The TRIPS Agreement and Intellectual Property in Health and Agriculture

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ABSTRACT

This chapter sets out the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as related to intellectual property in health and agriculture and the policy work done in the World Trade Organization (WTO). The first part focuses on matters related to public health, including the protection of patents and undisclosed information. An overview is given of the three key instruments addressing the flexibilities available to Members of the WTO: the Doha Declaration on the TRIPS Agreement and Public Health, the Decision on the Implementation of Paragraph 6 of this Declaration, and the Protocol amending the TRIPS Agreement. The second part looks into TRIPS provisions relevant to agriculture and sets out the issues reviewed in the Council for TRIPS with respect to optional exclusions to patentability and the protection to be given to plant varieties. The second part also addresses work related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), including the suggested introduction of a disclosure requirement into the patent system, as well as the protection of traditional knowledge. In addition, two issues relating to geographical indications are taken up, namely, the ongoing negotiations on the establishment of a multilateral register of geographical indications for wines and spirits, and the extension of the higher level of protection currently available for wines and spirits to other products. To complete the picture, the third part discusses WTO programs aimed at enhancing capacities in the developing world with respect to the TRIPS Agreement.

1. INTRODUCTION

This chapter describes provisions of the Agreement on Trade-Related Aspects of Intellectual Property

Rights (TRIPS) and the policy work done by the World Trade Organization (WTO) with respect to intellectual property (IP) in health and agriculture, as of July 2006. The chapter discusses WTO programs aimed at enhancing capacities in the developing world with respect to the TRIPS Agreement.

The WTO came into existence in January 1995. Its 149 current Members account for over 97% of world trade, and around 30 other countries are negotiating membership. Decisions are made through the consensus of the entire WTO membership, and the TRIPS Agreement applies to all Members.

The TRIPS Agreement establishes minimum levels of protection that each government has to provide to the IP of fellow WTO Members. By establishing these minimum levels, the WTO seeks to strike a balance between the long-term benefits and possible short-term costs to society. Society benefits in the long term when IP protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain. The Agreement contains provisions enabling governments to reduce short-term costs (for example, through various exceptions to the rights conferred). The WTO's dispute settlement system is available to resolve disputes between WTO Members about compliance with TRIPS rules.

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The Agreement covers five broad issues1:

- how basic principles of the trading system and other international IP agreements should be applied
- how to give adequate protection to IP rights
- how countries should provide for those rights to be adequately enforced in their own territories
- how to settle IP disputes between Members of the WTO
- how to accommodate transitional arrangements during the new system's introduction

2. RELEVANT PROVISIONS OF THE TRIPS AGREEMENT

The TRIPS Agreement requires Member countries to make patents available for all inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness, and industrial applicability. The Agreement also requires that patents be available and patent rights enjoyable without discrimination as to the place of invention or whether products are imported or locally produced (Article 27.1). Although many aspects of the TRIPS Agreement could potentially bear on health or agriculture, the sections on patents, test data protection, and geographical indications are perhaps the most relevant.

There are three permissible exclusions from patent grant. One is for inventions contrary to *ordre public* or morality; this explicitly includes inventions that are dangerous to human, animal, and plant life or health or that are seriously prejudicial to the environment. The use of this exclusion is subject to the conditions that the commercial exploitation of the invention must also be prevented and that this prevention must be necessary for the protection of *ordre public* or morality (Article 27.2).

The second exclusion is for inventions that are diagnostic, therapeutic, and surgical methods for the treatment of humans or animals (Article 27.3(a)). The final exclusion is for inventions that are plants and animals (other than

microorganisms) and essentially biological processes (other than nonbiological and microbiological processes) for the production of plants or animals. However, any country excluding plant varieties from patent protection must provide an effective sui generis system of protection. Moreover, the whole Provision is subject to review four years after the Agreement comes into force (Article 27.3(b)).

A product patent must confer the following exclusive rights on the right holder: making, using, offering for sale, selling, and importing the patented product. Process patent protection must give exclusive rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts (Article 28). Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties, as well (Article 30). Finally, the term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (Article 33).

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Members may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1). If the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating a likelihood that the protected process was used are met (Article 34).

Compulsory licensing and government use without the authorization of the right holder are allowed, but they are subject to conditions aimed at protecting the legitimate interests of the right holder. Mainly contained in Article 31, these conditions include the obligation not to, as a general rule, grant such licenses unless an unsuccessful attempt has been made to acquire a voluntary license on reasonable terms and conditions within a reasonable period of time. The requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the license, must also be observed, as must a requirement that decisions be subject to judicial or other independent review by a distinct higher authority. Another important condition is that such use must be made predominantly to supply the domestic market. Some of these conditions are relaxed when compulsory licenses are employed to remedy practices that have been established as anticompetitive by a legal process or in cases of emergency or public noncommercial use.

The TRIPS Agreement also contains provisions to protect undisclosed information. The Agreement requires that a person lawfully in control of such information must have the possibility of preventing it from being disclosed to, acquired by, or used by others without his or her consent in a manner contrary to honest commercial practices. "Manner contrary to honest commercial practices" includes breach of contract, breach of confidence and inducement to breach, as well as the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition (Article 39.2). In addition, undisclosed test data and other data that governments require to be submitted as a condition of approving the marketing of pharmaceutical or agricultural chemical products that use new chemical entities must be protected against unfair commercial use. Members must also protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use (Article 39.3).

For the purposes of the TRIPS Agreement, geographical indications identify a good as originating in the territory of a Member, or

a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin. The TRIPS Agreement requires a standard level of protection to be available for all geographical indications (Article 22). In essence, interested parties must have the legal means to prevent geographical indications from being used to mislead the public or in a way that constitutes unfair competition. Article 23 provides a higher level of protection for geographical indications for wines and spirits: subject to a number of exceptions, they have to be protected even if use would not cause the public to be misled or constitute unfair competition. Information supplied by Members shows that countries employ a wide variety of legal means to protect geographical indications: ranging from specific geographical indications laws to trademark law, consumer protection law, and common law. The TRIPS Agreement and current work in the WTO's TRIPS Council takes account of that diversity.

In some cases, however, geographical indications do not have to be protected or the protection can be limited. Among the exceptions that Article 24 allows are: continuous use of the geographical indication for at least 10 years preceding 15 April 1994 or in good faith prior to that date; pre-existing trademark rights; and when a name has become a common (or "generic") term for describing that type of product.

3. CLARIFICATIONS AND FLEXIBILITY REGARDING TRIPS AND PUBLIC HEALTH

On the issue of TRIPS and public health (including access to patented medicines), the WTO has adopted three instruments:

- The Doha Declaration on the TRIPS Agreement and Public Health, November 2001
- The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Geneva, August 2003
- A Protocol amending the TRIPS Agreement, December 2005.

3.1 The Doha Declaration on the TRIPS Agreement and public health

The Doha Declaration on the TRIPS Agreement and Public Health² responded to concerns about the possible implications of the TRIPS Agreement for public health, in particular, access to patented medicines. As mentioned earlier, the TRIPS Agreement allows countries to take various kinds of measures to qualify or limit IP rights, including for public health purposes. However, some doubts had arisen as to whether the flexibility in the TRIPS Agreement was sufficient to ensure that it supported public health. It was unclear whether it promoted affordable access to existing medicines, while supporting research, and development into new ones.

The Declaration responds to these concerns in a number of ways. First, it emphasizes that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. It reaffirms the right of Members to use, to the full, the terms of the TRIPS Agreement that provide flexibility for this purpose. Through these important declarations, all WTO Members have signaled that they will not seek to prevent other members from using the provisions.

Second, the Declaration makes clear that the TRIPS Agreement should be interpreted and implemented in a way that supports the right of Members of the WTO to protect public health and, in particular, to promote access to medicines for all. Further, it highlights the importance of the objectives and principles of the TRIPS Agreement regarding the interpretation of its provisions. These statements thus provide important guidance to both individual Members and, in the event of disputes, WTO dispute settlement bodies.

Third, the Declaration clarifies some of the flexibilities contained in the TRIPS Agreement. It makes clear that each Member is free to determine the grounds upon which compulsory licenses are granted. This is a useful corrective to views often expressed in some quarters that some form of emergency is a precondition for compulsory licensing. The TRIPS Agreement does refer to national emergencies or other circumstances of extreme urgency in connection with compulsory

licensing, but this is only to indicate that, in these circumstances, the usual condition that an effort must first be made to seek a voluntary license does not apply. The Declaration makes it clear that each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency. It also declares that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent such circumstances.

With regard to the exhaustion of IP rights and a Member's right to permit parallel imports, the TRIPS Agreement states that a Member's practices in this area cannot be challenged under the WTO dispute settlement system. The Declaration makes clear that the effect on exhaustion of the provisions in the TRIPS Agreement is to leave each Member free to establish its own regime without challenge—subject to the general TRIPS provisions that prohibit discrimination on the basis of the nationality of persons.

For Members of the WTO that are least developed countries, the Declaration agrees to provide them with an extension of their transition period until the beginning of 2016 for protecting and enforcing patents and rights in undisclosed information with respect to pharmaceutical products. This was given legal effect through a Decision of the TRIPS Council that extended the transition period for least developed countries until 1 January 2016³ and another Decision of the General Council that waived the exclusive marketing rights provisions of Article 70.94 for the same period. In 2005, the TRIPS Council extended, to July 2013, the time given for these countries to implement other provisions of the TRIPS Agreement.5

While emphasizing the flexibility in the TRIPS Agreement to take measures to promote access to medicines, the Declaration also recognizes the importance of IP protection for developing new medicines and reaffirms the commitments of WTO Members in the TRIPS Agreement.

3.2 Paragraph 6 of the Doha Declaration

In paragraph 6, the Doha Declaration recognized the problem of countries with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing. Such countries could, under normal TRIPS rules, import under a compulsory license as there is no special problem with Members issuing compulsory licenses for importation as well as for domestic production. The problem, however, was whether sources of supply from generic producers in other countries to meet such demand would be available, particularly given Article 31(f) of the TRIPS Agreement, according to which production under a compulsory license in those other countries must be "predominantly for the supply of the domestic market of the Member." The problems facing countries with insufficient capacities in the pharmaceutical sector in accessing sources of supply were expected to increase as some countries with important generic industries were coming under an obligation to provide patent protection for pharmaceutical products as from 2005.

In order to solve this problem, the WTO General Council adopted on 30 August 2003 a Decision⁶ that waives in certain circumstances Article 31(f) and (h) of the TRIPS Agreement. This Decision was adopted in the light of a Chairman's statement⁷ that set out several key shared understandings of Members on how the Decision would be interpreted and implemented. The Decision covers any patented pharmaceutical products, or pharmaceutical products manufactured through a patented process, needed to address public health problems recognized in paragraph 1 of the Doha Declaration on the TRIPS Agreement and Public Health, including active ingredients necessary for the manufacture of pharmaceutical products and diagnostic kits needed for their use. The Decision grants three waivers from the obligations set out in subparagraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products, subject to certain conditions. The three waivers are:

1. A waiver of the obligation of an exporting Member under Article 31(f) of the TRIPS Agreement to the extent necessary for the purposes of production and export of the needed pharmaceutical products to those countries that do not have sufficient capacity to manufacture them. This waiver is subject to certain conditions to ensure transparency in the

operation of the system and that only countries with insufficient domestic capacity import under it, and to provide for safeguards against the diversion of products to markets for which they are not intended.

- 2. A waiver of the obligation under Article 31(h) of the TRIPS Agreement on the importing country to provide adequate remuneration to the right holder in situations where remuneration in accordance with Article 31(h) is being paid in the exporting Member for the same products. The purpose of this waiver is to avoid double remuneration of the patent owner for the same product consignment.
- 3. A waiver of the obligation under Article 31(f) of the TRIPS Agreement on any developing or least developed country that is party to a regional trade arrangement at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries. The purpose of this waiver is to enable such countries to better harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.

The above Chairman's statement was designed to meet the concerns of those who feared that the Decision was too open ended and might be abused to undermine the benefits of the patent system. It recognizes that the paragraph 6 system set out in the Decision should be used in good faith to protect public health and not to pursue industrial or commercial policy objectives. It addresses some concerns relating to the risk of diversion, and it sets out ways in which any differences arising from the implementation of the system can be settled expeditiously and adequately. The Decision also records that the 33 most-advanced countries have agreed to opt out of the system as importers, including since their accession to the European Communities, the 10 acceding countries.8 In addition, 11 other Members have agreed to use the system only as importers in situations of national emergency or other circumstances of extreme urgency.9

The Decision went into effect on 30 August 2003, and since then a number of Members have modified their laws/regulations to enable exports under their legislation. As of July 2006, Canada, Norway, India and the European Communities have notified the WTO of these modifications.¹⁰

3.3 A Protocol amending the TRIPS Agreement

Paragraph 11 of the August 2003 Decision called for the TRIPS Council to prepare an amendment, based, where appropriate, on the Decision that would replace its provisions. Agreement on such an amendment was reached on 6 December 2005, when the General Council adopted a Protocol amending the TRIPS Agreement and submitted it to WTO Members for acceptance. In substance, the amendment closely tracks the August 2003 text. The Decision on the amendment was also taken in the light of a rereading by the General Council Chairman of the statement of August 2003. The Protocol will enter into force upon acceptance by two thirds of the Members. The waiver provisions of the August 2003 Decision remain applicable until the date on which the amendment takes effect for a Member.

4. WORK ON TRIPS PROVISIONS RELATING TO AGRICULTURE

4.1 Article 27.3(b)

As mentioned earlier, Article 27 of the TRIPS Agreement defines which inventions governments are obliged to make eligible for patenting and what they can exclude from patenting. Inventions that can be patented include both products and processes, and should generally cover all fields of technology. Part (b) of paragraph 3 allows governments to exclude some kinds of inventions from patenting (for example, plants, animals, and other "essentially biological" processes—but microorganisms and nonbiological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible for protection either through patent protection or a system created specifically for the purpose ("sui generis"), or a combination of the two.

A review of Article 27.3(b) began in 1999 as required by the TRIPS Agreement. The topics raised in the TRIPS Council's discussions included:

- how to apply the existing TRIPS provisions on whether or not to patent plants and animals, and whether they need to be modified
- how to handle moral and ethical issues (for example, to what extent invented life forms should be eligible for protection)
- how to deal with the commercial use of traditional knowledge and genetic material by those other than the communities or countries where these originate, especially when these are the subject of patent applications
- how to ensure that the TRIPS Agreement and the Convention on Biological Diversity (CBD) support each other.

With respect to the protection of plant varieties, the meaning of effective protection for new plant varieties has been a part of the discussion under this review.¹¹ The discussion has included consideration of the kind of flexibility that should be available (for example, allowing traditional farmers to continue to save and exchange seeds that they have harvested). It is widely agreed that, while the standards of protection under the UPOV Convention would be considered adequate for TRIPS purposes (with some differences of view about whether the 1978 or 1991 version is the most appropriate point of reference), WTO Members are not bound to apply UPOV standards as long as they can ensure effective protection of plant varieties.¹² The privilege of farmers to replant, on their own holdings, propagating material of protected plant varieties that have been harvested is not in dispute, but no conclusion has yet been reached about how much further the flexibilities might go and be consistent with TRIPS. There is no authoritative guidance in the WTO on these matters. However, the responses of some Members to a questionnaire about domestic implementation of Article 27.3(b) are contained in a TRIPS Council document. 13

Following the 2001 Doha Ministerial Conference, the review of Article 27.3(b) has

been accompanied by parallel work on the relationship between the TRIPS Agreement and the CBD, as well as on protecting traditional knowledge and folklore.14

4.2 Biodiversity and Traditional Knowledge

Discussions on the relationship between the TRIPS Agreement and the CBD first began in the WTO in the Committee on Trade and Environment in 1995. They were brought into the TRIPS Council through the built-in review of Article 27.3(b) in 1999. In the Doha Ministerial Declaration under paragraph 19, the ministers instructed the Council for TRIPS "to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore." The Hong Kong Ministerial Declaration of December 2005¹⁵ calls for the TRIPS Council to continue this work and for the General Council to report on it to the next ministerial meeting.

In paragraph 12, the Doha Ministerial Declaration also addressed the question of outstanding implementation issues (that is, outstanding issues and concerns raised by developing countries about some existing WTO rules, including a number relating to biotechnology, biodiversity, and traditional knowledge). With regard to these issues, the work has focused on the relation between the TRIPS Agreement and the CBD. Some countries want a solution to the their related concerns to be negotiated as part of the ongoing Doha Round of trade negotiations. Other WTO Members contend that there is no negotiating mandate on this matter and that it would not be appropriate to create one. Consultations on this issue have been held under the auspices of the Director General of the WTO since the end of 2002. The Hong Kong Ministerial Declaration of December 2005 provided for the consultative process to be intensified further and for the Director General to report to each regular meeting of the Trade Negotiating Committee (TNC) and the General Council. This issue is one of the two outstanding implementation issues explicitly referred to in the text of the Hong Kong Declaration (alongside that of the extension of the protection of geographical

indications). The General Council is to review progress and take any appropriate action no later than 31 July 2006.

In the TRIPS Council sessions and at other discussions relating to the relationship between the TRIPS Agreement and the CBD,16 Members' positions fall into three broad categories. First, a group of developing countries propose to amend the TRIPS Agreement to make obligatory disclosure in patent applications of (a) the origin of biological resources and/or traditional knowledge used in the claimed invention, (b) evidence of prior informed consent under the relevant national laws/regulations/procedures, and (c) evidence of fair and equitable benefits sharing with those holding such resources or knowledge. Second, the European developed countries are willing to envisage some measure of disclosure of source or origin within the patent system, but not of access or benefit sharing. Those who agree with the disclosure approach differ on several other aspects, such as whether the requirement should be mandatory or voluntary, and under what instrument (the TRIPS Agreement or the Patent Cooperation Treaty of the World Intellectual Property Organization [WIPO]). There is also disagreement about the legal effects of wrongful disclosure or nondisclosure (invalidation of the patent or outside the patent system under civil/ criminal law).

Third, other WTO Members are opposed to a disclosure requirement but are willing to engage substantively on the issue of how the shared objectives in these areas, such as the avoidance of erroneously granted patents and compliance with national access and benefit-sharing regimes, can most effectively be realized. They hold the position that a national-based approach using tailored national solutions, including contracts, is sufficient to ensure that the objectives of the CBD in relation to access and benefit sharing are met. They believe that it would be neither helpful nor desirable to involve the patent system.

The TRIPS Agreement has no specific provisions regarding traditional knowledge. Members are obliged to protect traditional knowledge when it falls under covered IP rights, and they are free to introduce a sui generis law to protect it, as long as that does not conflict with TRIPS. They can similarly implement Article 8(j) of the CBD (to respect, preserve, maintain knowledge, innovations and practices of indigenous and local communities and encourage the equitable sharing of benefits). Quite detailed work is going on in the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore. The question of the appropriate forum for fleshing out the details of the subject comes up repeatedly in the TRIPS Council discussions. Some want to wait for WIPO to develop an appropriate framework so that it can be determined to what extent such protection can be included in TRIPS. Finally, as indicated above, the focus in the TRIPS Council is presently on the relationship between the TRIPS Agreement and the CBD, which covers some aspects of traditional knowledge.

4.3 Geographical indications

Two issues relating to geographical indications are debated under the 2001 Doha Work Program: the establishment of a multilateral register of geographical indications for wines and spirits and the extension of the higher Article 23 level of protection beyond wines and spirits.

4.3.1 Multilateral register

The agreed aim of the multilateral system of notification and registration that is currently under negotiation is to facilitate the protection of geographical indications for wines and spirits. Work was initiated as early as 1997 and is mandated under TRIPS Article 23.4 and paragraph 18 (the first sentence of the Doha Declaration). The negotiations on this matter are being conducted in a Special Session of the council for TRIPS.

Two main lines of argument have been advanced in the negotiations. The "joint proposal" of Argentina, Australia, Canada, Chile, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Japan, Mexico, New Zealand, Paraguay, Chinese Taipei, ¹⁷ and the United States¹⁸ suggests that the Council for TRIPS should decide to set up a voluntary system under which notified geographical indications would be registered in a database. Those

governments choosing to participate in the system would have to consult the database when deciding on the protection of geographical indications and trademarks for wines and spirits in their own countries. Non-participating Members would be encouraged, but not obliged, to consult the database. At the other end of the spectrum, the European Communities propose a TRIPS amendment to establish a system under which the registration of a geographical indication should lead to rebuttable presumptions of its protectability, except where a reservation has been lodged within a specified period, for example, 18 months. Permitted grounds for a reservation would include when a term has become generic or when it does not meet the definition of a geographical indication. In the absence of any reservation, a Member could not refuse protection on these grounds after the term has been registered. These proposals, together with a compromise proposal from Hong Kong, China, have been set forth side by side in a WTO Secretariat document.19

Important differences remain, particularly on two key issues: (1) the extent to which legal effects at the national level should be consequent on the registration of a geographical indication for a wine or a spirit in the system and (2) the question of participation, including whether any legal effects under the system should apply to all WTO Members or only to those opting to participate in the system. The Special Session has also discussed a range of other points, including questions of costs and administrative burdens for WTO Members, particularly for developing countries.²⁰

4.3.2 Extension

Article 22 requires protecting geographical indications for all goods. The issue here is whether to expand the higher level of protection under Article 23, currently required only for wines and spirits, to other products, including agricultural products and foodstuffs, handicrafts, and industrial products.

Paragraph 18 of the Doha Declaration notes that the TRIPS Council will handle work on extension under paragraph 12 of the Declaration, which deals with implementation issues. As indicated earlier, WTO Members interpret paragraph 12 differently. Many developing country and European Members argue that the so-called outstanding implementation issues are already part of the "single undertaking" and therefore are also part of the negotiating agenda of the Doha Round. Others argue that these issues can only become negotiating subjects if the TNC decides to include them in the talks-and so far it has not done so. Presently, the topic is the subject of consultations under the auspices of the WTO Director General. At the Hong Kong Ministerial Conference, ministers requested the Director-General to intensify consultations on all outstanding implementation issues, including the extension of the protection of geographical indications, and 31 July 2006 was set as the deadline for the General Council to review progress and take any appropriate action.²¹

With regard to the substance of the TRIPS Agreement, Members remain divided, but there is a willingness to continue discussing the issue. The proponents consider, among other things, that progress on geographical indications would make it easier for them to agree to a significant deal in agriculture. The proponents see the higher level of protection as a tool to enhance rural development, support quality production, and enable them to improve the marketing of products by differentiating them more effectively from other competing products. Consequently, the latest proposal from the European Union calls for the TRIPS Agreement to be amended so that all products would be eligible for the higher level of protection in Article 23.22 To meet the concerns of other countries, the exceptions in Article 24 would also apply, adapted as necessary. Opponents argue that the existing level of protection pursuant to Article 22 is adequate. They caution that providing enhanced protection would be burdensome and disruptive to existing, legitimate marketing practices, that the interests of prior trademark right holders and other third parties may be affected, and that considerable costs may result from the need to re-label their products.

The issues raised and the views expressed in this debate have been compiled in a document prepared by the WTO Secretariat.²³ The issues include, among others, those relating to the protectable subject matter (definition and eligibility), potential implications for administrative costs and burdens, and the impact of extension on (1) producers in and outside the area designated by geographical indications, (2) the relationship between trademarks and geographical indications, and (3) consumers.

5. TRANSFER OF TECHNOLOGY

Article 7 of the TRIPS Agreement reflects the objective that the transfer of technology should be promoted by the protection of IP. Some developing countries have expressed the view that more needs to be done to "operationalize" this notion. The TRIPS Agreement calls for more proactive measures to promote technology transfer and dissemination in the case of the least developed countries. Article 66.2 obligates developed countries to provide incentives for the transfer of technology to these countries. The effective monitoring of this obligation through regular reporting and TRIPS Council reviews was the subject of a political agreement at Doha that was turned into the TRIPS Council Decision of February 2003.²⁴ Reports under this new mechanism, submitted at the end of 2003, 2004, and 2005, are being studied by the Members that are least-developed countries.

6. TECHNICAL COOPERATION AND CAPACITY BUILDING PROGRAMS

Article 67 of the TRIPS Agreement obligates developed country WTO Members to provide, on request and according to mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developedcountry Members. This cooperation includes assistance in preparing laws and regulations for the protection and enforcement of IP rights, as well as the prevention of their abuse. The cooperation also includes support for the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel. On the basis of annual reports from developed-country Members, each autumn the TRIPS Council reviews the technical cooperation that is being provided.²⁵

Considerable assistance is also provided by other intergovernmental organizations, notably WIPO, UPOV, the World Bank, and the WHO. Such organizations are annually invited to share information on their activities with the TRIPS Council.²⁶ In addition, the WTO Secretariat's technical cooperation program includes activities related to the TRIPS Agreement.²⁷ These activities seek to help Members understand their rights and obligations—including the options and flexibilities—under the TRIPS Agreement and relevant decisions of WTO bodies. The cooperation program encourages Members to participate fully in the ongoing work of the WTO on TRIPS matters and emphasizes the importance of ensuring complementarity and cooperation with other intergovernmental organizations, in particular the WIPO and the WHO.

These activities include regional workshops on topical issues under discussion, examination, or negotiation in the TRIPS context, in particular TRIPS and public health, biotechnology, traditional knowledge, biodiversity, and geographical indications. These regional workshops, as well as specialized workshops held in the regions and Geneva, also aim to provide information that will assist developing-country Members in implementing and making effective use of the mechanism set out in the Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Upon request by developing- country Members, the WTO Secretariat regularly organizes national seminars or workshops devoted to IP matters. TRIPS issues also figure prominently in broader WTO training courses, seminars, and workshops held in Geneva and in developing countries. An important new component of the Secretariat's capacity-building activities is the annual joint WIPO/WTO colloquiums for teachers of intellectual property in Geneva, for participants from developing countries. This program seeks to enhance the capacity for teachers to train IP personnel in their own countries, by providing teachers with expertise on international aspects and allowing them to provide informed policy advice to their governments. ■

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- 1 For more details, see <u>www.wto.org/english/tratop_e/</u> trips_e/trips_e.htm#WhatAre.
- 2 Document WT/MIN(01)/DEC/2.
- 3 Document IP/C/25, June 2002.
- 4 Document WT/L/478, July 2002.
- 5 Document IP/C/40.
- 6 Documents WT/L/540 and Corr.1.
- 7 Contained in paragraph 29 of document WT/GC/ M/82.
- 8 The Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic, and Slovenia.
- 9 Hong Kong, China; Israel; Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; Chinese Taipei; Turkey; and the United Arab Emirates.
- 10 Notifications about the use of the system will be accessible through a dedicated Web page on the WTO Web site: <u>www.wto.org/english/tratop_e/trips_e/</u> public health e.htm.
- 11 See document IP/C/W/369/Rev.1, paragraphs 51–60 available at www.wto.org/english/tratop_e/trips_e/ artz7 3b e.htm.
- 12 See document IP/C/W/369/Rev.1, paragraphs 61–66 available at www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.
- 13 Document IP/C/W/273/Rev.1, available at <u>www.wto.</u> org/english/tratop e/trips_e/art27_3b_e.htm.
- 14 Secretariat summary notes of the work done on these issues (IP/C/W/368/Rev.1, IP/C/W/369/Rev.1, IP/C/W/370/Rev.1) are available at www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.
- 15 Document WT/MIN(05)/DEC.
- 16 Summarized in Secretariat paper IP/C/W/368/Rev. 1.

- 17 In the WTO accession document, Chinese Taipei is referred to as Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu.
- 18 Document TN/IP/W/10 and Add.1.
- 19 Document TN/IP/W/12.
- 20 See Chairman's report on the work done in 2005, document TN/IP/14.
- 21 Paragraph 39 of document WT/MIN(05)/DEC.
- 22 Document TN/IP/W/11.

- 23 Document WT/GC/W/546, document TN/C/W/25.
- 24 Document IP/C/28.
- 25 The most recent reports can be found in document IPC/W/445 and addenda.
- 26 The most recent information documents are in document IPC/W/456 and addenda.
- 27 The most recent information can be found in document IP/C/W/454.