The TRIPS Agreement

(summary of presentation – part 1)

Relevance to GR Professionals

A. Scope

The TRIPS Agreement is one of the agreements of the WTO, adopted in 1994 at the close of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade (GATT). It entered into force in 1995, simultaneous with the inauguration of the WTO, the creation of which was also an outcome of the Uruguay Round. The TRIPS Agreement obliges all WTO Member countries to comply with minimum standards of protection of intellectual property. It does not establish, however, a world system of intellectual property rights.[1]

The Agreement covers patents, copyrights, trademarks, industrial designs, geographical indications, integrated circuits and undisclosed information. It does not specifically deal with breeders' rights (a *sui generis* form of protection for plant varieties).

Technically there is no hierarchy in types of international regimes, be they trade, environment or development-oriented. Nevertheless, in practice, the WTO trade agreements are likely to carry more weight because of a mechanism for settling disputes with the possibility of sanctions. Non-compliance with the provisions of TRIPS may be the basis for initiating a dispute-settling procedure, as established by the Dispute Settlement Understanding (DSU). If a violation is determined, the complaining Member may impose commercial retaliatory measures on the infringing Member.[2]

As an agreement setting minimum standards for intellectual property, TRIPS may also have general relevance to GR professionals involved with access to and/or development of research products, or for those involved with providing technical advice to policymakers. A familiarity with its key provisions and how these have been interpreted by the national government is therefore useful.

B. Article 27.3(b): Protection of plant varieties and sui generis regimes

The article of most direct potential relevance to GR professionals is Article 27.3(b), which deals with exclusions from patentability and, in its contents, sets up a requirement for the protection of plant varieties. The provision states that Members may exclude the following from patentability:

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[1] The Agreement included transitional provisions that allowed developing countries and economies in transition to delay its implementation, particularly in relation to the patenting of pharmaceutical and agrochemical products. However, the general transitional period for adaptation to the Agreement's provisions expired on 1 January 2000. Least-developed countries can delay the implementation of the Agreement until 2006 (2016 for pharmaceutical patents) and thereafter request additional extensions.

[2] So far there has been no decision under WTO relating to Article 27.3(b). However, the USA initiated consultations with Argentina relating to the patentability of microorganisms. See WTO document WT/DS196/1.

> 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. This provision shall be reviewed four years after the entry into force of the WTO Agreement.

Article 27.3(b) gives Member States considerable flexibility in providing protection to plant varieties. They can develop *sui generis* forms of protection which do not exactly correspond to a breeders' rights model to the extent that the *sui generis* regime is 'effective'. They can, for example, create *sui generis* systems that explicitly deal with the issue relating to the conservation and sustainable use of plant biodiversity. In contrast, such flexibility does not exist with regard to microorganisms, which must be patentable according to the Agreement, if they meet the patentability requirements. Since a microorganism cannot be disclosed in written form like other inventions, the disclosure requirement is generally considered to be met with a deposit of the microorganism at an authorized institution. The Budapest Treaty on the international Recognition of the deposit of microorganisms for the purposes of patent procedure (made on April 28, 1977, and amended on September 26, 1980) establishes a mechanism for the recognition by national law of the deposit of a microorganism with 'international depositary authorities' designated according to the Treaty rules. Deposited microorganisms may be accessed by third parties after the application or the granting of the patent, depending on national law.

GR professionals accessing or developing new varieties need to be aware of any national laws implementing Article 27.3(b). Technical advice from GR professionals to policymakers may have particular value here because Member States have flexibility to ensure a system that balances the public and private interests in a manner appropriate to the national situation and, as noted above, to explicitly deal with issues relating to the conservation and sustainable use of plant biodiversity. The design of a *sui generis* regime can also take into account the peculiar features of each national seed supply system as well as the national context and the international instruments relating to the access and use of PGR. These include the CBD and the IT.

'Sui generis' means adapted to a particular object or situation. There are several 'sui generis' regimes in the field of intellectual property, such as the protection for the design/topographies of integrated circuits and the special regime adopted in Europe for data bases. A 'sui generis' regime for the protection of plant varieties may be based on existing modalities of IPRs, or it may be developed on new grounds. It could combine elements of different categories of intellectual property rights, such as patents and plant variety protection (PVP).

A *sui generis* regime may deal not only with the protection of plant varieties, but it may also address other relevant policy issues, such as protecting the innovations of indigenous and local farming communities. Thus, such a regime may provide dual protection for 'commercial' plant varieties that meet the stability requirements of seed legislation and/or PVP protection, as well as for 'landraces' that, by definition, continuously evolve. It may also include a PVP-type of protection and elements for the implementation of different aspects of 'Farmers Rights', which recognize farmers' contributions through 'informal' innovations and the conservation of germplasm, as recognized in Article 9 of the IT (see Session 5).

Despite the flexibility to frame a regime for the protection of plant varieties and to determine the scope, level and form of protection to be conferred, such a regime would have to comply with the minimum standards established by the TRIPS Agreement. First, the regime would therefore need to recognize the national treatment principle whereby like products are treated the same regardless of their origin. Second, it would also have to respect the most-favoured-nation standard, which requires that any advantage accorded to nationals of a WTO member country has to be extended to any other member country. Third, the regime would also have to confer 'effective' protection. This qualification—contained in the body of Article 27.3(b)—is ambiguous since the Treaty provides no criteria to judge 'effectiveness'. It could be argued that the qualification goes not to the level of protection but to the availability of legal mechanisms to enforce them (as required by Part III of the TRIPS Agreement). Finally, in the absence of an exception, the protection should also be granted to varieties of all genera and species.[3]

C. Patent-related provisions

Patents

The TRIPS Agreement does not define what an 'invention' is. Member States have followed different approaches on this matter, particularly in relation to biotechnological inventions. Thus, some (e.g., the United States) admit the patentability of biological materials if claimed in isolated form. Others (e.g., Brazil, the Andean Community) require that the material be otherwise modified in order to be patentable.

WTO Members may exclude animals and plants (even if genetically modified), animal races and plant varieties from patentability. They must, however, ensure protection to *micro-organisms*, non-biological processes and microbiological processes and, as noted above, plant varieties, either by patents or by an effective *sui generis* system (or some combination of both).

Although Members can exclude from patentability plant varieties and/or plants *as such,* patents may have implications for research and for seed production and distribution in many situations, such as the following.

Patents on plant materials

In many countries, the concept of 'microorganism' has been extended to encompass biological materials, such as cells, plasmids, etc., of a microscopic nature. If such materials are patented, the patent owner may interfere with the use of a plant variety that incorporates any protected matter.

Some countries, moreover, allow patents to be obtained over merely isolated genes. If patents on plants are not permitted, but genes can be patented, several complex questions arise. Thus, the interface between patents and PVP in genetically modified plants is not clear at present. When a patented gene is incorporated in a plant and a farmer saves seed and uses it to replant, will this be an infringement of the patent? Can a breeder using a plant incorporating a patented gene invoke the breeder's exception to develop a new variety?

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[3] UPOV 1978 does not require protection for all genera and species; UPOV 1991 does provide for transitional periods for new members (Article 3).

In the case of *Percy Schmeiser and Schmeiser Enterprises Ltd. v. Monsanto Canada Inc.,*[4] the Canadian Supreme Court found that a farmer's practice of seed saving and reuse of a genetically modified plant variety was an infringement of a patent on genes, even though there were no patents on the plant variety or plants *per se*.

The extent to which patented material may be used as a basis for further research will depend on the admissibility of an exception for research or experimentation under national law. In the USA, for instance, such exemption has been interpreted in a very narrow way. The Court of Appeals for the Federal Circuit in *Madey v. Duke University* held that the 'very narrow and strictly limited experimental use defense' can be exercised only if the use of the patented invention is 'solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry'. Further, the defense does not apply if the use is 'in furtherance of the alleged infringer's legitimate business', regardless of the 'profit or non-profit' status of the user[5]. In Europe, however, the exemption is broader. Experimentation *on* a patented invention (as opposed to *with* it), including where a commercial purpose is at stake, is generally deemed permissible. The situation in developing countries, where little or no jurisprudence on this issue exists, will depend on whether and how national law incorporates the exception.

Process patents

The TRIPS Agreement permits the exclusion from patentability of essentially biological processes (i.e., processes where technical intervention does not play an important role in the determination of, or control over, the results) for the production of plants and animals. However, the Agreement requires WTO Members to grant patent protection to any other processes used for that purpose. According to Article 28.1(b) of the Agreement, the protection conferred to a process extends to the product that has been *directly* obtained with it. An important—and yet open— question is whether this extension operates in cases where the obtained product is specifically excluded from patentability by national law, as may be the case of plants and animals. When a unique process for obtaining a product is known, such extension may be tantamount to the protection of the resulting product, thereby *de facto* overriding the prohibition to patent it.

Patents on biotechnological tools

Many tools routinely used in agro-biotechnology, such as gene promoters and markers, are patented. Their use in research or incorporation into new products, hence, may be subject to authorization by the patent owner. In some cases, several patents may be relevant to the development of a particular product, leading to complex negotiations and high transaction costs. There are examples, however (such as in the case of the pro-vitamin A 'golden rice'), of successful collaboration between the public and private sector to make protected material available to a CGIAR Centre (IRRI, in this case) for further use and development.

Exceptions

Exceptions to the exclusive rights conferred by patents are permitted by the TRIPS Agreement (Article 30). As mentioned above, Member countries may establish exceptions for research or experimentation. They can exempt private use of an invention or its use for training and

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4 2004 SCC 34.

5 307 F.3d 1351, 1362 (Fed. Cir. 2002).

education. They may also allow parallel imports under the doctrine of international exhaustion.[6]

The TRIPS Agreement specifically permits the granting of compulsory licences[7], such as in cases of emergency, anti-competitive practices and for non-commercial governmental use (Article 31). The grounds on the basis of which such licences may be granted are not limited by the Agreement.

Undisclosed information (trade secrets)

The protection of undisclosed information, in accordance with Article 39 of the TRIPS Agreement, is also relevant to GR professionals. It obliges WTO Member countries to protect undisclosed information of commercial value, so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Unlike patents and other IPRs, the protection of undisclosed information does not confer an *exclusive* right, but only the faculty to act against misappropriation in cases of *unfair commercial practices* (such as creating confusion with the establishment or products of a competitor, making false allegations in the course of trade, obtaining competitors' trade secrets by hiring their technical personnel, etc.).

This distinction is important, since it means that trade-secrets law does not protect against discovery or independent development of the same information by a third party, nor against accidental or willful disclosure. Moreover, under many laws (including those in the United States) as well as the TRIPS Agreement, the evaluation (reverse engineering) of trade secrets is legitimate.

Trade secrets are particularly relevant in the case of hybrids. Since hybrid seeds need to be replaced for each cycle of production, they are inherently protected against unauthorized reproduction (this type of protection is often called 'technological' as opposed to 'legal'). Hybrid-seed producers have tended to keep the parent lines secret, although they may be protected under PVP. To the extent that the hybrid producer takes reasonable measures to preserve the secrecy of such lines, it will not be possible for third parties to undertake improvement activities without the producer's authorization. The breeder's exception does not operate in this case.

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[6] Doctrine according to which a patent holder 'exhausts' his/her rights after the first legitimate sale of the patented product in a country, region or on the international market. See Article 6 of the TRIPS Agreement.

[7] Compulsory license is the authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patentee, against payment of compensation to the right-holder.

Trademarks

Plant varieties must be commercialized with a generic denomination, which shall be of free use in connection with the variety, even after the expiration of the breeder's right (see Article 20.1(a) and (b) of UPOV 1991).

However, when a variety is marketed or offered for sale, the registered variety denomination is permitted to be associated with a trademark, trade name or other similar indication. According to UPOV 1991, if such an indication is so associated, the denomination must nevertheless be easily recognizable (Article 20.8).

The use of trademarks helps to avoid consumer confusion about the source and quality of a product, and prevents the misappropriation of commercial goodwill, which has come to be seen as an important part of the commercial value of a business or product. In order to be protectable as a trademark, signs (symbols, colours, letters, shapes, names) must be distinctive, so as to distinguish the trademark owner's goods or services from those of third parties dealing with the same class of goods or services.

Geographical indications

Finally, it is necessary to mention geographical indications among the intellectual property rights subject to TRIPS discipline that are relevant to agriculture. A geographical indication consists of the name of a locality, region or country, which is used by producers located therein in order to indicate the geographical origin of certain products. Such a use is subject to different requirements under existing domestic legislation. In order to be protectable, the characteristics or reputation of the products need to be essentially attributable to a given geographical origin. European countries champion the global protection of geographical indications, as many products in the Old Continent can obtain a premium price when identified as originating in particular regions or localities.

D. Implementation issues of note

The Ministerial Meeting of WTO, which took place at Doha, Qatar, in November 2001, adopted a Ministerial Declaration and the Decision on Implementation-Related Issues. Each of these contains a section on the TRIPS Agreement covering three areas: geographical indications, Article 27.3(b) and technology transfer to least-developed countries. While the provisions do not contain any new commitments in the sense of creating norms, the decisions could ultimately result in a negotiation that goes beyond the mere clarification of existing rules.[8]

The Ministerial Declaration acknowledges that issues relating to the extension of the protection of geographical indications on products other than wine and spirits will continue to be discussed by the TRIPS Council. It does not commit members to resolution, however. The use of geographical indications has been an important issue for countries concerned with misappropriation of high-value goods. Countries that have been seeking additional protection are mainly from Asia, Europe and Africa. They include countries such as Thailand and India that have complained about what they see as a misappropriation of high-value goods, namely, jasmine and basmatic rices. For these countries, the GI issue is important because it can be used to promote the export of valuable products and prevent misappropriation.

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[8] Bridges, Vol. 1, No. 1, 22 November 2001; http://www.ictsd.org/biores/01-11-22/story3.htm.

Article 27.3(b) was also discussed at the Doha meeting. The TRIPS Council was ultimately instructed to 'examine, *inter alia*, the relationship between TRIPS, 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'.[9] No explicit commitments were made with regard to traditional knowledge and folklore but its inclusion in the Ministerial Declaration indicates the issue is now mainstream.

Developing countries are actively pursuing the recognition, through an amendment of the TRIPS Agreement, of an obligation to disclose the origin of biological resources and the associated traditional knowledge (TK) claimed in patent applications. While such an obligation can be imposed at the national level (as Brazil, Costa Rica, the Andean Community members and India have done), developing countries argue that its effectiveness will be limited in the absence of an *international* rule that sets the terms of the obligation and the consequences of failure to comply with it. The European Union has indicated its general agreement with the idea (which is strongly opposed by the USA) but it disagrees with the developing countries' approach that lack of compliance with the disclosure obligation should lead to the invalidation of the patent (even if it meets the patentability requirements).

Work on this and other issues related to genetic resources and traditional knowledge has been conducted at the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, established by WIPO. The Committee's mandate includes access to genetic resources and benefit sharing, protection of TK and protection of expressions of folklore. So far, however, no substantial progress has been made in addressing the concerns of developing countries about benefit sharing and the misappropriation of traditional knowledge.

[9] Article 71.1 deals with a review of implementation of the Agreement, with a possible view to modifying or amending it.