21: Patents: Biotechnological Inventions: Genetic Resources, Plant Variety Protection, Traditional Knowledge

> Article 27.3(b) Patentable Subject Matter
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> Members may also exclude from patentability:
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> plants and animals other than micro-organisms, 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 date of entry into force of the WTO Agreement.

1. Introduction: terminology, definition and scope

Article 27.3(b) addresses one of the most controversial issues covered by TRIPS. The often called "biotechnology clause" describes subject matter that Members *may* exclude from patentability while, at the same time, specifically obliges Members to protect microorganisms and certain biotechnological processes.

The drafting of this clause – the single one in the whole TRIPS Agreement subject to an early review[643] – reflected, on the one hand, the strong interests of some developed countries in ensuring protection of biotechnological innovations and, on the other, the important differences existing among such countries with regard to the scope of protection, as well as the concerns of many developing countries about the patentability of life forms.

Since the adoption of the Agreement, the differences in the treatment of biotechnological inventions among developed countries have been reduced,[644] but not eliminated.[645] Many developing countries have indicated, in the process of review of Article 27.3(b) and in preparations for the Third WTO Ministerial Conference (December 1999), their discomfort with the implications of this provision, particularly in view of several cases of protection, in developed countries, of biological

[643] Which should have taken place in 1999.

[644] Particularly with the approval of the EU Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996).

[645] Thus, plant varieties and animal races are not patentable in Europe, while they are eligible for protection in the USA.

resources or traditional knowledge (such as quinoa, ayahuasca and curative uses of turmeric)[646] originating in developing countries. In the opinion of these countries, there is need to reconcile Article 27.3(b) with the relevant provisions of the Convention on Biological Diversity, particularly on prior informed consent and benefit sharing.

Article 27.3(b) leaves considerable flexibility for Members to adopt different approaches to the patentability of inventions relating to plants and animals, but unambiguously requires the protection of micro-organisms.[647] In addition, this Article obliges Members to provide protection for "plant varieties". The distinction between a "plant", that is, a living organism that belongs to the plant kingdom, and a "plant variety"[648] must be borne in mind for the interpretation of this clause. For example, when a pest-resistant gene is introduced by means of genetic engineering in a certain number of cotton plants[649], one or more "transgenic" plants are obtained. The patentability of these plants may or may not be admitted under national law. These plants, however, do not necessarily constitute a "plant variety", unless whenever cultivated, the resulting plants retain certain predetermined characteristics and can be propagated unchanged.

In case a Member chooses to protect living organisms through patents,[650] only such organisms having undergone a certain technical modification are not

[646] See Correa, 2001 and UNCTAD-ICTSD, Policy Discussion Paper (2003).

[647] A "micro-organism" is "an organism not visible to naked eye" (*The Concise Oxford Dictionary*, Oxford University Press, Seventh Ed., 1982). Note, however, that in the Council for TRIPS, there is no agreement on a common definition of what constitutes a micro-organism (see Communication from the European Communities and their Member States to the Council for TRIPS of 17 October 2002, IP/C/W/383, page 1).

[648] According to the UPOV Convention (as revised in 1991) a "plant variety" is "a plant grouping within a single botanical taxon of the lowest 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". One essential element in this definition is that a plant "variety" is a *grouping* of plants which retain their distinguishing characters when reproduced from seeds or by asexual means (for example, cuttings). See National Research Council, Committee on Managing Global Genetic Resources: *Agricultural Imperatives, Managing Global Genetic Resources. Agricultural Crop Issues and Policies*, National Academy Press, Washington, D.C. 1993, p. 412. Expressed in less technical terms, a plant variety is the technical modification of a naturally existing plant. The result of this modification is a transformed plant which retains certain characteristics when reproduced from seeds or by asexual means (the latter meaning reproduction not from seeds but through methods such as cutting, division, layering, etc.).

[649] While inserting genes is the task of *biotechnologists*, developing a variety is the responsibility of *breeders*. "Plant breeding" is the science-based activity that aims to improve the quality and yield of plant varieties yield, see W. Hale and J. Margham, *The Harper Collins Dictionary: Biology*, Harper Perennial, New York 1991, p. 430 [hereinafter Hale and Margham]. Two ways of breeding have to be distinguished. "Conventional " breeding" (as opposed to genetic engineering) utilizes selection, crossing and other methods in order to obtain the expression of the desired traits in a group of plants. Genetic engineering is the general term referring to all techniques used to isolate particular genetic material (i.e. DNA) from one organism and introduce it into another organism, thus resulting in the latter being "transgenic". See Geoff Tansey, *Food Security, Biotechnology and Intellectual Property. Unpacking some issues around TRIPS*. A Discussion Paper, Quaker United Nations Office, Geneva 2002, p. 6, quoting Peter Lund.

[650] Note that under Article 27.3(b), only micro-organisms, microbiological and non-biological processes have to be protected through patent law. For plant varieties, Members may establish *sui*

pre-existent in nature and may thus be considered as new. Since the determination of the precise meaning of novelty (like the other patentability criteria) is left to the WTO Members' discretion, the degree of technical intervention required to satisfy the novelty criterion varies widely among domestic patent laws.[651]

While Article 27.3(b) is flexible about the form of protection of plant varieties, it forced the introduction of IPR protection in an area in which most developing countries had none before the adoption of the Agreement. This obligation has raised concerns in some of those countries about the impact of IPR protection on farming practices (particularly the re-use and exchange of seed by farmers), genetic diversity, and food security.

2. History of the provision

2.1 Situation pre-TRIPS

After the decision by the U.S. Supreme Court in *Diamond v. Chakrabarty* (1980),[652] which accepted for the first time a patent on a living organism *per se*,[653] the patentability of such matter expanded in industrialized countries to include cells and sub-cellular parts, including genes, as well as multicellular organisms. An accepted principle since the 1980s in those countries was that the fact that an invention consisted of, was based on or employed living matter, was not a sufficient reason to exclude patent protection, including for biological materials pre-existing in nature (provided that the latter were claimed in an isolated or purified form). Despite this trend, considerable differences remain in those countries with regard to the scope of patentability of biotechnology-related inventions. Divergences were even more profound with respect to developing countries.[654]

In the field of plant varieties, few countries (most of them developed countries) had adopted at the time of the negotiation of TRIPS specific regulations on breeders' rights and had adhered to the Convention for the Protection of New Varieties of Plants ("the UPOV Convention") of December 2, 1961, which was subsequently revised in 1972, 1978 and 1991.[655] In addition, the 1978 Act of the UPOV Convention did not permit the provision of both breeders' rights and patent protection for the same genera or species (Article 2).[656]

generis systems that do not rely on the same criteria for protection as patents (i.e. novelty, inventive step and industrial applicability). For details, see Sections 3 and 5 of this chapter.

[651] For more details, see Section 3 of this chapter.

[652] 447 U.S. 303 (1980).

[653] The patent, filed in 1972, related to a genetically modified microorganism. It asserted 36 claims related to the invention of "a bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of these plasmids providing a separate hydrocarbon degradative pathway".

[654] See World Intellectual Property Organization, Memorandum on Exclusion from Patent Protection, Doc. No. HL/CE/IV/INF/1, reprinted in 27 Industrial Property, 192 (1988).

[655] UPOV is a French acronym for what is referred to in English as the International Union for the Protection of New Varieties of Plants. WIPO and UPOV are closely associated. The UPOV Convention is a shorthand for the treaty administered by that organization.

[656] This limitation was lifted by the 1991 revision of the Convention (see below, Section 5.2 of this chapter).

2.2 Negotiating history

The initial negotiating proposals by the United States, Japan, the Nordic countries and Switzerland aimed at broad patent coverage for plants and living organisms.[657] In contrast, most developing countries (joined by the European Community countries in relation to plant varieties and animal races) rejected such an approach.

2.2.1 The Anell Draft

The Anell Draft text under negotiation in July 1990 (W/76) showed how substantial the divergences among the parties were. A heavily bracketed text alluded to the possible exclusion from patentability of

> "1.4.4 [Any] plant or animal [including micro-organisms] [varieties] or [essentially biological] processes for the production of plants or animals; [this does not apply to microbiological processes or the products thereof]. [As regards biotechnological inventions, further limitations should be allowed under national law]."

2.2.2 The Brussels Draft

By December 1990, the parties had not agreed on the issue of patent protection for plants and animals, and the differences were still outstanding. The Brussels Draft text provided, in bracketed language, that parties could exclude from patentability:

> "[b) A. Animal varieties [and other animal inventions] and essentially biological processes for the production of animals, other than microbiological processes or the products thereof. PARTIES shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. This provision shall be reviewed [. . .] years after the entry into force of this Agreement.]
>
> [b) B. Plants and animals, including microorganisms, and parts thereof and processes for their production. As regards biotechnological inventions, further limitations should be allowed under national law.]"

Paragraph A essentially reflected the views of developed countries, and paragraph B of developing countries. As a simple comparison with the adopted Article 27.3(b) shows, the developed countries' approach finally prevailed to a large extent.

3. Possible interpretations

3.1 Plants and animals

Members may also exclude from patentability . . . plants and animals

Article 27.3(b) allows for the exclusion from patentability of "plants and animals" in general. In the absence of any distinction, and in the light also of the second

[657] See Terence Stewart (Ed.), *The GATT Uruguay Round. A negotiating History* (1986–1992), Kluwer Law and Taxation Publishers 1993, p. 2294.

sentence of the same Article that introduces an exception for one particular classification (plant varieties), the scope of the exception under Article 27.3(b) is to be interpreted in broad terms. Consequently, Members may exclude plants as such (including transgenic plants),[658] plant varieties (including hybrids), as well as plant cells, seeds and other plant materials. They may also exclude animals (including transgenic) and animal races.

Members may opt to exclude from patentability only certain categories of plant and animal inventions. Thus, in European countries the prohibition to patent a plant "variety" does not prevent the patenting of plants as such. Similarly, the granting of a patent by the European Patent Office on the "Harvard oncomouse" (a mouse genetically modified to facilitate the testing of anti-cancer drugs) was also based on the judgment that it was not a "race" but a specifically altered "animal".[659]

3.2 Micro-organisms

. . . other than micro-organisms . . .

A "micro-organism" is an organism that is not normally perceptible by the eye. The scientific concept of "micro-organism" refers to "a Member of one of the following classes: bacteria, fungi, algae, protozoa or viruses."[660]

An important question is whether microorganisms as found in nature should be patented under this provision. It is generally accepted that "to be patentable, a micro-organism cannot be as it exists in nature".[661] However, in some jurisdictions it is sufficient to isolate a microorganism and identify a use therefore to obtain a patent.

Thus, in countries that are parties to the European Patent Convention a patent may be granted when a substance found in nature can be characterized by its structure, by its process of isolation or by other criteria, if it is new in the sense that it was not previously available to the public. The European Directive on Biotechnological Inventions clarifies that "biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature" (Article 3.2).

In the United States, an isolated or purified form of a natural product is patentable. The concept of "new" under the novelty requirement does not mean "not preexisting" but "novel" in a prior art sense, so that the unknown but natural

[658] Note that the transgenic character alone is not sufficient for the plant to be considered a plant variety. On top of the transgenic modification, the transformed plant would have to be stable in its characteristics, i.e. retain them after reproduction. See above, under Section 1.

[659] Article 27.2 of the TRIPS Agreement allows Members not to grant patents on inventions which are contrary to *ordre public* or morality. See Chapter 19. An exception of this kind, provided for under European law, has been invoked (albeit unsuccessfully) before the European Patent Office in relation to patent applications related to transgenic plants and animals. See Frédéric Pollaud-Dulian, *La Brevetabilité des inventions. Etude comparative de jurisprudence*, France-OEB, Le Droit des Affaires, No. 16, Paris 1997.

[660] See J. Coombs, *Macmillan Dictionary of Biotechnology*, Macmillan, London and Basinstoke 1986, p. 198.

[661] U.S. Communication to the Council of TRIPS, IP/C/W/209, 3 October 2000.

existence of a product does not preclude the product from the category of statutory subject matter. Similarly, in Japan the Enforcement Standards for Substance Patents stipulated that patents can be granted on chemical substances artificially isolated from natural materials, when the presence of the substance could not be detected without prior isolation with the aid of physical or chemical methods.

Members may also opt for a narrower scope of patentability, confining it to microorganisms that have been genetically modified.[662] TRIPS, in effect, does not define what an "invention" is; it only specifies the requirements that an invention should meet in order to be patentable (Article 27.1).[663]

Another important practical issue relates to the patenting of cells, genes and other sub-cellular components. In many jurisdictions, the patenting of these materials has become common practice.[664] Though these materials are not visible to the naked eye, they do not constitute "microorganisms" and, therefore, are not subject to the obligation established in Article 27.3 (b).

3.3 Processes

> Members may also exclude from patentability . . . essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Another possible exclusion from patentability relates to essentially biological processes for the production of plants or animals. Processes for the therapeutic treatment or utilization of plants and animals are not covered by the exception.[665]

The notion of "essentially biological process" has been defined by the European Patent Office on the basis of the degree of "technical intervention"; if the latter plays an important role in the determination of or control over the results, the process may be patentable.[666] Under this notion, conventional breeding methods are generally not patentable. In contrast, methods based on modern biotechnology (e.g., tissue culture,[667] insertion of genes in a plant) where the technical intervention is significant, would be patentable.

[662] See, e.g., Article 10.XI of the Brazilian Industrial Property Code (Law No. 9.279, 14 May 1996), which excludes from patentability "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being.

[663] See Chapter 17.

[664] For instance, genetic materials may be patented in many countries if claimed in a non-naturally occurring form, that is, as an isolated or purified molecule. In the United States, the doctrine of *Re Deuel* (1995) has paved the way for the patenting of DNA even when encoding known proteins, on the grounds that – due to the degeneracy of the genetic code – their structure could not have been predicted. In Europe, however, gene sequences which code for a known protein are generally now regarded as *prima facie* obvious, although such was not the case in the earliest days of molecular biology.

[665] Diagnostic, therapeutic and surgical methods for the treatment of animals may be exempted from patentability under Article 27.3 (a) of the TRIPS Agreement.

[666] Guidelines for Examination of the EPO, No. X-232.2.

[667] This is a technique in which individual cells grow and divide in a bath of sterile, nutritive fluid, used *inter alia*, in plant breeding (Hale and Margham, p. 528).

The exclusion of "essentially biological processes" does not extend to "non-biological" processes for the production of plants or animals. It does not extend either to microbiological processes which are generally patentable. It is not so simple to determine when a process is "microbiological". In principle, this concept would include any process that uses or modifies microorganisms. There are, however, processes that only include one or more steps that are "microbiological." In accordance with the European Directive on Biotechnological Inventions, such processes should be deemed as "microbiological" if at least one essential step is microbiological (Article 2.2).

3.4 Plant varieties

> 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.

TRIPS obliges Members to protect plant varieties by means of patents, an effective *sui generis* regime or a combination of both. While the granting of patents is regulated under considerably detailed standards, the only requirement with respect to a *sui generis* system is that it must confer an "effective" protection. Countries can, thus, determine the scope and contents of the rights to be granted.

The flexibility permitted by Article 27.3(b) in relation to the form of protection for plant varieties has been the reflection, to a large extent, of the lack of consensus on the matter among the industrialized countries during the TRIPS negotiations. While in the USA, Australia and Japan a plant variety may be patented as such, this is not the case in Europe, as mentioned above. The reference to a "*sui generis* system" may be deemed to suggest the breeder's rights regime, as established in the UPOV Convention. However, the possibility is open to combine the patent system with the breeders' rights regime, or to develop other *"sui-generis"* forms of protection.

Industrial property protection for plant varieties is not new. In the 1920s and 1930s several countries introduced legislation that gradually evolved into a *sui generis* system of protection ("breeders' rights") distinct from the patent system. Based on requirements of distinctness, novelty, uniformity and stability, breeders' rights have typically been permitted to control the commercialization of propagating materials (like seeds), without interfering, however, either with the use of saved seeds by farmers on their own land ("farmers' privilege") or with the development of new varieties by a third party taking as a starting point a protected variety ("breeders' exemption"). Such *sui generis* regime obtained recognition at the international level in the 1960s with the adoption of the UPOV Convention. The Convention introduced minimum standards for the recognition of breeders' rights and, as mentioned, it initially prohibited the provision of patent and *sui generis* protection for plant varieties.[668]

[668] The limitation contained in Article 2 of the 1978 Act was not applicable to countries that provided double protection before the expiry of the period for signature of the 1978 Act (Article 37). This allowed the United States to maintain both patents and breeders' rights for plant varieties.

Breeders' rights protect plant varieties, which are new, distinct, uniform and stable. They grant the faculty to exclude non-authorized persons from using and multiplying propagating materials of protected varieties. Several features differentiate breeders' rights from patents. The former apply to a specific variety (which must physically exist), while patents may refer to genes, cells, plants, seeds or (where allowed) the varieties as such. Another important difference is that the breeder's rights system generally allows farmers to re-use in their own exploitations the seeds they have obtained, a possibility that patents generally exclude.[669] In addition, under breeders' rights protected varieties may be used for further breeding without the authorization of the title-holder ("breeders' exemption"). This may not be possible, depending on national legislation, under patent law.

3.5 Review

> The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

TRIPS entered into force on 1 January 1995. Though the review should have taken place in 1999 there has been no agreement at the Council for TRIPS on the meaning of "review". Developed countries have held that a "review of implementation" is what is called for,[670] while for developing countries a "review" should open the possibility of revising the provision itself.[671]

The review of Article 27.3(b) was also one of the TRIPS issues dealt with at the Ministerial Meeting at Doha in 2001. In this respect, the Doha Declaration included the following mandate for the Council for TRIPS:[672]

> "19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

[669] Since living organisms are self-replicating, the sale of a patented organism is at the same time the sale of the means by which the organism can be replicated. Patent rights are deemed in this case to extend to the descendants of the protected organism.

[670] See, e.g., U.S. communication IP/C/W/209; Australia communication IP/C/W/310 ("the coverage of this agenda item is relatively narrow, that is, the item is concerned with a review of the effectiveness of the operation of an optional exclusion to patentability . . . ").

[671] This view is based on the literal text of the provision, as compared to Article 71.1 where the negotiating parties used the expression "review the implementation". According to *The Concise Oxford Dictionary* (Oxford University Press, Seventh edition, 1982, reprinted in 1989), "review" is "revision" which in turn means "to read or look over or reexamine or reconsider and correct, improve, or amend . . . law, constitution, etc."

[672] See paragraph 19 of the Ministerial Declaration, WT/MIN(01)/DEC/1 of 20 November 2001.

Implementing this mandate, the Council for TRIPS has been discussing, *inter alia*, the following agenda items:

(a) the review of the provisions of Article 27.3(b);

(b) the relationship between TRIPS and the Convention on Biological Diversity (CBD);

(c) the protection of traditional knowledge (TK) and folklore.[673]

The Council has addressed these items together, due to their interrelated character. Despite consultations held by the Chair, Members have so far not been able to remove their substantive differences over these issues. A number of proposals made under the three items above will be analyzed in the following paragraphs.

3.5.1 Review of Article 27.3(b)

With respect to the review of Article 27.3(b), some developing country Members, as mentioned above, interpret "review" as opening up the possibility of *amending* Article 27.3(b). In particular, the African Group in a June 2003 submission to the Council[674] proposed an amendment of Article 27.3(b):

> "The African Group maintains its reservations about patenting any life forms as explained on previous occasions by the Group and several other delegations. In this regard, the Group proposes that Article 27.3(b) be revised to prohibit patents on plants, animals, micro-organisms, essentially biological processes for the production of plants or animals, and non-biological and microbiological processes for the production of plants or animals. For plant varieties to be protected under the TRIPS Agreement, the protection must clearly, and not just implicitly or by way of exception, strike a good balance with the interests of the community as a whole and protect farmers' rights and traditional knowledge, and ensure the preservation of biological diversity.
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> In any case, the Council for TRIPS must ensure that the exceptions for ordre public or morality in paragraph 2 of Article 27 are not rendered meaningless by any provisions in its paragraph 3(b) through requiring Members to do what is otherwise contrary to ordre public and morality in their societies. The barest minimum in this regard, would be to clarify that paragraph 3(b) does not in any manner restrict the rights of Members to resort to the exceptions in paragraph 2.
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> [. . .]
>
> As pointed out above, the African Group has consistently raised serious concerns about patents on life forms and research tools and on the basis of these concerns the Group has maintained that there should not be a possibility, within the framework of the TRIPS Agreement, of patents on micro-organisms as well as on non-biological and microbiological processes for the production of plants and animals.
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> It is the view of the Group that the distinction drawn in Article 27.3(b) for micro-organisms, and for non-biological and microbiological processes for the

[673] See, e.g., WTO/AIR/2322 of 27 May 2004, WTO/AIR/2246 of 5 February 2004, and WTO/AIR 2104 of 20 May 2003.

[674] See Joint Communication from the African Group, IP/C/W/404 of 26 June 2003 [hereinafter African Group June 2003].

> production of plants or animals, is artificial and unwarranted, and should be removed from the TRIPS Agreement, so that the exception from patentability in paragraph 3(b) covers plants, animals, and micro-organisms, as well as essentially biological processes and the non-biological and microbiological processes for the production of plants or animals."

This proposal has been the basis of controversial debates within the Council in 2003 and 2004. Developed Members have rejected an amendment of Article 27.3(b) in the above sense, referring, *inter alia*, to their biotechnology industries.[675] The EC, for example, has proposed that those Members seeking to avoid the patenting of natural materials could make use of the TRIPS flexibilities, i.e. to define narrowly the patentability criteria. In this vein, genetic resources occurring in nature would not be patentable (failing to meet the novelty requirement).[676]

The aim of some developed countries, if a revision did take place, would be to eliminate the exception for plants and animals, and to establish that the UPOV Convention as revised in 1991 should be the *only* means of protection available for plant varieties, excluding other *sui generis* systems. Thus, according to the United States, 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 agreement regarding plant variety protection."[677]

For many developing countries, in contrast, it would be important to maintain the exception for plants and animals, as well as the flexibility to develop *sui generis* regimes on plant varieties which are suited to the seed supply systems of the countries concerned.

3.5.2 Relationship between TRIPS and CBD

Different views on the TRIPS-CBD relationship have been expressed at the Council for TRIPS in relation to the review of Article 27.3(b). While developed countries have found no inconsistencies between the two treaties,[678] several developing countries have indicated the need to reconcile them, possibly by means of a revision of TRIPS.[679]

[675] This point was raised by the EC in the March 2004 Meeting of the Council.

[676] The EC expressed this view during the March 2004 Meeting of the Council. See also the Communication from the European Communities and their Member States to the Council for TRIPS of 17 October 2002, IP/C/W/383 [hereinafter EC October 2002], in which the EC rejects an amendment of Article 27.3(b), stating that this provision provides sufficient flexibility to design patent protection according to a country's needs, interests or ethical standards.

[677] Communication from the United States of 19 November 1998, WT/GC/W/115, under item II.A. See also the Communication from the European Commission to the Council and the European Parliament, *The EU approach to the Millennium Round* 1999, p. 16. Note that in recent bilateral free trade agreements, there is a trend towards qualifying UPOV as the sole possible means of plant variety protection. See Section 6.3 of this chapter.

[678] See, e.g., U.S. communication IP/C/W/209; Australia communication IP/C/W/310.

[679] See, e.g., the African Group proposal to harmonize the TRIPS Agreement with the CBD in WT/GC/W/202, and the Indian proposal in WT/GC/W/225.

The main concern of many developing countries is that TRIPS does not require patent applicants whose inventions incorporate or use genetic material or associated knowledge to comply with certain obligations under the Convention for Biological Diversity (CBD). This convention makes access to genetic material subject to prior informed consent of and equitable benefit sharing with the Contracting Party providing the genetic resources.[680] Developing countries have repeatedly voiced concern about possible misappropriation of their genetic resources by developed country patent applicants.[681]

In order to address such concerns, developing countries have proposed in the Council for TRIPS to amend TRIPS in a way as to require an applicant for a patent relating to biological materials or traditional knowledge to provide, as a condition for obtaining the patent:

- disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
- evidence of prior informed consent through approval of authorities under the relevant national regime; and
- evidence of fair and equitable benefit sharing under the relevant national regime.[682]

The approach to enforce CBD obligations through the TRIPS patent system is opposed by a number of developed countries,[683] supporting the alternative idea of pursuing ongoing work in WIPO's Intergovernmental Committee on Intellectual

[680] See Article 15 CBD. For more details, see Section 5.2 of this chapter.

[681] See, e.g., African Group June 2003, p. 4.

[682] See Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403 of 24 June 2003. These three issues were also included in a checklist submitted to the Council for TRIPS on 2 March 2004 by Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela (see IP/C/W/420). The African Group has made a similar proposal, advocating the amendment of Article 29, TRIPS Agreement (conditions on patent applicants), to include an obligation to disclose the country of origin of any biological resources and traditional knowledge as well as to provide confirmation of compliance with domestic access regulations. See African Group June 2003, p. 6.

[683] At the March and June 2004 Council Meetings, the USA and Japan expressed particular opposition to this approach. Switzerland, on the other hand, acknowledged that these issues should be dealt with under the patent system and has proposed to amend the WIPO Patent Cooperation Treaty (PCT) to include, in appropriate cases, the declaration of origin of genetic material in patent applications as a voluntary requirement (IP/C/W/400; reiterated in IP/C/W/423). The proposal includes a concrete description of when disclosure would be relevant, as well as a penalty system for failure to comply in which case the patent would be rejected or withdrawn. Finally, the EC (see EC October 2002) has signalled its agreement to examine and discuss the possible introduction of a system that keeps track of all patent applications regarding genetic resources. At the same time, however, the EC has made clear (ibid.) that legal consequences of the non-respect of a disclosure obligation should lie outside the ambit of patent law. As opposed to the issue of disclosure of origin, the EC at the March 2004 Meeting of the Council for TRIPS expressed reluctance to engage in discussions on the item of prior informed consent. For an overview of the June 2003 and June 2004 Meetings of the Council for TRIPS, see ICTSD Bridges Trade BioRes, 13 June 2003, *CBD-TRIPS Discussion Picking Up Speed At the WTO* (<http://www.ictsd.org/biores/03-06-13/story1.htm>); and ICTSD, Bridges Weekly Trade News Digest, 23 June 2004, *Quiet TRIPS Council Focuses on Health, Biodiversity-Related Issues* (<http://www.ictsd.org/weekly/04-06-23/story3.htm>).

Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).[684] Overall, the issue remains controversial.

3.5.3 The protection of traditional knowledge (TK) and folklore

Discussions in the Council for TRIPS have mainly focused on the question of the right forum for TK protection. Developing countries are almost unanimous in their firm support of the idea that TK protection should be negotiated in the WTO.[685] In these countries' view, any other forum, including WIPO, would not provide the appropriate means for the enforcement of rights.

On the other side, developed Members are opposed to treating TK in the WTO and insist that the matter be dealt with under WIPO auspices (in the IGC).[686] Some of the arguments relate to the expertise of WIPO as well as to the overloaded Doha agenda of the WTO that would not permit sufficient resources to take up a new issue such as TK.

Another controversial issue in this context is the term of protection of TK. While developing countries support the African Group's position[687] that there should be no limitation, like in the case of GIs, developed Members stress the necessity to preserve the public domain in this area.[688]

4. WTO jurisprudence

There is no WTO jurisprudence so far on this subject.[689]

5. Relationship with other international instruments

5.1 WTO Agreements

Other WTO Agreements do not have direct implications on the matters regulated under Article 27.3 (b).

[684] For an overview of the ongoing work in the IGC, see South Centre/CIEL IP Quarterly Update: First Quarter 2004. *Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral, and Bilateral Fora*, available at <http://www.ciel.org/Publications/IP_Update_Spring04.pdf>. See also South Centre/CIEL IP Quarterly Update: Second Quarter 2004. *Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral, and Bilateral Fora*, available at <http://www.ciel.org/Publications/IP_Update_Summer04.pdf>.

[685] See, e.g., the African Group June 2003.

[686] See, e.g., EC October 2002, p. 2: "The EC support further work towards the development of an international *sui generis* model for legal protection of TK in WIPO. At this stage, the TRIPS Council is not the right place to negotiate a protection regime for a complex new subject matter like TK or folklore. This is an issue where the WTO should ideally be able to build on the work done by the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore. Depending on the outcome of the WIPO process, the TRIPS Council will have to determine whether this result warrants further work in the WTO."

[687] See the African Group June 2003, Annex Draft Decision on Traditional Knowledge, para. 4 (c).

[688] This point was raised by the EC at the March 2004 Meeting of the Council for TRIPS. The EC maintained that TK and GIs are different, the latter protecting only the name, while TK protects the knowledge incorporated in a product.

[689] The USA requested consultations under the DSU against Argentina in relation, *inter alia,* to the patentability of micro-organisms (WT/DS 196/1).

5.2 Other international instruments

5.2.1 UPOV

The International Convention for the Protection of New Varieties of Plants, administered by the Union for the Protection of New Varieties of Plants (UPOV), was established in Paris in 1961 and revised three times since then. UPOV sets forth standards, including national treatment, for the granting of "breeders' rights" as a *sui generis* form of protection for plant varieties. The last revision, which took place in 1991,[690] introduced significant reforms to the 1978 Act of the Convention.[691]

In order to be eligible for protection, a plant variety must meet the following requirements:

(i) Novelty. The variety must not – or, where the law of a state so provides, must not for more than one year – have been offered for sale or marketed with the consent of the breeder in the state where the applicant seeks protection, nor for more than four years (six years in the case of grapevines and trees, including rootstocks) in any other state. The 1991 Act makes the one-year period of grace compulsory and requires that "propagating or harvested material of the variety" must not have been "sold or otherwise disposed of to others" (Article 6 of the 1991 Act).

(ii) Distinctness. The variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge (Article 7 of the 1991 Act).

(iii) Uniformity. Subject to the variation that may be expected from the particular features of its mode of propagation, the variety must be sufficiently uniform in its relevant characteristics (Article 8 of the 1991 Act).

(iv) Stability. Subject to the variation that may be expected from the particular features of its mode of propagation, the variety must be stable in its essential characteristics. This is the case if the latter remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle (Article 9 of the 1991 Act).

(v) Denomination. The variety must be given a denomination enabling it to be identified; the denomination must not be liable to mislead or to cause confusion as to the characteristics, value or identity of the new variety or the identity of the breeder (Article 5 (2) in conjunction with Article 20 (2) of the 1991 Act).

The Convention in Article 11 provides for the so-called right of priority. Any breeder (national or a resident of a Member state) may file a first application for

[690] Though new members to UPOV can only join the 1991 Act, many countries still remain obliged under the 1978 Act of the Convention.

[691] The main changes included the expansion of the coverage of protection to all plant genera and species; the extension of the breeder's exclusive rights, in certain cases, beyond reproductive material, to harvested material and products obtained through illegal use of propagating material; allowing members the option to accumulate breeders' rights and patent protection for plant varieties (a possibility excluded under the 1978 Act); and introduction of the concept of "essentially derived varieties" (For an explanation of this term, see below under this Section).

protection of a given plant variety in any of the Member states. If the breeder files an application for the same variety in any other Member state within 12 months from the filing of the first application, the breeder will enjoy a right of priority for this later application.

Protection is granted after the competent authority of the Member state in which protection is sought has ascertained that the plant variety for which protection is sought fulfils the above criteria. The examination of homogeneity and stability, as mentioned, must take into account the particularities of the mode of propagation of the variety.

According to Article 14(1)(a) of the Convention, as amended in 1991, there are seven acts of exploitation for which the breeder's authorization is required: (i) production or reproduction (multiplication); (ii) conditioning for the purpose of propagation; (iii) offering for sale; (iv) selling or other marketing; (v) exporting; (vi) importing; (vii) stocking for any of these purposes.

The above mentioned rights may be exercised in respect of the propagating material, and also in respect of the harvested material (including whole plants and parts of plants), provided that the latter has been obtained through the unauthorized use of propagating material, and that the breeder has had no reasonable opportunity to exercise his right in relation to the propagating material.

The breeder's right extends, in addition to the protected variety itself, to varieties which are not clearly distinguishable from the protected variety, which are "essentially derived" from the protected variety,[692] and those whose production requires the repeated use of the protected variety.

As in the case of UPOV 1978, according to UPOV 1991 the underlying genetic resource embodied in a protected plant variety is freely available to third parties for the purpose of breeding other varieties (breeders' exemption). This is crucial for the further improvement of existing varieties. However, Article 15(1)(iii) in conjunction with Article 14(5) of UPOV 1991 now makes clear that the breeders' exemption does not apply where the third party's breeding activities do not result in a genuinely new variety, but in one that is essentially derived from the initial, protected variety.[693] This is because the breeder's exclusive rights to the initial variety extend to those essentially derived varieties, as observed above.[694]

[692] See Article 14 (5)(a) of UPOV 1991. A variety which is essentially derived from a protected variety and which fulfils the criteria of novelty, distinctness, uniformity and stability, may be the subject of protection by a third party but cannot be exploited without the authorization of the breeder of the original variety. The concept of essential derivation applies to varieties which are predominantly derived from another variety and which, except for the differences that result from the act of derivation, conform to the initial variety in the expression of the essential characteristics that result from the genotype or a combination of genotypes of the initial variety (Article 14(5) of the UPOV Convention, 1991 Act).

[693] See also Biswajit Dhar, *Sui Generis Systems for Plant Variety Protection. Options under TRIPS*. A Discussion Paper, Quaker United Nations Office, Geneva 2002, p. 15 [hereinafter Dhar].

[694] In effect, this provision means that the breeder of breeders' right-protected variety A has the right to demand that the breeder of variety B secure his or her authorization to commercialise B if it was essentially derived from A. The main idea here is that breeders should not be able to acquire protection too easily for minor modifications of extant varieties or free-ride without doing any breeding of their own, problems that the increased application of biotechnology in this field appeared likely to exacerbate. Beyond resolving these particular issues, the provision was

It can thus be noted that the new concept of "essentially derived" varieties as introduced by UPOV 1991 enlarges the exclusive right of breeders, extending those rights from the initial variety to all varieties essentially derived therefrom (Article 14 (5)(a)(i)).

Under UPOV 1978, farmers were permitted to save seeds for re-use in their exploitations. UPOV 1991 made this exemption optional for Member countries, which may restrict the breeder's rights "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" (Article 15 (2)). This exemption, in addition, is to be applied "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder". Thus, the Diplomatic Conference that adopted the 1991 revision indicated that Article 15 (2) should not be interpreted as extending the "privilege" to sectors of agricultural or horticultural production where it is not "a common practice".[695] Here again, UPOV 1991 provided for a considerable strengthening of the exclusive breeders' rights. While under UPOV 1978, farmers were authorized to re-use in any way protected material without the obligation to pay any royalty to commercial breeders,[696] Article 15 (2) of UPOV 1991 results in an important limitation of the farmers' privilege. Farmers are not allowed to sell protected seeds, but are limited to their re-use for propagating purposes on their own land.[697]

also intended to ensure that patent rights and breeders' rights operate in a harmonious fashion in jurisdictions where plants and their parts, seeds and genes are patentable and access to these could be blocked by patent holders. Such a practice would undermine one of the main justifications for breeders' rights protection, which is that breeders should be able to secure returns on their investments but without preventing competitors from being able freely to access breeding material. An example here might be useful. Let us consider the case of a breeders' right-protected variety called A and a patented genetic element owned by a separate company. The owner of a patent on this genetic element is free to use A to produce his or her variety B and, absent of the essential derivation provision, place B on the market with no obligations to the owner of A despite the fact that B differs from A only in the addition of the patented genetic element. However, the owner of A would need a license from the producer of B to use the patented genetic element in the breeding of further varieties. In such a situation, then, patents can have the effect of blocking the breeders' exemption that breeders' rights normally provide. It should be noted here that the breeders' right-issuing office will not itself determine whether a variety is essentially derived from an earlier one. This will be left to the courts. See Graham Dutfield, *Intellectual Property Rights, Biogenetic Resources and Traditional Knowledge*, Earthscan: London 2004, p. 35; R. Jördens, *Legal and technological developments leading to this symposium: UPOV's perspective*. Paper presented at WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments. 25 October 2002, Geneva, p. 6. It is noteworthy that the EC Directive on the Legal Protection of Biotechnological Inventions seeks to make breeders' rights and patents operate more harmoniously by providing that where the acquisition or exploitation of a breeder's right is impossible without infringing a patent, or vice versa, a compulsory license may be applied for. If issued, the licensor party will be entitled to cross-license the licensee's patent or breeder's right.

695 It should be noted that the UPOV Convention contains minimum standards of protection and, hence, any member country may decide to provide higher protection than that resulting from the Convention rules.

696 See Dhar, p. 15.

697 In addition, the exercise of the farmers' privilege shall be "subject to the safeguarding of the legitimate interests of the breeder" (Article 15(2) UPOV 1991), which might be taken by some countries as an authorization to require the farmer to pay royalties to the breeder for the re-use of protected seeds.

The UPOV Convention also allows access to and the use of protected material without the consent of the title-holder in cases of public interest, against an equitable remuneration.

5.2.2 Convention on Biological Diversity

The Convention on Biological Diversity (CBD) of 1992 deals with the conservation and sustainable use of genetic resources. It recognizes the states' sovereign rights over the genetic resources residing in their jurisdictions (Article 3). The Convention requires each Contracting Party to implement several measures in order to ensure the *in-situ* and *ex-situ* conservation of genetic resources.

Article 15 of the CBD recognizes the authority of national governments to determine access to genetic resources, subject to national legislation.[698] Notwithstanding this recognition, each Contracting Party "shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention" (Article 15.2).

According to Article 15 para. 4 and 5 of the Convention, access, where granted, shall be on mutually agreed terms and subject to prior informed consent (PIC) of the Contracting Party providing genetic resources,[699] unless otherwise determined by that Party. In addition, the CBD stipulates that each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties. Most importantly, each Contracting Party is bound to take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms (Article 1 para. 6 and 7).

Article 16 regulates the access to and transfer of technology, which are deemed "essential elements for the attainment of the objectives" of the Convention. Contracting Parties undertake to provide and/or facilitate access for and transfer to other Contracting Parties of "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" (Article 16.1). For the case of developing countries, access "shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms

[698] Under the framework established by the 1983 International Undertaking on Plant Genetic Resources (IU, the predecessor of the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture), plant genetic resources for food and agriculture (PGRFA) were deemed a "common heritage of mankind" and subject to a system of free exchange among the parties to the IU ("Plant genetic resources are a common heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations", IU Preamble).

[699] For the purpose of the Convention, the "genetic resources being provided by a Contracting Party" are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with the Convention (Article 15.3).

where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21" (Article 16.2).

The Convention addresses the case where technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources are subject to intellectual property rights. In such a case, the access and transfer shall be provided on terms which recognize and are consistent with the "adequate and effective protection" of intellectual property rights (Article 16.2). However, the Contracting Parties shall cooperate "subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives" (Article 16.5).

Moreover, each Contracting Party undertakes to take legislative, administrative or policy measures, as appropriate, with regard to intellectual property, the handling of biotechnology and the distribution of its benefits, with the aim that

- Contracting Parties, in particular those that are developing countries, which supply genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 of Article 16 (Article 16.3).
- The private sector facilitates access to, joint development and transfer of technology referred to in Article 16.1 for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 2 and 3 of Article 16 (Article 16.4).
- An effective participation in biotechnological research activities is ensured to those Contracting Parties, especially developing countries, which provide the genetic resources for such research (Article 19.1).
- Priority access by Contracting Parties, especially developing countries, is promoted on a fair and equitable basis to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms (Article 19.2).

Finally, each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing any living modified organism resulting from biotechnology, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced (Article 19.4).

The relationship between the provisions of TRIPS and the CBD has given rise to different opinions,[700] ranging from perfect harmony to collision. The collision has been associated with the possible granting of IPRs, based on or consisting of genetic resources, without observing the prior informed consent and benefit sharing obligations established by the CBD. It has also been held that a possible

[700] See UNCTAD-ICTSD Policy Discussion Paper. For an overview of the current discussion at the Council for TRIPS, see Section 3 of this chapter, above.

conflict may arise in the context of the *implementation* of both instruments, but not necessarily as a result of normative contradictions.[701]

6. New developments

6.1 National laws

Considerable differences exist in national laws with regard to the patentability of biotechnological inventions. The facultative exceptions allowed by Article 27.3(b) have been incorporated into the national laws of many developed and developing countries.[702] Plant and animal varieties are not patentable in the majority of countries.[703] Based on the exceptions allowed by TRIPS, some developing countries have explicitly excluded the patentability of pre-existing biological materials, including genes, unless they are genetically altered. Patents may still be granted, in these cases, for the process used to obtain a biotechnology-based product.

For most developing countries, Article 27.3(b) called for a substantial change in national law, since the majority did not protect plant varieties at the time of negotiation and adoption of the Agreement. Many developing countries have joined or are in the process of joining UPOV, while others have explored the development of non-UPOV modes of protection,[704] including the recognition of "Farmers' Rights".[705] For instance, the Parliament of India passed, on 9 August 2001, a Plant Variety Protection and Farmers' Rights Act. The Act includes provisions for farmers' varieties to be registered, with the help of governmental or non-governmental organizations. The applicant for registration of a variety must disclose information regarding the use of genetic material conserved by any tribal or rural family. Any village or local community may claim compensation for the contribution made in the evolution of a variety. A Gene Fund is created, which should be the

[701] "Many policy-makers and members of civil society are concerned that the TRIPS Agreement promotes private commercial interests at the expense of other important public policy objectives, such as those contained in the CBD. Specifically they are concerned that the TRIPS Agreement is creating serious challenges to the successful implementation of the CBD, including in relation to . . . access and benefit sharing, protection of traditional knowledge, technology transfer, and the conservation and sustainable use of biological diversity", WWF/CIEL, *Biodiversity & Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity*, Joint Discussion Paper, Gland–Geneva 2001, pp. 11–12.

[702] See, e.g., the replies to the questionnaire circulated by the WTO Secretariat, IP/C/W/122 and 126; OMPI/BIOT/WG/99/1, 28 October 1999. See also OECD, *Intellectual property practices in the field of biotechnology*, Working Party of the Trade Committee, TD/TC/WP(98)15/Final, Paris 1999 [hereinafter OECD].

[703] Only in five OECD countries plants *per se*, parts of plants *and* plant varieties are patentable. In only six of such countries patents may cover animals *per se*, animal organs *and* animal varieties (OECD, p. 5). Many patent laws adopted in developing countries have excluded the patentability of plants and animals or, more narrowly, of plant varieties and animal races.

[704] See, e.g., Organization of African States (OAU), *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*.

[705] See on this concept, Carlos Correa, *Options for the implementation of Farmers' Rights at the national level*, South Centre, Working Paper, Geneva 2000.

recipient of all revenues payable to the farming communities. The Act also contains a provision on "Farmers Rights" according to which

> "The farmer . . . shall be deemed to be entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act, provided that the farmer shall not be entitled to sell branded seed of a variety protected under this Act" (Section 39 (iv)).[706]

Peru has established a comprehensive legal system for the protection of traditional knowledge associated with biodiversity.[707] This law reflects the CBD requirements of prior informed consent and benefit sharing. It enables indigenous and local communities to assert their rights over collectively held knowledge. For this purpose, the law obliges interested parties to obtain the prior informed consent of those communities providing the biodiversity-related knowledge. In case of industrial or commercial use, interested parties are required to sign a contract with an organization representing the indigenous communities. According to Article 27 of the new law, such contracts (or licences) have to include, *inter alia*, the right of indigenous communities to claim a minimum compensation, i.e. 5 percent of gross sales of commercial products derived from collective knowledge.

6.2 International instruments

6.2.1 The ITPGRFA

In November 2001, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was agreed upon at the FAO Conference in Rome. It builds on the 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture (IU) and entered into force on 29 June 2004, after ratification by 40 Parties. As opposed to the IU, the ITPGRFA contains legally-binding obligations with respect to access to and benefit-sharing of plant genetic resources in the particular area of food and agriculture. It harmonizes the earlier provisions of the IU with the CBD, recognizing both the Parties' sovereignty over their plant genetic resources and their dependence for food security on the exchange of those resources with other Parties. The ITPGRFA seeks to avoid high transaction costs resulting from bilateral exchanges of breeding material as required under the CBD (Article 15) by establishing a multilateral system to facilitate access and benefit-sharing of genetic resources.[708] This multilateral system of exchange operates by means of a standard Material Transfer Agreement to be adopted by the

[706] For the purpose of clause (iv) branded seed means any seed put in a package or any other container and labeled in a manner indicating that such seed is of a variety protected under this Act.

[707] Law No. 27811, in force since 10 August 2002. For more details, see M. Ruiz and I. Lapena, *New Peruvian Law Protects Indigenous Peoples' Collective Knowledge*, in: Bridges Between Trade and Sustainable Development, September 2002 (year 6, no. 6), p. 15, available at <http://www.ictsd.org/monthly/bridges/BRIDGES6-6.pdf>.

[708] See Tansey, p. 10.

ITPGRFA's Governing Body (Article 12.4). A general pool of the resources of those crops covered by the Treaty is established and made available for further research, breeding and education purposes.[709]

As far as the relationship between the ITPGRFA and TRIPS is concerned, it is in particular Article 12.3(d) of the ITPGRFA that has been subject to controversy.[710] There are several areas of possible conflict of those two agreements. Article 12.3(d) and (f), dealing with access to plant genetic resources for food and agriculture, provides that such access shall be provided, *inter alia*, according to the following conditions:

(d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, *in the form received* from the Multilateral System; (emphasis added)

(f) Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;

Paragraph (f) makes clear that the ITPGRFA is not intended to circumvent the disciplines of TRIPS. It thus informs the interpretation of paragraph (d), which cannot be seen as an authorization of the Parties to violate the TRIPS patent provisions. According to its terms, paragraph (d) does not disallow the patenting of plant genetic resources in general, but only *in the form received* from the Multilateral System. This clearly excludes the patenting of seeds as acquired from a seed bank. On the other hand, it is not clear if the provision also excludes the patenting of such genetic material that has been modified or isolated from its natural environment. A more detailed analysis of this issue would however go beyond the scope of this book.

Finally, Article 13 of the ITPGRFA provides that benefits accruing from the facilitated access to the covered plant genetic resources shall be shared fairly and equitably (Article 13.1). Four benefit-sharing mechanisms are foreseen (Article 13.2): exchange of information; access to and transfer of technology; capacity building; and sharing of the benefits arising from commercialization.

Article 13.2(b)(i) of the Treaty subjects the access to and transfers of technology to the respect of applicable property rights and access laws. Subsection (d)(ii) of the same provision specifies that the standard Material Transfer Agreement (i.e. the Treaty's standardized means of providing facilitated access to the covered genetic resources) shall include a requirement obliging recipients of material accessed from the Multilateral System to pay to a specific financial resources body an equitable share of the benefits arising from the commercialization of products incorporating such material.[711]

[709] For further details on the ITPGRFA, see Tansey, p. 10, as well as the UNCTAD-ICTSD Policy Discussion Paper.

[710] See UNCTAD-ICTSD Policy Discussion Paper, p. 109.

[711] For more details on the benefit-sharing provisions of the ITPGRFA see Tansey, p. 11. On the ITPGRFA's approach to Farmers' Rights see UNCTAD-ICTSD Policy Discussion Paper, p. 109.

6.2.2 The Doha Declaration

As mentioned under Section 3 of this chapter, paragraph 19 of the 2001 Doha Ministerial Declaration provides the Council for TRIPS with a mandate to examine, under the review of Article 27.3(b), issues such as the relationship between TRIPS and the Convention on Biological Diversity and the protection of traditional knowledge and folklore.

6.2.3 The COP 7

At its seventh meeting in February 2004, the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) decided to mandate its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention[712] and the three objectives of the Convention (i.e. conservation of biodiversity; sustainable use of biodiversity; and fair and equitable benefit sharing).[713] In the same context, the COP also addressed the relationship between IPRs and genetic resources and associated traditional knowledge:

> "7. *Requests* the Ad hoc Open-ended Working Group on Access and Benefit-Sharing to identify issues related to the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights, including those raised by a proposed international certificate of origin/source/legal provenance, and transmit the results of this examination to the World Intellectual Property Organization and other relevant forums.
>
> 8. *Invites* the World Intellectual Property Organization to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the Convention on Biological Diversity, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:
>
> (a) Options for model provisions on proposed disclosure requirements;
>
> (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
>
> (c) Options for incentive measures for applicants;
>
> (d) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties;
>
> (e) Intellectual property-related issues raised by proposed international certificate of origin/source/legal provenance; and regularly provide reports to the Convention on Biological Diversity on its work, in particular on actions or steps proposed to

[712] On Article 15, CBD, see above, Section 5.2. Article 8(j), CBD provides that each Contracting Party shall, as far as possible and appropriate, "Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".

[713] See UNEP/CBD/COP/7/L.28 of 20 February 2004.

address the above issues, in order for the Convention on Biological Diversity to provide additional information to the World Intellectual Property Organization for its consideration in the spirit of mutual supportiveness;

9. *Invites* the United Nations Conference on Trade and Development and other relevant international organisations to examine the issues in, and related to, the matters specified in paragraphs 7 and 8 in a manner supportive of the objectives of the Convention on Biological Diversity and prepare a report for submission to the on-going process of the work of the Convention on Biological Diversity on access and benefit sharing."[714]

6.3 Regional and bilateral contexts

6.3.1 Regional and bilateral

The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996) has set forth, as mentioned, specific standards for the patent protection of biotechnological inventions. The Directive may be considered as essentially declaratory of long standing law throughout much of Europe.[715]

In numerous bilateral and regional agreements the issue of patentability of biotechnological inventions and of the protection of plant varieties have been addressed. In many cases such agreements require the patentability of plants and animals, and the adherence (by the developing country partner) to the UPOV Convention. In fact, the most active negotiations on TRIPS-plus provisions in the area of biotechnology have been taking place on the regional and bilateral levels. An exhaustive analysis of these agreements would go beyond the scope of this Book. Recent examples include the Central American Free Trade Agreement,[716] NAFTA, the draft Free Trade Area of the Americas (FTAA), and the free trade agreements USA – Jordan, EU – Mexico and some Euro-Mediterranean Association Agreements.[717] These agreements declare UPOV to be the appropriate vehicle for the protection of plant breeders' rights, despite Members' freedom under Article 27.3(b) to implement a non-UPOV *sui generis* system of protection. The effect of such regional and bilateral agreements is illustrated by the quickly increasing number of new Members of UPOV.[718]

[714] See UNEP/CBD/COP/7/L.28, pages 10/11.

[715] See, e.g., Grubb, p. 213.

[716] The negotiations between the USA and El Salvador, Guatemala, Honduras, Nicaragua and Costa Rica were concluded in January 2004.

[717] See OECD, *The Relationship Between Regional Trade Agreements and the Multilateral Trading System: Intellectual Property Rights*, TD/TC/WP(2002)28/FINAL, 2002. In the case of the free trade agreement between the USA and Chile, the latter has committed to adhere to the 1991 Act of UPOV by 1 January, 2009. In addition, the Chile – USA FTA provides a "best effort" clause in order for each Party to undertake best efforts to develop and propose legislation to make available patent protection for plants under certain circumstances. For a detailed analysis of the USA – Chile FTA, see Roffe, 2004.

[718] After 1 January 1995, Belarus, Bolivia, Brazil, Bulgaria, Chile, China, Colombia, Croatia, Ecuador, Estonia, Kenya, Kyrgyzstan, Latvia, Lithuania, Mexico, Nicaragua, Panama, Paraguay, Portugal, the Republic of Korea, the Republic of Moldova, Romania, the Russian Federation, Singapore, Slovenia, Trinidad and Tobago, Tunisia, and Ukraine became Members of UPOV 1991 or 1978.

6.4 Proposals for review

As mentioned above, several proposals have been made in relation to the review of Article 27.3(b).[719]

7. Comments, including economic and social implications

Although biotechnology was known since fermentation was used to produce beer and make bread, the economic interest in biotechnology has increased extraordinarily since "modern" biotechnology emerged in the late 1970s as a result of the development of monoclonal antibody technology and the techniques of molecular biology and recombinant DNA.[720] Since the 1980s considerable progress has been made in the development of biotechnology-based pharmaceuticals (e.g., recombinant erithropoietin, growth hormone) as well as in the application of genetic engineering to animals and plants (e.g., transgenic varieties resistant to herbicides or insects).

While genetic engineering-based industries are largely concentrated in developed countries, developing countries possess most of the biodiversity available in the world. They are the source of genetic resources of great value for agriculture and industry (e.g., medicinal plants). Traditional farmers, in particular, have contributed in the past and continue to improve plant varieties and to preserve biodiversity. They provide gene pools crucial for major food crops and other plants. Developing countries have voiced their concerns, and in some cases have taken concrete action in relation to what they consider an illegitimate appropriation by foreign companies or researchers under the patent system.[721,722]

The recognition of IPRs, more specifically of patents, on plants has also raised significant concerns. Many, particularly in developing countries, fear that IPRs may prevent farmers from re-using saved seeds, thus limiting traditional practices that are essential for their survival. In addition, the patenting of certain traits (e.g., higher oil content, disease resistance, higher yield, etc.), genes or plant varieties may limit further research and breeding, including in crops essential for food security. Finally, according to one view, IPRs may contribute to further uniform and monoculture strategies that erode biodiversity, and to increased concentration in farming and in the seeds industry.[723] Small

[719] See Section 3 of this chapter.

[720] CEFI, *The Challenges of Biotechnology*, Madrid 1997, p. 218.

[721] Thus, the Council for Scientific and Industrial Research (CSIR) from India asked for a re-examination of the U.S. patent No. 5,401,5041 granted for the wound healing properties of *turmeric*. The U.S. Patent and Trademark Office (USPTO) revoked this patent after ascertaining that there was no novelty, the innovation having been used and reported on in India for centuries. India has also set up a project to document traditional medicinal knowledge in a digital form, and has proposed the inclusion of a special classification in the International Patent Classification (IPC) in order to enable the retrieval of information on traditional knowledge for patent examination.

[722] See in this regard the Communication from the USA to the Council of TRIPS, IP/C/W/209, 3 October 2000.

[723] In this context, it has been observed that the patenting of genetic material through one company may prevent other companies from further research depending on that genetic material. A frequent reaction in both developed and developing countries is an increasing number of mergers and

and medium farmers and breeders are likely to suffer the most devastating impact.[724]

In the opinion of the proponents of an expanded and reinforced, patent-based approach, however, protection is required to provide an incentive to innovate and the necessary reward for R&D high investments. In their view, the possible negative impact of IPR protection would be offset by benefits in terms of new and better plant varieties.

The possible development of *sui generis* regimes for plant varieties and for traditional knowledge[725] has also attracted considerable interest as means to do justice to traditional and indigenous communities, and to provide them with economic compensation for their contributions.[726]

Finally, attention shall be drawn to the recommendations adopted by the Commission on Intellectual Property Rights (IPR Commission) in its final report. As to plants and intellectual property protection, the Commission concluded:

> "Developing countries should generally not provide patent protection for plants and animals, as is allowed under Article 27.3(b) of TRIPS, because of the restrictions patents may place on use of seed by farmers and researchers. Rather they should consider different forms of *sui generis* systems for plant varieties.
>
> Those developing countries with limited technological capacity should restrict the application of patenting in agricultural biotechnology consistent with TRIPS, and they should adopt a restrictive definition of the term "micro-organism."
>
> Countries that have, or wish to develop, biotechnology-related industries may wish to provide certain types of patent protection in this area. If they do so, specific exceptions to the exclusive rights, for plant breeding and research, should be established. The extent to which patent rights extend to the progeny or multiplied product of the patented invention should also be examined and a clear exception provided for farmers to reuse seeds.
>
> The continuing review of Article 27.3(b) of TRIPS should also preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals, as well as to develop *sui generis* regimes for the protection of plant varieties that suit their agricultural systems. Such regimes should permit access to the protected varieties for further research and breeding, and provide at least for the right of farmers to save and plant-back seed, including the possibility of informal sale and exchange."[727]

acquisitions by multinational companies in order to control or benefit from other companies' patents. This again creates important entry barriers to innovative start-ups, thus raising serious concerns about the maintenance of effective competition in the agricultural industries' sector. See IPR Commission report, p. 65. The report is available at <http://www.iprcommission.org/graphic/documents/final_report.htm>. The page numbers refer to the pdf version of the full report as available on the internet and as a hard copy.

[724] For an analysis of the implications of patents on plants, see The Crucible Group, *People, plants and patents. The impact of intellectual property on trade, plant biodiversity, and rural society*, IDRC, Ottawa, 1994.

[725] See, e.g., the OAU *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*.

[726] For a review of the literature on this subject, see Graham Dutfield, *Literature survey on intellectual property rights and sustainable human development*, Geneva 2002.

[727] IPR Commission report, p. 66.

With regard to the issue of access to plant genetic resources and farmers' rights, the Commission recommended that:

> "Developed and developing countries should accelerate the process of ratification of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and should, in particular, implement the Treaty's provisions relating to:
>
> • Not granting IPR protection of any material transferred in the framework of the multilateral system, in the form received.
>
> • Implementation of Farmers' Rights at the national level, including (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilisation of plant genetic resources for food and agriculture; (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture."[728]

The Commission also addressed the concern that overly broad patents might inhibit further research by recommending:

> "Developing countries providing patent protection for biotechnological inventions should assess whether they are effectively susceptible to industrial application, taking account of the USPTO guidelines as appropriate.
>
> Developing countries should adopt the best mode provision to ensure that the patent applicant does not withhold information that would be useful to third parties. If developing countries allow patents over genes as such, regulations or guidelines should provide that claims be limited to the uses effectively disclosed in the patent specification, so as to encourage further research and commercial application of any new uses of the gene."[729]

[728] Ibid, p. 69.

[729] Ibid, pp. 117/118.