

CHAPTER 13

PROTECTION OF INTELLECTUAL PROPERTY

A. OVERVIEW OF RULES

1. BACKGROUND OF RULES

In today's highly-developed economic environment, intellectual creativity (*e.g.*, inventions, design know-how, and artistic creations) is becoming increasingly important in daily business. In these contexts, inventions, designs, literary works, layout-designs of integrated circuits and trade secrets are subject to legal protection. In addition, trademarks are entitled to legal protection to safeguard reputations gained as a result of marketing and production activities, as well as to protect consumers and ensure fair competition. As the volume of trade in goods and services involving intellectual property has greatly increased in recent years, the importance of the protection of intellectual property for the world economy has grown enormously. Inappropriate and insufficient protection of intellectual property among WTO Members can distort free trade.

In developing countries, the protection of intellectual property rights (IPR) was often insufficient. For example, developing countries often had insufficient standards for protection such as limited coverage of protection, very limited protection period, or ineffective practices of enforcement. There were some developed countries that maintained problematic intellectual property regimes that, for example, provided excessive protection, or were quite different from those employed by the rest of the world, so that their administration alone constituted discrimination.

To address the trade distorting effects caused by these problems, through the negotiation in the Uruguay Round, establishment of an appropriate framework for the protection of intellectual property was sought. A number of international treaties already form a common legal framework for the protection of intellectual property. The Paris Convention, which entered into force in 1883, covers patents, trademarks and other industrial property rights. The Berne Convention, which entered into force in 1886, covers copyrights. Recently, however, as countries paid more attention to the trade-related aspects of this subject, they have frequently placed intellectual property protection on the agenda of trade negotiations. Countries recognized that, to establish standards on aspects of trade regarding the protection of intellectual property, as many governments as possible needed to take part in framing an international agreement. As a result, GATT negotiators developed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - one of the most important new areas in the Uruguay Round negotiations. A final consensus on the TRIPS Agreement was reached in Marrakesh in April 1994. The TRIPS Agreement took effect on January 1, 1995.

2. LEGAL FRAMEWORK

THE TRIPS AGREEMENT

Although a few problems remain, the TRIPS Agreement establishes valuable standards for the trade-related aspects of protecting intellectual property. The significance of this agreement is manifold: (a) it covers the full range of protections afforded intellectual property; (b) in principle, it raises the levels of protection from those in existing treaties, like the Paris Convention and Berne Convention, and obligates countries that have not joined these conventions to adhere to them; (c) it is the first treaty on IPR to explicitly mandate MFN treatment; (d) it specifies substantial levels of protection and rights that WTO Members are obligated to guarantee in their domestic laws and contains detailed provisions on the procedures for enforcing rights should they be infringed; and (e) it contains dispute-settlement procedures. A detailed overview of the major aspects of the TRIPS Agreement is provided in Figure II-13.

3. ECONOMIC ASPECTS AND SIGNIFICANCE

The IPR system provides the institutional framework to promote two economic goals.

First, patent and copyright laws grant certain exclusive (monopolistic) rights to the developers and creators of intellectual property, encouraging intellectual creativity and promoting the effective use of resources in the development of new technologies and the discovery of new knowledge, thereby enhancing the intellectual infrastructure for economic development. However, because these IPR laws allow a certain amount of monopolistic use of new technology and knowledge, these systems restrain use by both third parties and competition, reducing the social benefits to consumers by limiting the industrial application of technology and knowledge. It is therefore important to seek a balance between the above-mentioned interests. Second, marks and indications of goods and services, such as trademarks and geographical indications, enable businesses to maintain the public trust and to promote fair competition.

To balance these competing interests, intellectual property rights systems need to be instituted carefully so as not to prevent free and fair competition taking into account those aspects. Essentially, those systems should be designed in line with the national policy of each country; however, minimum institutional harmonization at the international level is needed along with growing international trade of goods and services.

(1) The Impact of Introducing a New IPR System

When introducing a new international IPR system, redistribution of income results from new limits on the use of existing intellectual property. This redistribution has an asymmetrical impact on the economic welfare of individual countries. Developing countries fear that they will bear the burden of new IPR systems because there would be an international redistribution of income from the developing countries that use intellectual property to the developed countries that create the intellectual property. This concern made negotiating the introduction of new IPR systems more difficult.

(2) The Trade Distortionary Effects of Inadequate or Inappropriate Protection of IPR

As international economic activity is growing and thereby the importance of intellectual property is increasing, the trade distortionary effects of inadequate or inappropriate protection of IPR have become increasingly worrisome.

First, if a country's IPR system permits excessive intellectual property protection, or discriminates against foreign interests, or varies widely from generally agreed-upon international rules and procedures, excessive time and money must be spent in the acquisition and enforcement of rights of foreign origin, which could be a non-tariff barrier.

Second, the inadequate protection of intellectual property in certain countries in which free trade is progressing leads to the proliferation of production and circulation of products that infringe on intellectual property rights, such as merchandise suspected of being counterfeit trademarks, pirated copyrighted films and music and design imitations. This leads to direct and adverse impact on the normal economic activities of the copyright holders and thereby not only possibly reduces the economic incentives for new product development within the country, but also may initiate the disruption of trade by having the price of genuine products become comparatively higher. Furthermore, regulations that prevent property owners from exercising their legitimate property rights, such as unreasonable time limits on technology licensing contracts entered into with foreign companies or prohibitions on confidentiality obligations after the completion of a contract, impede and impair investment and technology transfers from other countries. Such requirements reduce domestic technological development and ultimately cause a detrimental effect on the countries involved and the world economy as a whole.

Figure II-13 Outline of the TRIPS Agreement

<i>Scope of Coverage</i>	All legally-recognized intellectual property rights (copyright and related rights, patents, industrial designs, trademarks, geographical indications, layout-designs of integrated circuits and undisclosed information)
<i>Relation to Existing Conventions</i>	The TRIPS Agreement incorporates and improves upon protection levels of the Paris Convention (industrial property rights) and the Berne Convention (copyrights). WTO Members who are not parties to the Paris Convention or Berne Convention will thereby be obligated to meet the standards of these conventions.
<i>Basic Principles</i>	The TRIPS Agreement requires national intellectual property regimes to provide MFN treatment (Article 4) and national treatment (Article 3) to the nationals of WTO trading partners. These obligations are excluded from transitional arrangement and have been imposed on developing countries from the effective date of the WTO Agreement. The TRIPS Agreement adopts the national treatment exceptions found in the Berne and Paris Conventions and the MFN exceptions found in existing international and multilateral agreements. Regarding the issue of exhaustion of intellectual property rights (parallel imports), no provisions except national treatment and most-favored-nation treatment under TRIPS Agreement must be used in dispute settlement (Article 6).
<i>Levels of Protection (Standards)</i>	<ul style="list-style-type: none"> ● In the area of copyrights and related rights, the TRIPS Agreement specifies the protection of computer programmes (protected as literary works under the Berne Convention) and rental rights.

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	<ul style="list-style-type: none"> ● In the area of patents, the TRIPS Agreement establishes a wide definition of patentable subject matter and requires Members to introduce patent protection for products. As such, it does not allow for the exclusion of pharmaceutical products or foods from patentable subject matter. Protection shall be afforded for at least 20 years from the filing date of the application. The TRIPS Agreement also stipulates strict conditions on authorizing compulsory licenses. ● The TRIPS Agreement contains provisions governing the protection of trademarks, geographical indications, industrial designs, layout-designs of integrated circuits, and undisclosed information. It also contains rules on anti-competitive practices in contractual licenses. ● The TRIPS Agreement obligates signatories to provide the legal means to prevent misrepresentations of geographical indications and requires additional protection for wines and spirits in relation to geographical indication.
<i>Enforcement</i>	<p>The TRIPS Agreement requires that domestic enforcement procedures be fair and equitable. Enforcement against infringement must be conducted via the civil and criminal judicial processes, administrative procedures, including border measures and administrative remedies.</p>
<i>Dispute Settlement</i>	<p>WTO dispute settlement procedures apply to disputes under the TRIPS Agreement. Violations of the TRIPS Agreement may result in the suspension of tariff concessions or cross retaliation through the suspension of WTO benefits in another trade sector.</p>
<i>Transitional Arrangements</i>	<ul style="list-style-type: none"> ● Developed countries had a transitional period of one year from the date of entry into force of the WTO Agreement with respect to the obligation to apply the TRIPS Agreement, except for Articles 3-5; developing countries and transformation countries had five years (until January 2000); and least-developed countries had 11 years (until January 2006) (Articles 65 and 66)¹. ● Developing countries that did not provide product patent protection were accorded an additional transitional period of five years (ten years in total, until January 2005) for application of the provisions on product patents (paragraph 4, Article 65). The TRIPS Agreement also contains provisions that, from the date of entry into force of the Agreement, required developing countries during the transitional period to: (a) provide a means for filing patent applications for pharmaceutical and agricultural chemical products, and (b) grant exclusive marketing rights for pharmaceutical and agricultural chemical products that are the subject of a patent application under certain conditions (Article 70, paragraphs 8 and 9)². <p>¹ The TRIPS Council decided in November 2005 to extend the transition period for least-developed country Members until July 1, 2013. Furthermore, the TRIPS Council decided in June 2013 to extend the transition period until July 1, 2021.</p> <p>² Paragraphs 8 and 9, Article 70 are the provisions for supplementing the transitional period, notwithstanding the provisions of Part VI of the TRIPS Agreement such as Article 65 and 66. With regard to the application of paragraph 9, Article 70 (granting of exclusive marketing rights for pharmaceutical products), however, the WTO General Council had decided in July 2002 to waive the obligations to grant exclusive marketing rights for pharmaceutical products for least-developed countries until January 1, 2016, with annual reviews on the waivers to be held during this period. As a result of the discussion held during 2015, the waiver of the obligations under both paragraphs 8 and 9, Article 70 was extended until January 1, 2033 (see also “(4) Recent Developments” below).</p>

(3) Considerations in New Rulemaking

There is an underlying acknowledgement that appropriate protection for intellectual property rights is vital to further promotion of free trade and sound economic development. We note, however, that in establishing this system, consideration will need to be given to: (1) assure fair and equitable competition; (2) address the impact of the income redistribution from the introduction of the new system; and (3) secure improvements in economic welfare that will promote new intellectual creation and business.

4. RECENT DEVELOPMENTS

1) WORK IN THE TRIPS COUNCIL

The TRIPS Council held three regular sessions during 2015, at which discussions were held regarding the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), as well as conducting reviews of decisions regarding the implementation of the Doha Ministerial Declaration paragraph 6, which pertains to the TRIPS Agreement and public health. At special sessions of the Council, discussions are to be held regarding a multilateral system of notification and registration of geographical indications on wines and spirits, for which further negotiations were mandated within the TRIPS Agreement (the Built-in Agenda). No progress has been made, however, as substantive discussions were not held during 2012-2015 since the Chairman's report with the combined texts that summarized the negotiation status attached was presented in April 2011.

Also, the issue regarding expansion of items covered by the additional protection of geographic identification and the relationship between the TRIPS agreement and the CBD, which were to be examined as directed by the Doha Ministerial Declaration in 2001, were not discussed during 2015, and no further progress has been made after the report which the WTO Director-General released in April 2011 stated that the discrepancy between the viewpoints of different countries remained significant.

The transition period granted to least developed countries (LDCs) under Article 66 of the TRIPS Agreement was extended until July 1, 2013 at the TRIPS Council meeting in 2005. The transition period was further extended for eight more years, until July 1, 2021, at the TRIPS Council in June 2013 (*see* "Transitional Arrangements" in Figure II-13).

Meanwhile, pursuant to paragraph 7 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health, LDCs are subject to (i) a transition period (TRIPS Council decision in 2002 [IP/C/25]; Part II, Section 5 (Patents) and Section 7 (Protection of Undisclosed Information) of the TRIPS Agreement are not applied to LDCs) and (ii) a waiver of obligations (General Council decision in 2002 [WT/L/478]; LDCs are exempt from the obligation to comply with paragraph 9 of Article 70 of the TRIPS Agreement) concerning the provisions on pharmaceutical products. Both decisions set January 1, 2016, as the time for expiration of the respective treatments. However, at the TRIPS Council session held in February 2015, the LDCs proposed that application of both the (i) transition period and (ii) waiver of obligations should be extended "as long as the WTO Member remains a least developed country," and that, with regard to (ii), LDCs should be exempt not only from paragraph 9 of Article 70 of the TRIPS Agreement, but also from paragraph 8 of that Article (for which the obligation of implementation was already supposed to have occurred). These matters

were subsequently discussed at TRIPS Council sessions and unofficial meetings, and in the end, it was decided/agreed at the TRIPS Council's reconvened meeting in November 2015 that both the (i) the transition period and (ii) waiver of obligations will be extended to January 1, 2033 ((i): decision of IP/C/73) and ((ii): agreement of IP/C/74). With regard to (ii), it was recommended to the General Council that a draft decision to exempt LDCs from the obligation to comply with paragraphs 8 and 9 of Article 70 of the TRIPS Agreement be adopted; subsequently, the General Council officially adopted the decision.

2) DISCUSSIONS OF GEOGRAPHICAL INDICATIONS

“Geographical indications” refer to those indications which identify a product based on its origin within a territory or region of a Member and is associated with a certain quality and/or reputation (e.g., “Champagne” (a wine) or “Gorgonzola” (a cheese)). Under the TRIPS Agreement, geographical indications are protected as intellectual property rights.

Article 22 of the TRIPS Agreement protects geographical indications in general, but allows for products not produced in the geographic region to be labeled as “like” or “style” (e.g., “Gorgonzola type” cheese). However, Article 23 grants powerful legal protection to geographical indications for wines and spirits that does not permit “kind”, “like”, “type” or “style” forms of labeling. Protection as stipulated in Article 23 is referred to as “additional protection” because it goes beyond the protection afforded under Article 22.

Regarding geographical indications, the Doha Ministerial Declaration of 2001 (Paragraphs 12(b) and 18) provided for: (i) negotiation of the establishment of a multilateral system for the notification and registration of geographical indications for wines and spirits within the framework of the new round (Built-in Agenda); and (ii) the granting of additional protection of Article 23 for geographical indications for products other than wines and spirits. The TRIPS Council was instructed to report its discussions to the Trade Negotiations Committee by the end of 2002.

Following vigorous discussions, the Hong Kong Ministerial Declaration of December 2005 resolved to: (i) intensify negotiations regarding the establishment of a multilateral system for the notification and registration of geographical indications for wines and spirits so as to complete within the overall time-frame for the conclusion of the negotiations that was foreseen in the Doha Ministerial Declaration (Paragraph 29); and (ii) intensify the consultation process concerning the extension of the protection for geographical indications provided for in Article 23 of the TRIPS Agreement to products other than wines and spirits, and take appropriate action by the General Council by July 31, 2006 at the latest (Paragraph 39).

At the Ministerial Conference in July 2008, concentrated discussions were held at the small group meeting of senior officials regarding the establishment of a multilateral system for the notification and registration of geographical indications for wines and spirits, along with the extension of the protection of geographical indications. The EU, Switzerland, India and others argued for further strengthening of protections, but the US, Canada, Australia, New Zealand and others argued for maintaining the current levels of protection. The division of opinion was significant, and the discussions were unable to reach a compromise.

In 2009, the establishment of a multilateral system for the notification and registration of geographical indications for wines and spirits was discussed at special sessions of the TRIPS Council, and the issue of the extension of the protection of geographical indications was further discussed at informal consultations hosted by the WTO Director-General. Furthermore, discussions

were conducted on both points during the brainstorming sessions between ambassadors in 2010. However, there remained a significant discrepancy between opinions of Member countries, and agreement was not reached.

In 2011, discussions on the multilateral system of notification and registration of geographical indications on wines and spirits were conducted in the unofficial special session amongst a small number of countries held beginning in January. In March, the outline result was shared with Member countries during the special session held in March. On April 21, the Chairman's report that attached the compiled texts that summarized the negotiation status was released. The Chairman's Report indicated the position that the areas to be negotiated for the items covered by the notification and registration system were limited to wines and spirits. The report also mentioned that there was a major discrepancy between the two proposals concerning the legal effects and participation requirements of the registration; the W52 proposal (made by the EU and developing countries) gives legal effects to the notification and registration system and makes participation mandatory, while joint proposals (made by countries such as Japan, the US, Canada, Australia, and New Zealand) do not give the system legal effect and make participation voluntary. Ever since the special session was held in March 2012, the Chairman had held informal consultations on negotiation procedure with individual Member countries and Groups, and its result was reported in the unofficial special session held in November of the same year. The Chairman's report emphasized that even though discrepancies remain in the scope of negotiation for the items covered by the notification and registration system, proceeding with technical work for future progress would be important. However, no meeting was held in 2013, and although an unofficial special session was held on April 1, 2014, discrepancies remained on how to proceed with negotiations, etc. between Members, and a Chairman's report stating that "Members are not ready to make practical discussions on the notification and registration system" was released. (The report was cited at the Trade Negotiations Committee meeting held in the same month). After that, until the July 2015 deadline to formulate the post-Bali work plans, unofficial special sessions and information meetings were held several times at the Chairman's proposal. However, no substantive progress was made, and at the Trade Negotiations Committee meeting held in December 2015, a Chairman's report (TN/IP/23) was released, stating that the situation had not improved since 2014 and that it seemed that in the preparations for the 10th Ministerial Conference substantive work on the GI notification and registration system did not represent a priority for Members.

Furthermore, concerning the expansion of items covered by the additional protection of geographic indication, as mentioned above, in April 2011, at the same time as the Chairman's report, the WTO Director-General released a report which summarized the current situation; it stated that the discrepancy between views of each country remained significant, no significant progress has been made since then.

3) RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

The Convention of Biological Diversity (CBD), which went into effect in 1993, includes provisions related to intellectual property. The Doha Ministerial Declaration of November 2001 (Paragraphs 12(b) and 19) provided for examination of the relationship between the provisions of the CBD and the TRIPS Agreement and it was discussed mainly at the TRIPS Council. The Hong Kong Ministerial Declaration of December 2005 decided to intensify the consultation process and to take appropriate action by the General Council by July 31, 2006 at the latest (Paragraph 39).

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However, there was still no progress at end of July 2006, and since then discussions have been going on in the TRIPS council and informal consultations.

In 2010, discussions were held at the regular sessions of the TRIPS Council and informal consultations under the auspices of the WTO Director-General. Some developing countries, such as India, Brazil Peru, the African group and the LDC group argued that the TRIPS Agreement should be amended to include a disclosure requirement of source and country of origin of genetic resources, prior informed consent to the use of genetic resources and provisions evidencing fair and equitable benefit sharing in order to obligate disclosure of such information in patent applications. To the contrary, other countries (including Japan and the US, etc.) find no conflict between the TRIPS Agreement and the CBD, and believe that it is possible to apply the two agreements in a mutually supportive manner. Therefore, there is a large gap between those countries that believe that amendment of the TRIPS Agreement is unnecessary in order to achieve the purpose of the CBD and those countries that believe it is necessary. Discussions have not converged. Furthermore, since January 2011, unofficial special sessions, chaired by the WTO Director-General, amongst chief delegates of a small number of countries on the relationship between the TRIPS agreement and CBD have been conducted in parallel with the discussions on the expansion of items covered by the additional protection of geography indication. Thereby, discussions on the current state and experiences regarding the issue of illegal use of genetic resources in each country have been conducted. However, this has not advanced beyond the point of the WTO Director-General releasing in April 2011 a report that stated that the discrepancy between views of each country remain significant. Discussions continued at the regular sessions of the TRIPS Council in 2012 to 2015 but each country only confirmed its views.

With regards to CBD, the Nagoya Protocol concerned with Access and Benefit-Sharing was adopted in the 10th Conference of Parties of United Nations Conventions (COP10) in October 2010. As one of the adherence measures, at least one check point for monitoring the utilization of genetic resources was specified for each of the countries, and it was agreed to work out a plan for necessary measures. The number of countries required to ratify the Protocol and put it in force was met in July 2014, and the Protocol came into effect in October 2014. The 1st Conference of Parties to the Nagoya Protocol (MOP1)¹ was held in conjunction with the 12th Conference of Parties of United Nations Conventions (COP12) held in the Republic of Korea in the same month. In the Nagoya Protocol, at the insistence of the developing countries, the patent office and the like were designated as the check points, and it was made obligatory to submit recorded proof of information of the place where the concerned genetic resource was obtained, the contract details, etc., at the time of patent applications for inventions that utilize genetic resources etc. However, no regulations were incorporated against noncompliance, whereas measures should have been taken, such as not allowing the examination procedure.

4) EU ENFORCEMENT PROPOSAL

Following the proposal concerning enforcement put forth by the EU in June 2005, a joint statement was submitted by the EU, Japan, the US and Switzerland at the regular meeting of the TRIPS Council held in October 2006 requesting discussions concerning a method for efficiently implementing provisions relating to enforcement under the TRIPS Agreement. While Australia,

¹ Japan has not ratified the Protocol due to domestic procedures in progress, and is participating as an observer without voting rights.

Canada and other countries reacted favorably, developing countries including Brazil, Argentina, China and India displayed strong opposition to the very fact that the issue had been placed on the agenda, arguing that since implementation was left to the discretion of each country, the discussions exceeded the authority of the TRIPS Council. Thus, agreement regarding the handling of enforcement issues was not obtained.

At a regular meeting of the TRIPS Council in February 2007, the United States requested that enforcement of intellectual property rights be placed on the agenda. Switzerland made a similar request at the regular meeting in June 2007, and Japan did so at the regular meeting in October 2007. (Each country included discussion of border measures in its request.) While some countries such as China, India, Argentina and South Africa opposed its inclusion as a permanent agenda item, they did not block the request as long as it was discussed as a temporary agenda item of each meeting.

Although it was not directly related to this proposal, "Enforcement trends" was added to the agenda of the TRIPS council meeting held in June 2010, in response to the request by developing countries such as China and India, as they were anxious regarding intensification of the enforcement, including the ACTA negotiations. On the other hand, developed countries such as Japan, US and EU welcomed the developing countries' request for discussions on enforcement, and they explained the importance of the issue to the developing countries. Furthermore, in the regular session of TRIPS Council held in February 2012, as in the regular session held in October 2011, ACTA Members, including Japan, the US and the EU, added an agenda item called "enforcement trends" in order to dispel the misunderstandings held by developing countries concerning ACTA. In addition to the reporting of the ACTA signing ceremony held on October 1, the regular session included a briefing on the significance, necessity and realities of ACTA. In 2013 and thereafter, no discussions were made on the agenda items related to such enforcement.

As seen in Part I, however, it is clear that the core issue regarding compliance with the TRIPS agreement in Asian countries is the lack of effective enforcement. Effective enforcement of intellectual property rights is essential for economic development in these countries. Accordingly, Japan must actively join in efforts to deal with this issue.

5) INTELLECTUAL PROPERTY AND INNOVATION

This agenda item aims to focus on the positive side of the intellectual property rights system by presenting successful cases of intellectual property rights utilization in the respective countries. The United States has been leading the discussion since the TRIPS Council meeting in November 2012. Many Members, including both developed and developing countries, have made remarks, mainly presenting examples, under the themes of small- and medium-sized enterprises (March), cost effective innovations (June), and sports (October) in 2013; technological collaboration with universities (February), incubation (June), and promotion of the intellectual property rights system (October) in 2014; and in 2015 women and innovation (February), the role of intellectual property in financing innovation (June), and entrepreneurialism and new technologies (October). While developed countries, including Japan, in their presentation on their concrete efforts assert the importance of intellectual property rights that contribute to innovations, some countries, including India, etc., object to addressing this agenda item at the TRIPS Council meetings, stating that it merely presents successful experiences.

6) CONTRIBUTION OF INTELLECTUAL PROPERTY RIGHTS TO THE PROMOTION OF ENVIRONMENTAL TECHNOLOGY TRANSFER

At the TRIPS Council meeting in March 2013, Ecuador submitted a document, stating that “the current intellectual property rights system has been a barrier in transferring environmental technologies, and therefore intellectual property rights protection of environmental technologies should be weakened”. In response to this, this issue has been discussed as a temporary agenda item since June of the same year. Developing countries, including Brazil, India, and China, etc., welcomed this proposal and claimed that the flexibility of the TRIPS Agreement and the compulsory license system should be actively utilized to reduce adverse effects of climate change. In contrast, developed countries, including Japan and the US, etc., objected, expressing the view that the intellectual property rights system facilitates technology transfer, and the fact that technology transfer is not progressing in developing countries is due to financial issues or the impacts of infrastructure/market size, etc. The difference of opinions continues. This agenda item was not addressed during 2015.

7) AMENDMENT OF TRIPS AGREEMENT CONCERNING TRIPS AND PUBLIC HEALTH

Based on the Doha Ministerial Declaration of 2001, a decision regarding implementation of paragraph 6 of the Doha Ministerial Declaration on the TRIPS Agreement and public health was adopted at the General Council held on August 30, 2003 concerning specific resolutions related to use of compulsory licenses by developing countries that do not have the capacity to manufacture pharmaceutical products. It was agreed to temporarily waive the obligations stipulated in Articles 31 (f) and (h) of the TRIPS Agreement, making possible the export of pharmaceutical products manufactured through compulsory licensing to developing countries that do not have manufacturing capacity (paragraph 6, System). At the meeting of the General Council held on December 6, 2005, an amendment to reflect the content of the decisions was incorporated into Article 31.2 of the TRIPS Agreement. Its annex and the appendix to the Article were adopted, accompanied by the Chairman’s statement, on August 30, 2003.

In the TRIPS Council, the Secretariat reported on the implementation status of decisions mentioned above and the approval status of the protocol based on the annual review of the Paragraph 6 system, which is conducted based on the decisions mentioned above. At the annual review of the TRIPS Council in October 2015, developing countries requested, just like in the 2014 meetings, workshops that invite all parties related to the NGO and related companies, claiming that the small usage of the Paragraph 6 system comes from the defects in the system. On the other hand, developed countries including Japan called for the continuation of analytical and logical discussions based on specific examples of Member countries within the framework of normal meetings, stating that the system has not been sufficiently proven to have issues. As result, the developing and developed countries failed to reach an agreement in their discussions.

The TRIPS Agreement revision protocol becomes effective within the Member countries that approved the revision when two-thirds of the WTO Members approve the protocol. The protocol will become effective for other Member countries when each Member approves the protocol. Although the approval period of the initial TRIPS Agreement revision protocol was December 1, 2007, this has been extended four times by decision of the TRIPS Council after receiving the approval of the General Council (first to December 31, 2009, next to

December 31, 2011, then to December 31, 2013, and further to December 31, 2015). Thereafter, the acceptance period was further extended by two years (until December 31, 2017) during the October 2015 TRIPS Council; subsequently, it was approved by the General Council.

As of January 2016, 65 countries and regions have agreed to the TRIPS Agreement revision protocol. From 2014 to 2015, various approaches were made to Members that have yet to accept the protocol, such as WTO Director-General Roberto Carvalho de Azevedo mentioning the need to adopt the protocol at a General Council meeting to make it an achievement of the WTO's 10th Ministerial Conference. However, the protocol has not yet been accepted by the required number of Members for it to take effect. Japan completed its acceptance procedure on August 31, 2007.

8) CONSIDERATIONS REGARDING OTHER ISSUES

“Non-violation,” which has been the subject of dispute settlement under GATT, refers to an action by a Member which, while not violating the TRIPS Agreement *per se*, infringes on or nullifies the interest of other Members. The timeline for postponement of application of this concept has been extended several times: The Doha Ministerial Declaration of 2001 aimed to complete it by the 5th Ministerial Conference; at the General Council held in July 2004, it was extended to the 6th Ministerial Conference; in the 6th Ministerial Conference (Hong Kong) held in December 2005, it was extended to the 7th Ministerial Conference; in the 7th Ministerial Conference (Geneva) held in December 2009, it was extended to the 8th Ministerial Conference; at the 8th Ministerial Conference (Geneva) held in December 2011, it was extended to the 9th Ministerial Conference; in the 9th Ministerial Conference (Paris) held in December 2013, it was extended to the 10th Ministerial Conference. Although the scope and aspects of a “non-violation declaration” were discussed more actively than before at the TRIPS Council meetings during the two years prior to the 10th Ministerial Conference (Nairobi), the gap between those supporting the adoption and those against could not be bridged, and at the 10th Ministerial Conference, it was decided to extend the discussions until the 11th Ministerial Conference.

9) OVERVIEW OF TRIPS DISPUTE SETTLEMENT

Since the TRIPS Agreement took effect on January 1, 1995 until the end of December 2015, 34 matters have been referred to consultations under the WTO dispute settlement procedures; of these matters, 15 panels have been established (see Chapter 3 of Appendices). In particular, in March 2009, the Panel report was released in regard to the China-Intellectual Property dispute (DS362), in which Japan participated as a third party. (See Part I Chapter 1 “China” for further details of the China-Intellectual Property issue). Further, in May 2010, India and Brazil respectively requested discussions regarding the problem of seizures of generic drugs by EU member state customs authorities (DS408, 409). Japan participated as a third party, and discussions were held twice that year. Also, in March 2012, Ukraine requested consultations regarding the problem of Australia's regulation on packing tobacco products (DS434), and a panel was established in August that year in which Japan is scheduled to participate as a third party. Furthermore, regarding the same Australian regulation, consultations were also requested by Honduras in April 2012 (DS435) and by Dominican Republic in July of the same year (DS441), by Cuba in May 2013 (DS458), and by India in September of the same year (DS467), respectively. At the DSB meeting in April 2014, a decision was made to establish a unified panel for these requests. The panel was established in May 2014. As of the end of 2015, the unified panel procedures for these five cases are ongoing. Meanwhile, in May 2015, Ukraine requested suspension of its

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proceedings in accordance with paragraph 12 of Article 12 of the Dispute Settlement Understanding (DSU), and the panel allowed the suspension.

Until 2000, most of the cases dealt with issues regarding developing countries after expiry their transitional period or those regarding the national treatment and MFN obligations incurred by all the Members at the time the Agreement took effect. Due to the recent intense debate regarding the TRIPS Agreement, fewer matters have been referred to dispute settlement procedures. Now that the TRIPS Council has conducted Member implementation reviews, Japan urges Members to focus not only on WTO-inconsistent legislation, but also on further improvements in enforcement by actively identifying problems and cooperating with rights holders.

Japan will continue to monitor the status of disputes between Members. Japan also believes appropriate measures should be taken to enhance effectiveness of the TRIPS Agreement.