture of the microorganisms has been deposited with a recognized depository institution not later than the date of filing of the application; (b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the microorganisms; (c) the depository institution and the file number of the culture deposit are stated in the application [26].

In case of *NA BISCO/ Microorganisms*, [27] the *Technical Board of Appeal of the European Patent Office* briefly discusses the US and European practices as regards the procedure for depositing microorganisms. It says, “according to the US practice, a deposited microorganism is normally not made available to the public without the consent of the depositor unless (and until) a US patent related to the deposit is granted. However, under the EPC system, a deposited organism shall always be made available to the public from the date of publication of the European Patent application irrespective of whether or not a European patent will subsequently be granted and when such grant becomes effective.” [28]

While referring to this application, the Board had outlined in its decision the relationship between Article 83 and Rule 28. It had, *inter alia* stated that “...a culture of a microorganism, which is not available to the

public and which cannot be described in the European application in such a manner as to enable the invention to be carried out by a man skilled in the art, must, *inter alia*, be deposited with a depository institution recognized by the EPO not later than the date of filing of the application.” [29]

4. The Trade Related Aspect of Intellectual Property Rights Agreement and Biotechnology Invention

One of the most controversial provisions in the TRIPS Agreement is the one relating to patenting of microorganisms and microbiological processes. Article 27 of the Agreement deals with patentable and non-patentable subject matter.

4.1 Patentable subject matters

It provides that patents shall be available for any invention, whether products or processes in all fields of technology provided that they are new, involve an inventive step and are capable of industrial applications [30]. The terms "inventive step" and capable of industrial applications may be deemed to be synonymous with terms "non-obvious" and "useful" respectively.

It further provides that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the

field of technology and whether products are imported or locally produced" [31].

Thus, under the TRIPS agreement, the member country has to grant patents to any invention in any field of technology without any discrimination, for products as well as process whether, the products are imported or locally produced. However, in order to be a patentable invention, following requirements have to be complied with.

- (a)The inventions must be new,
- (b)They must involve an inventive step (non-obvious),
- (c)The inventions are capable of industrial application (useful).

These provisions do not establish any discrimination to the patentability of the invention in any field of technology including biotechnological inventions. However, certain exceptions and conditions to patentability are provided. These provisions are more or less similar to the provisions provided in the patent laws of various developed countries and also the provisions under the European Patent Convention(EPC).

4.2 Non-patentable subject matters

The TRIPS agreement has excluded certain inventions from the ambit of patentability. It provides that "members may exclude from patentability any invention, which is necessary to protect *ordre public* or morality, including to

Trips: Patenting of Biotechnological Inventions

protect human, animal or plant life or health or to avoid serious prejudice to the environment provided that such exclusion is not made merely because the exploitation is prohibited by domestic law" [32].

It further provides that "members may also exclude from patentability (a) diagnostic, therapeutic and surgical methods for the treatment of human or animals, (b) plants and animal other than microorganism, and essentially biological processes for the production of plants and animals other than non-biological and micro-biological processes" [33].

Thus, TRIPS agreement allows discretion to members (Contracting States) to exclude certain kinds of inventions from patentability, in order to protect public order and morality, and also to protect human, animals and plant life to avoid serious prejudice to the environment.

The notions of *ordre public* (public order), and morality are not defined in the agreement. However, it is clear that those inventions that cause injury to human, animal and plant life as well as the environment are excluded. Member countries are given flexibility to adjudicate such matters. Some countries may still provide patent protection for inventions that cause damage to the environment. Patenting of genetically engineered organisms and life forms is generally possible under these provisions. Further, it is also possible for a state to provide

patent protection to a gene or a whole organism [34].

The discretion has also been vested in members to exclude certain inventions from patentability relating to the following matters,

- (a) diagnostic, therapeutic and surgical methods for treatment of human beings or animals;
- (b) plants, and animals and
- (c) essentially biological processes for the production of plant or animals.

These provisions are similar to the provision as provided under the European Patent Convention (EPC) [35].

4.3 Exception to exclusion

Although certain kinds of inventions have been excluded from the patentability but patenting of microorganisms and non-biological processes is allowed. Therefore, in other words, microorganisms *per se*, process of their production and process of their use are made patentable, TRIPS agreement however, neither defines the term "microorganism" nor does it specify any parameters concerning the scope of protection to microorganism such as microorganism *per se*, whether found in nature or created artificially such as genetically modified organism (GMO) etc. However, the EC directives on microorganisms define it as "any micro biological entity, cellular or non-cellular, capable of replication or transferring

genetic material. EC directives have also defined "biological material" as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system [36].

4.4 Term of protection

The provisions under TRIPS agreement provide the term of patent protection for 20 years from the date of filing. Thus, the inventions relating to biotechnology or to any other fields of technology will have uniform term of protection without any discrimination or classification as to the field of technology unlike as was provided in Iranian Patent and Trademark Act, 1931.

4.5 Exclusive marketing rights (EMRs)

The Iranian Patent and Trademark Act, 1931 does not allow the patent protection for pharmaceutical per se. Article 28 of the Act prohibits patenting of 'medicinal formulas and arrangements'. Till recently, it was not clear that this particular provision prohibits patenting of drugs. However, the Iranian Patent Office ignored the implication of this provision and granted patent to drugs. This practice was later on got the judicial assent from the Supreme Court. The Court held that what has been prohibited in Art. 28, para.3, of the Patent Act is the registration of the 'medicinal formula and arrangements' and not the 'medicinal

compounds' and Art. 27 of the Act in question has authorized the registration of the cases such as the invention of a new industrial product or the discovery of a new thing or the application of a new method for the use of the existing instruments. Therefore, the legislator has not intended to prohibit the registration of the real discoveries and inventions made through scientific methods or of a new material which is made from two or more chemical substances, and which is different, from the view point of the nature and property, from its constituent substances. In addition, the meaning of the word 'arrangements' is literally different from the meaning of the word 'compounds', and the legislator has learnedly used the former in Art.28, para.3' [37]. However, the TRIPS agreement provides that "where a member does not make available as on the date of entry into force of the agreement, patent protection for pharmaceutical and agriculture chemical, products exclusive marketing rights shall be granted, for a period of five years from the date of such grant after obtaining market approval in that member or until a product patent is granted or rejected in that member whichever is shorter provided that a product patent application has been filed and a patent granted for that product in another member and marketing approval is obtained in such other member" [38].

Thus, the member country of WTO which does not grant product patent for the inventions

Trips: Patenting of Biotechnological Inventions

relating to pharmaceuticals and agro-chemicals are required to provide exclusive marketing rights if the following requirements are fulfilled,

- (a) an application for the grant of patent has been filed
- (b) marketing approval has been obtained,
- (c) a patent has been granted for that product in another country and
- (d) marketing approval has been obtained in such other country.

Such EMRs will be granted for the period of five years after obtaining marketing approval or until a product patent is granted or rejected. The EMR may therefore be available for pharmaceutical produced by using biotechnological process or methods.

Therefore, in order to implement these provisions, the member country must accept the filing of applications for patents for pharmaceutical and agrochemical products from January 1, 1995. Even if the member country delays the application of other provisions of TRIPS agreement, and after expiry of that delay, it must take a decision in respect of the application either to reject or grant a patent. But in doing so, it must apply the criteria of patentability as lays down in the TRIPS agreement retroactively. If the decision is to grant a patent, it will be available for the remainder period of term of patent [39].

4.6 Product patent for inventions not protectable:

The pharmaceutical, chemical products, agro-chemicals, microorganism, genetic engineering products etc., are currently excluded from patentability in many countries including Iran [40]. In 1988, WIPO found that 49 countries, excluded the pharmaceutical products, and 22 countries, chemical products from patentability. A majority of the countries provided process patents. In some of the countries, neither were patentable [41]. Even in some developed and developing countries like India, the life of a patent is shorter in pharmaceuticals than in other sectors of technology [42]. The exclusion of product patent for pharmaceuticals and chemicals is motivated by the concern for public health and availability of these products to the general public at a reasonable price [43]. The TRIPS agreement allows any developing country member to delay the application of provisions concerning patents for products, if the subject matter of invention falls in an area of technology not patentable in that member country when TRIPS came into effect. Pharmaceuticals, chemical microorganisms etc., are such areas. Such delay may be five years, (Art 65.4) added to the four years general delay granted to developing countries (Art. 65.2) and the one year delay granted to all members, for total of ten years [44]. A least developed country is entitled to a general transitional

period of 11 years. The TRIPS council shall, upon duly motivated request by a least developed country member, accord extensions of this period [45].

4.7 Burden of proof

According to the provisions, under TRIPS agreement, the burden of proof has been shifted to defendant. It provides that "if the patent is granted for a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process" [46]. The burden of proof, however shall be subject to following conditions: (a) if the product obtained by the patented process is new or (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used. However, a member country is free to provide only one of these two conditions for such presumption. Due to shifting of burden of proof, a manufacturer will be required to provide the details of the manufacturing process to rebut the infringement of patent [47]. In such a case, the courts are required to take into account the legitimate interest of the defendant in adducing the evidence to the country [48].

4.8 Sufficient disclosure and best mode

TRIPS agreement provides that, "the applicant

for patents shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or where priority is claimed, at the priority date of the application." [49] For all practical purposes, the same result is accomplished by the corresponding provision of Patent Cooperation Treaty (PCT), which includes describing the nucleotide sequences, deposition of microorganism to supplement the written description. The provisions as mentioned above, also exist in the patent laws of almost all countries for the reason that when term of protection (patent) is over, the public should be able to take benefit of the invention. It is very difficult to describe the invention relating to biotechnology by written description as it involves the use of living material such as microorganism. Budapest Treaty, provides facility to deposit the microorganism in any of the International Depository Authority (IDA) recognized by WIPO to supplement the written description to avoid deposition of such microorganism in each country where the applicant applies for grant of Patent.

4.9 Rights of patebtee

According to the provisions of Article 28, a patent shall confer on its owner the following

Trips: Patenting of Biotechnological Inventions

exclusive rights:

(a) where the subject matter of patent is a product, to prevent third party from making, using, offering for sale, selling or importing that product for these purposes, and

(b) where the subject matter of patent is a process, to prevent third party from using the process, offering for sale, selling or importing for these purposes, at least the product obtained directly by that process.

Thus, importation of patented product is allowed as one of the exclusive rights conferred on patentee under Article 28 of the TRIPS which will be considered equivalent to commercial working of patents. The provisions relating to compulsory license, enforcement etc., have been made stricter.

5. Protection of Plant Varieties

One of the Lord Buddha's disciples was sent to find a useless plant. After months and years of wandering, he came back and told the Lord Buddha that there was no such thing. Every plant has a use ... one must only find out what the use is [50].

The importance of plant genetic resources for human welfare and the world economy is incalculable. They provide the foundation of all food production and the key to feeding unprecedented numbers of people in times of climate and other environmental changes and,

therefore, comprise perhaps the most important category of biological resources [51]. Millions of farmers depend upon them for their very survival. Hence, it will be a futile exercise to quantify the social, cultural and spiritual values of plant varieties in monetary terms.

The increase in food demand due to population growth and the limited amount of new land being opened up for the food production led to the breeding of new plant varieties from the existing ones. These new varieties are superior in quality and yield compared to the parent varieties. The wonders that biotechnology did in the last decades of 19th century and the whole of the 20th century are remarkable.

These developments in biotechnology had its impact in the legal field also. A question was mooted whether patent rights can be granted to the invention of a new plant variety. This is still an unsettled issue. In its study in 1988, the WIPO found that 44 countries expressly excluded plant varieties, 45 excluded animal varieties and 42 excluded biological processes for producing plant and animal varieties [52]. But the United States by enacting the Plant Patents Act, 1930 and the Plant Variety Protection Act, 1970 has been according patent-like protection for asexually produced plant varieties and sexually produced plant varieties respectively for a long time.

Article 53 (b) of European Patent Convention (EPC) 1973 excluded from patentability “plant or animal varieties or essentially biological processes for the production of plants or animals”. The Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents on Inventions, 1963 and the WIPO Model Law for Developing Countries on Inventions, 1979 also contain similar provisions. Thus, the approach is not to oblige the member countries to provide patent protection for new plant varieties. But there is nothing which prohibits the states to provide the same.

The key international IPR agreements relevant to new plant varieties are TRIPS Agreement and UPOV Convention. The most relevant provisions of these agreements and their implications are analysed below.

5.1 The TRIPS agreement

The relevant provision in the TRIPS with regard to patenting of plant varieties is contained in Art 27 (3). It states that members may exclude from patentability:

- a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.
- b) plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological

processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the entry into force of the WTO Agreement.

What it means is that with respect to ‘products’, plants and animals may be excluded from patentability and as regards to ‘processes’, essentially biological processes for the production of plants or animals may also be excluded. But patents must be available for microorganisms as ‘products’ and for non-biological and micro-biological ‘processes’ for producing plants or animals [53]. With regard to plant varieties the member countries have three options viz. 1) to provide patent protection, 2) to provide an effective *sui generis* system and 3) to provide for a system which is a combination of the first two.

There has been a lot of controversy as to what constitutes the *sui generis* system. The provision in TRIPS qualifies *sui generis* system, with the word *effective*. It is not, however, easy to define the limits of an effective *sui generis* system. The natural tendency is to rely on the standards set in the UPOV Convention, which essentially deals with the protection of new plant varieties. But it is pointed out that a *sui generis* system means a

Trips: Patenting of Biotechnological Inventions

unique system not classifiable with others [54]. Many argue that a *sui generis* system is contemplated, as it would be less vigorous than patents while considering the suitability of protection. What the provision mandates is to provide *sui generis* system of protection and exclusion from any kind of protection cannot be equated with this.

Another question that arises in the context of Art 27 (3) is how to distinguish plant varieties from plants and whether a transgenic plant is a 'plant variety' or a 'plant'? This question assumes great importance given the increased application of genetic engineering to crop research.

Defining and legally interpreting the term 'plant variety' is not easy. The UPOV Convention provided for two definitions. According to the Act of 1961, a plant variety is any 'cultivate, clone, line, stock or hybrid which is capable of cultivation'. But the Act of 1991 replaced it with a more detailed definition according to which, a plant variety is:

"A plant group within a single botanical taxon of the lowest known rank, which grouping irrespective of whether the conditions for the grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes distinguished from any other plant grouping by the expression of at least

one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged." [55]

The 1991 definition of plant variety has sought to be broadened to include the whole genome. For example, it is argued,[56]

It might no longer be sufficient to define a variety by a set of about 25 morphological characteristics [57]. It would rather be necessary to define it by its whole genome, represented in the standard sample of all the variety. Of course, it would not be possible to check all the genes. It would not even be sensible to try doing so, as the majority of the genes do not have any link to the important features of variety. So, again, the variety tests and identity checks would have to be restricted to a manageable set of characteristics – morphological characteristics, protein bands or others- for routine testing. These might be extended in particular cases to characteristics, which indicate a certain feature for the use of the variety. These could be certain protein bands, which are known to be linked to a feature, like a certain quality, resistance to a disease etc. It will be desirable to know as much as possible about the links between protein bands and specific features. The same is true

for DNA sequences... a common understanding should be reached within UPOV about the use of such genetic fingertips.

Another important point is the built-in agenda of the TRIPS Agreement contained in Article 27.3. (b) wherein, it is provided that it has to be reviewed after four years of implementation of TRIPS. This was to take place in 1999. But it foresees when a review takes place there is a danger that some developed countries may seek to have Art 27.3. (b) removed entirely from the TRIPS and to incorporate the UPOV standards. This appears to be the strategy of the US Government. A US Government communication to the WTO General Council dated 19 November, 1998 noted that the TRIPS Council should consider "whether it is desirable to modify the TRIPS Agreement by eliminating the exclusion from patentability of plants and animals and incorporating key provisions of the UPOV Convention regarding plant variety protection." [58] This will result in curtailing the options of formulating a *sui generis* system or a combination of patent and *sui generis* system available to the member states. Discussion about the review has already started. TRIPS council has already held its meeting at Doha in November, 2001 [59]. The review is also required to examine as to whether there is a possibility to amend TRIPS and to provide

effective *sui generis*-system conforming UPOV 1978 or UPOV 1991.

In 6 July 2006, 11 developing Countries (including Brazil, Thailand and Peru) discussed at the TRIPs Council for the creation of relation between the TRIPs Agreement and the Convention on Biological Diversity (CBD). They proposed the adoption of a new Article 29 in the TRIPs Agreement on disclosure of origin of biological resources and/or associated traditional knowledge. The main clause of the proposed text is: Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge. Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained and as known after reasonable inquiry, the country of origin. Also, the applicants shall provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from commercial or other utilization of such resources. However, Above proposal was not accepted because developed countries disagreed with it [60].

Developing countries like India and Iran should take heed of these possibilities and develop a coordinated strategy.

Trips: Patenting of Biotechnological Inventions

As granting of intellectual property rights on biological material has proven to be highly contentious issue internationally for cultural and ethical reasons and due to diverging economic interest, the WTO has all set to re-evaluate the obligations of member countries to protect plant material legally. This has resulted in biotechnology and seed industry to join hands to coordinate towards a more rigid protection of invention related to plant material and at the same time, to recognize the rights of local farming communities and their contribution in selective areas such as plant, medicine of economic value. However, some NGOs have already started opposing grant of patents for life forms. Thammasat Resolutions 1994 [61] had called for revision of TRIPS agreement in order to allow countries to exclude life forms and bio-diversity related intellectual property rights. The resolution also provides for recognition of *sui generis* system that exists independently from TRIPS agreement to protect the inalienable rights of farmers, local communities who drive their livelihood from diversity.

5.2 The UPOV convention

The International Convention for the Protection of New Varieties of Plants (the UPOV Convention) [62] was signed in Paris in 1961 and entered into force in 1968. The Convention was subjected to revision in 1972, 1978 and

1991. The 1978 act entered into force in 1981 and the 1991 Act in April 1998. The Convention established the International Union for the Protection of New Varieties of Plants, which is based in Geneva.

The origin of the UPOV Convention was limited to Europe. In fact, only twelve West European countries were invited by the French Government for the process of negotiations [63]. Its utility was also intended to be extended only to Europe. It is stated that even the administrative and other provisions aimed at market supply and consumer protection had its roots in the general shortage in food supply in the thirties and post-war Europe [64]. But it is this convention that most of the writers point to as the *sui generis* option available under Article 27.3(b) of the TRIPS Agreement.

5.2.1 Salient features of the UPOV convention

The Convention seeks its members to accord protection for the new varieties of plants. The protection is granted to a person who breeds or discovers and develops a new variety [65]. To be eligible for protection, thus the plant variety must be:

- (a) distinct, i.e., distinguishable by one or more characteristics from any other variety whose existence is a matter of common knowledge;

- (b) stable, i.e., remain true to its description after repeated reproduction or propagation;
- (c) uniform in its relevant characteristics, or homogenous with regard to the particular feature of its sexual reproduction or vegetative propagation; and
- (d) novel, i.e., not have been offered for sale or marketed, with the agreement of the breeder or his successor in title, in the source country, or for longer than a limited number of years in any other country[66].

The most important feature of the UPOV Convention relates to the extensive protection available to the breeder. These are commonly known as the Breeder's Rights. Under the 1978 UPOV Act, prior authorization of the breeder is required in the following acts[67]:

- (1) production for the purpose of commercial marketing;
- (2) the offering for sale; and
- (3) the marketing of the reproductive or vegetable propagating material, as such, of the variety .

The right of the breeder shall also extend to ornamental plants or parts thereof normally marketed for purposes other than propagation

when they are used commercially as propagating material in the production of ornamental plants or cut flowers.

However, the 1991 Act extends the scope of the breeders' rights. First of all, it increases the number of acts for which, prior authorisation of the breeder is required. As per Article 14(1) they are:

- production or reproduction (multiplication)
- conditioning for the purpose of propagation.
- offering for the sale
- selling or other marketing
- exporting
- importing
- stocking for any of the purposes mentioned in (1) to (6) above.

Again such acts are not just in respect of the reproductive or vegetable propagating material as with the 1978 version, but also encompass harvested material obtained through the use of propagating material. Article 14(2) provides:

In respect of harvested material, including entire plants and parts of plants obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said

Trips: Patenting of Biotechnological Inventions

propagating material. Such an authorization is also required in respect of products made directly from harvested material and through the unauthorized use of the harvested material.

This provision enables the breeder to license others to produce the variety but at the same time reserve to himself the right to sale, export or stock the end products. Such unauthorized dealings in the end products would constitute an infringement of the breeder's right[68].

The breeders' right in relation to a variety derived from a protected variety is a complicated one. The extent of the rights over the derived variety is different in 1978 Act. As per the 1978 Act, the second breeder is free both to breed and commercialize the new derived variety, if it is not a reproduction for the purpose of selling the protected variety and there is no repeated use of the reproductive material of the protected variety for the commercial production of the derived variety[69]. As far as the original breeder is concerned, his right is limited in its extent. But the 1991 acts enlarges the scope of this right and gives protection to the derived variety. As per Article 14(5) the breeder has the right in relation to:

- (a) Varieties which are essentially derived from the protected variety, where the

protected variety is not itself an essentially derived variety;

- (b) Varieties which are not clearly distinguishable in accordance with Art. 7 from the protected variety, that is, whose existence is commonly known at the time of application for registration; and
- (c) Varieties whose production requires the repeated use of the protected variety.

As per Article 14 (5) (b), variety is deemed to be essentially derived from another variety when:

- (a) It is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotype of the initial variety;
- (b) It is clearly distinguishable from the initial variety; and
- (c) Except for the differences, which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

But many scholars have raised concerns that determination of whether a new variety is essentially derived from an earlier one will likely to be made, not during the examination but through agreement or litigation. Dhar and Chaturvedi echo this concern:

“this implies that this critical issue would be settled by the relative strengths of the parties involved, an eventuality that would not favour developing countries like India who have long been involved in major programmes of plant breeding.”[70]

Another salient feature of the UPOV Convention is the exceptions made to the breeders’ rights. In this respect also there are some differences between the 1978 and 1991 Acts. As per 1991 Act, the breeders’ rights do not extend to (a) acts done privately and for non-commercial purposes; (b) acts done for experimental purposes; and (c) acts done for the purpose of breeding other varieties except where provisions of Article 14(5) apply, i.e. essentially derived variety[71].

The exception provided to farmers is an important feature of the UPOV Convention. But there has been a great dilution to ‘farmers rights’ in the 1991 Act. Under the 1978 Act, the saving of seed by farmers from their harvests out of the protected variety was not an infringement of the breeders’ rights. But some scholars question the very existence of such an exception under the 1978 Act. Graham Dutfield opines:

“It is often assumed that the 1978 version allows a farmer to re-sow seed harvested from protected varieties for his or her own use. In fact such a

farmers’ privilege is not referred to at all. The convention establishes minimum standards such that the breeder’s prior authorization is required for at least the three acts mentioned above[72]. Although the farmers’ privilege is not compulsory, many countries that are members of the 1978 convention do indeed hold it.”[73]

The 1991 Act is specific on this aspect. Whereas, the scope of the breeders’ right includes production or reproduction and conditioning for the purpose of propagation, the government can, if it wishes to protect the farmers’ right. Article 15 (2) states that a contracting party may:

Restrict the breeder’s right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting on their own holdings.

Thus as per the 1991 Act, the member state has to specifically provide for in the national legislations to protect the farmers’ right. Such an exemption should remain within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder.

The 1991 Act has extended the period of the breeders’ right. Now the period will not be shorter than 20 years from the date of the grant of the breeders’ right and for trees and vines

Trips: Patenting of Biotechnological Inventions

period will be 25 years. Under the 1978 Acts, these were 15 years and 18 years in case of vines, fruit trees, forest trees and ornamental trees.

It is evident that the UPOV Convention as revised in 1991 envisages a strict regime of PBRs. The rights available to a breeder have been substantially increased, the exemptions given to the farmers have severely been eroded and the period of protection has also been increased. Supporters of the UPOV argue that the 1991 revision encourages breeders to experiment with minor crops and to bring whole new species into cultivation. Opponents, however, point out that even if this is true, small farmers will still be worse off if they lose their privilege to re-sow seeds from their harvested crops.

But it remains a fact that only those countries where multinational seed companies have their presence, show eagerness to join the UPOV Convention. The overwhelming majority of UPOV members are in Europe, North America, Latin America and Australia. This seems to reflect the fact that in many developing countries, especially in Africa, the private sector's involvement in plant breeding and seed supply is quite limited [74]. It is the traditional communities that are responsible for much of the plant breeding and seed distribution in these countries[75].

Conclusion

The TRIPS Agreement makes it mandatory to provide patent protection to micro-organisms and non-biological and microbiological production of plants and animals. Plant varieties are to be protected either by patents or by a *sui generis* system or a combination of both. This makes it difficult for the developing countries to exclude inventions within this category altogether. Hence, the strategy should be how to limit the scope of these provisions. As far as the patent protection of micro-organism is concerned, TRIPS does not provide a definition of micro-organism. The national rule-makers should may define micro-organism in such a way as to include the following: bacteria, virus, fungus and alga's space. Another important way to limit the scope of patent protection to biological materials is to make a difference between the concept of invention and discovery. Since only inventions are qualified for patenting, naturally found micro-organisms, DNA structure, genes, blood cells, etc., can be excluded from patent protection. Developing countries can also exclude certain inventions in biotechnology by relying on the exclusion provision available under the TRIPS Agreement which permits the state parties to exclude certain inventions which are injurious to health and environment of human and animals. Using this exception, a member state can exclude

terminator type technologies from patent protection.

Developing countries can use the *sui generis* option for the protection of plant varieties. The Agreement is silent about the content of the *sui generis* system. Hence, the developing countries can adopt a *sui generis* system which is suitable to their socio-economic conditions. There is no compulsion to adopt an UPOV model system. If the countries are going for the UPOV model, the successive amendment made the UPOV system are very stringent, especially after 1991 amendment. Therefore, the desirable model is UPOV 1978 which provides for breeders exception and also does not affect the farmer's rights. However, it is better to recognize the farmer's right explicitly. An explicit recognition would not give room for confusion in this matter. While doing so, care should be taken in outlining the rights of the farmers. It should not result in the curtailment of any rights enjoyed hitherto by the farmers. Further, the protection should be limited to certain varieties and avoid food grains from protection.

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Trips: Patenting of Biotechnological Inventions

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Trips: Patenting of Biotechnological Inventions

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موافقتنامه تریپس و ثبت اختراعات بیوتکنولوژی

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اعطای حقوق مالکیت فکری به موجودات بیولوژیکی، می‌تواند از منظر فرهنگی، حقوقی، اخلاقی و مذهبی، موضوعی بسیار جنجالی باشد. به محض اینکه موضوع، بعد بین‌المللی پیدا می‌کند، حتی می‌تواند پیچیده‌تر نیز گردد. موافقت‌نامه راجع به جنبه‌های مرتبط با تجارت حقوق مالکیت فکری (تریپس)، آخرین نظام بین‌المللی است که براساس آن، ساختاری پیچیده برای حمایت بین‌المللی از حقوق مالکیت فکری ایجاد شده است. با این حال، از آنجا که این موافقت‌نامه در بردارنده برخی مقررات از اسناد بین‌المللی قبلی راجع به حقوق مالکیت فکری است، نمایی یگانه و بی‌نظیر از حمایت بین‌المللی حقوق مالکیت فکری را منعکس می‌سازد که تنش میان کشورهای توسعه‌یافته و در حال توسعه بخصوص در زمینه قابلیت ثبت اختراعات بیولوژیکی را نیز برجسته می‌کند. مقررات تریپس، نفی چنین حمایتی از سوی کشورهای در حال توسعه را دشوار می‌سازد. با این حال، این امکان برای آنها وجود دارد تا قلمرو چنین حمایتی را با استناد به استثنائات مقرر در تریپس و نیز با اتکا به تمایز اختراع و اکتشاف، محدود کنند. این ساز و کارها به کشورهای در حال توسعه اجازه می‌دهد تا در تعریف گستره بیوتکنولوژی‌های قابل ثبت، برخی اختیارات را اعمال دارند.

واژگان کلیدی: بیوتکنولوژی، حقوق مالکیت فکری، اختراعات

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