# 19 Progressive Development of Protection Framework for Pharmaceutical Invention under the TRIPS Agreement —Focusing on Patent Rights—

Research Fellow：Akiko Kato

*This study examines the international protection framework that the TRIPS Agreement of the WTO is forming in respect of the protection of pharmaceutical inventions by patent rights, from the standpoint of the treaty interpretation. The TRIPS Agreement constitutes an annex of the WTO Agreement, and it is interpreted by applying the customary rules of the interpretation of public international law. Therefore, this study initially clarifies the rules of interpretation that are applicable to the TRIPS Agreement. It then sorts out the relevant provisions for the protection of pharmaceutical inventions by patent rights and the interpretation of these provisions, and attempts to gain a dynamic understanding thereof by considering different cases. The interpretation of the TRIPS Agreement is in the process of progressive development in the sense that it is clarified as a result of inter-state disputes set forth to the WTO dispute settlement procedure and discussions at the TRIPS Council, especially discussions on developing countries that have difficulty accessing pharmaceutical products. Through consideration of this process, this study clarifies the fact that the WTO Members are proceeding with finding a balance between the protection of pharmaceutical inventions by patent rights and the social need to use such inventions, on the international plane called the TRIPS Agreement, as well as the necessity of such viewpoint.*

## Ⅰ Introduction

This study attempts to gain a dynamic understanding of the framework for the protection of pharmaceutical inventions by patent rights that the TRIPS Agreement has been forming, from the standpoint of treaty interpretation. The following characteristics of the TRIPS Agreement make a clear distinction between it and the existing IPR-related conventions: It (1) provides high-level protection and enforcement of IPR through the Plus-Approach, (2) has various compliance measures to facilitate Members' compliance with obligations, and (3) is premised on the application of various GATT principles.

The improvements of the TRIPS Agreement have been getting clearer through its application since it came into effect in 1995, in the same way as other annexes of the WTO Agreement. The 4th WTO Ministerial Conference in November 2001 has determined to discuss the TRIPS Agreement in terms of (1) the TRIPS Agreement and public health, (2) protection of geographical indications, (3) review of the implementation of the Agreement focusing on the protection of inventions regarding animals and plant life, biological diversity and traditional knowledge, (4) provision of incentives for the transfer of technology to developing countries, (5) treatment of non-violation complaints and situation complaints in inter-state disputes regarding the obligations under the TRIPS Agreement, (6) electric commerce, and (7) technical cooperation between the Members(*1). Among these, creating a balance between the protection of pharmaceutical inventions by patent rights and the protection of public health is a field that symbolizes a challenge for the patent system, i.e., creating a balance between the interest of right holders and social interest. In this field, nations have tended to establish their own systems under their domestic law in terms of patentability, the term of protection, the contents of exclusive rights and compulsory license, while placing the field out of the international harmonization of patent laws under international law. On the contrary, since the TRIPS Agreement became the first treaty to impose the obligation to protect pharmaceutical inventions without discrimination from inventions in other industrial fields, it is highly likely to conflict with Members' policies and has been causing many inter-state disputes.

Therefore, this study considers how the TRIPS Agreement has been developing a protection framework in regard to the protection of pharmaceutical inventions by patent rights, in light of the rules of treaty interpretation. The TRIPS Agreement is a treaty that constitutes an annex of the WTO Agreement. Therefore, it shall be interpreted by applying the rules of treaty interpretation. This study clarifies rules that are applicable to the TRIPS Agreement on the basis of the general rules of treaty interpretation and the

(*1) See *Ministerial Declaration*, WT/MIN(01)/DEC/1, 20 November 2001, paras.17-9, and *Implementation-Related Issues and Concerns*, WT/MIN(01)/DEC/17, 20 November 2001.

specific rules of interpretation formed by the WTO and its predecessor, GATT. On that basis, the study attempts to gain a dynamic understanding of the existing provisions of the TRIPS Agreement concerning the protection of pharmaceutical inventions by patent rights and changes in the interpretation of the provisions, while using inter-state disputes and the Ministerial Conference's declarations as examples.

## Ⅱ Rules and Sources of Law Applied to the Interpretation of the TRIPS Agreement

For clarifying the rules of interpretation and the sources of law applied to the TRIPS Agreement, it is necessary to consider (1) three theories in the general principles of international law, and Articles 31 and 32 of the Vienna Convention on the Law of Treaties, and (2) authoritative interpretation of the WTO and DSU under GATT and the WTO. Through the consideration, (3) the rules and sources of law applied to the interpretation of the TRIPS Agreement are derived: the rules of interpretation are the rules of interpretation under the Vienna Convention on the Law of Treaties, while the sources of law include a wide variety of subjects, such as the texts of both the TRIPS Agreement (including the provisions incorporated from the existing IPR-related conventions into the TRIPS Agreement) and the WTO Agreement, the relevant context, object and purpose, agreements between parties concerned at the time of conclusion of the conventions, or subsequent agreements or practices, and the records of negotiation.

## Ⅲ The Framework of the TRIPS Agreement to Protect Pharmaceutical Inventions by Patent Right

### 1 Framework for protection under the TRIPS Agreement

This section takes into consideration the relevant provisions for the protection of pharmaceutical inventions under the TRIPS Agreement and a framework formed by various measures to make sure Members comply with obligations.

The TRIPS Agreement first establishes a non-discrimination principle among the innovation fields in Article 27 (1) as a provision for the implementation of protection, and then provides the exclusive rights conferred on patent holders (Article 28) and the term of protection (Article 33). In order to reduce the burden on Members that comes from such imposition of the same obligations on all Members, the TRIPS Agreement set the transitional arrangements in Article 65 and Article 66 (1) that allow Members who have difficulties with immediately complying with the obligations to postpone the protection of patent rights. However, there are exceptional obligations to the postponement. Members are obliged to establish systems to file patent applications and to give exclusive marketing rights for pharmaceutical inventions (Article 70 (8) and (9)), in addition to the obligation to give national treatment and the most-favored-nation treatment, upon the date of entry into force of the WTO Agreement or upon accession to the WTO.

Secondly, the following four stages can be cited in terms of provisions regarding exceptions and limitations to protection: (1) limitation of patentable subject matters (Article 27 (2) and (3)), (2) limitation of exclusive rights (Articles 30 and 31), (3) general exceptions regarding IPR (Article 40 regarding anti-competitive practices, and Article 73 regarding security exceptions), and (4) the provisions of the object and purpose of the TRIPS Agreement (Articles 7 and 8). However, for example, regarding Article 30, which authorizes Members to establish some exceptions and limitations to the exclusive rights of patent holders under certain conditions, and Article 31, which is related to use without the authorization of the patent holder, including use by the government, there are different interpretations of the wording of the provisions and the relationship between the articles. Moreover, regarding Article 7 (Objectives) and Article 8 (Principles), there are both affirmative and negative opinions on whether these provisions are applicable to the interpretation of other provisions regarding IPR protection in the TRIPS Agreement as the provisions of the object and purposes of a treaty, in line with the rules of treaty interpretation.

Moreover, the WTO and the TRIPS Agreement institutionalized various compliance measures that have developed under international law, such as the notification and examination of Members' domestic IP-related systems. Members are strongly obliged to comply with the obligations under the TRIPS Agreement through the overlapped application of these measures, which is also a largely different point from the conditions under the system of conventional conventions.

### 2 Framework Formed by Implementation of the TRIPS Agreement

This study then considered how provisions relevant to the protection of pharmaceutical inventions considered in previous part are interpreted, on the basis of three inter-state disputes handled by the DSU and the "Declaration

on the TRIPS Agreement and Public Health" (*2) (hereinafter the Doha Declaration) which was adopted by the 4th Ministerial Conference in Doha.

### (1) Interpretation of Exceptions to Transitional Arrangements regarding Protection of Pharmaceutical Inventions—Case of India—(*3)

Since this case represented the first complaint regarding the obligations under the TRIPS Agreement filed with the DSU, the panel report and Appellate Body report made clear the positioning of the TRIPS Agreement within the WTO Agreement and the standards applicable to the interpretation of the TRIPS Agreement. While constituting an integral part of the WTO system, the TRIPS Agreement is "relatively self-contained" and occupies the *sui generis* status. However, the panel represented the view that the rules of interpretation under the Vienna Convention on the Law of Treaties and the practices of GATT 1947 are applicable, as "customary rules of the interpretation of public international law," to the interpretation of the TRIPS Agreement in the same way as other agreements under the WTO.

The panel then examined whether India complied with the obligations under Article 70 (8) and (9) of the TRIPS Agreement, which are exceptions to the transitional arrangements. In other words, since Members are free to determine a method of implementing obligations under the TRIPS Agreement in accordance with Article 1 (1) of the TRIPS Agreement, the fact that India established a mailbox for pharmaceutical inventions based not on a legislative measure but on an administrative measure, i.e. the Ordinance by the president, does not conflict with the obligations. However, despite the fact that both the draft Patents Act and the Ordinance by the president had elapsed, India did not give applicants any information on the treatment of filed applications, and thus created a legally insecure condition. This constitutes a breach of Article 70 (8). In addition, the fact that India did not give the authority to grant exclusive marketing rights to any appropriate authority constitutes a breach of Article 70 (9). In the Appellate Body's examination of an appeal made by India expressing its dissatisfaction with the findings of the panel, the Appellate Body found that India failed to comply with Article 70 (8) and (9) while correcting the panel's findings in some points. The panel and the Appellate Body gave strict interpretations in light of the text of provisions, and accurately indicated the balance between the respect to Members' sovereignty and the implementation of obligations under the TRIPS Agreement. This has also brought about the tendency to substantially stultify transitional arrangements. On the other hand, India takes a policy of manufacturing generic pharmaceuticals based on the compulsory license by utilizing the transitional arrangements to meet domestic demand as well as a policy of actively exporting such pharmaceuticals to other Members lacking the ability to manufacture domestic pharmaceutical products. India has also been vigorously raising issues in discussions on the Doha Declaration.

### (2) Interpretation regarding the Establishment of Exceptions and Limitations to Exclusive Rights—Case of Canada—(*4)

Secondly, in the case of Canada, a discussion was held on whether a regulatory review exception (i.e., work for tests) and a stockpiling exception provided in Section 55.2 of the Canadian Patent Law fell under exceptions and limitations to the exclusive rights of patent rights under Article 30 of the TRIPS Agreement.

The meaning of this case can be considered in the following three points: (1) broadening of the interpretation of patent right-related provisions in the TRIPS Agreement, (2) interpretation of object and purpose of the TRIPS Agreement, and (3) rules of interpretation and source of law of the TRIPS Agreement.

Regarding (1), the panel revealed the interpretation as follows. (a) Clarification of the relationship between provisions: Article 30 as well as Article 31 are provisions that allow Members to establish exceptions and limitations to the exclusive rights of a patent holder as provided in Article 28, and exceptions and limitations imposed under Article 30 are subject to the prohibition of differential treatment on the basis of the industrial field of inventions as provided in Article 27 (1). However, it has also been pointed out that the panel clarified neither the relationship between Article 30 and Article 31 nor the specific measures allowed under the said articles. The panel also revealed that (b) the acceptability of exceptions and limitations admitted under Article 30 would be determined in light of three conditions: whether the exceptions and limitations are "limited," "do not conflict with a

(*2) *Declaration on the TRIPS Agreement and Public Health*, WT/MIN (01)/DEC/2, 20 November 2001.

(*3) The complaint by the United States is WT/DS50, and the complaint by the EC is WT/DS79. This report considers the panel report (*India -- Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Panel*, WT/DS50/R, 5 September 1997) and the Appellate Body report (*Ibid, Report of the Appellate Body*, WT/DS50/AB/R, 19 December 1997) in response to the complaint by the United States.

(*4) The panel report for this case is *Canada -- Patent Protection of Pharmaceutical Products, Report of the Panel*, WT/DS114/R, 17 March 2000.

normal exploitation by the patent holder" and ensure the "legitimate interests" of the patent holder. However, the panel did not provide an evaluation of Canada's argument that the following provision should be added to these conditions: exceptions and limitations are measures for protecting the "legitimate interests of third parties" under Article 30. While (c) the panel did not generally present specific measures acceptable under Article 30, (d) it found that at least the test exception fell under the acceptable measure but the stockpiling exception did not. It can be pointed out regarding the panel's examination that although the panel found that the stockpiling exception curtails the exclusive rights of a patent holder to the extent that it cannot be considered to be "limited exceptions," the finding lacks specifics. It can also be pointed out that both exceptions are inconsistent in the point of whether the purposes of acts are used as standards. Therefore, the findings on the stockpiling exception are not considered to be sufficiently grounded.

In addition, regarding (2) interpretation of the object and purpose of the TRIPS Agreement, both parties and third countries provided some interpretations. However, the panel did not interpret the two exception measures under the Canadian Patent Law in light of the provisions of the object and purpose of the Agreement but made a finding in light of three conditions under Article 30. Due to this fact, it can be said that the panel did not eliminate the possibility that the provisions of the object and purpose were applied to the interpretation of provisions of the TRIPS Agreement, but that the panel's interpretative approach was unreasonable in the point that while acknowledging the abstractness of the wording in Article 30 and the presence of various interpretations, the panel formed interpretations only according to the wording. The cause of this is considered to be (3) an interpretative approach that ultimately attaches too much importance to the textual approach in which the panel uses the records of the negotiations and the subsequent practices of parties to the Agreement as rules of interpretation and source of law of the TRIPS Agreement but does not hold any specific discussions on the purpose and background of establishing the exception measures under the Canadian Patent Law as well as the effect brought by the measures on the exclusive rights of patent holders, including individuals, in other Members.

### (3) Interpretation of Grant of Compulsory License—Case of Brazil—(*5)

One of the topics of current discussions on the TRIPS Agreement is the relationship between the said Agreement and the Members' systems of compulsory licenses. According to Article 31 of the TRIPS Agreement, Members may grant a compulsory license to a third party other than the patent holder only when an applicant for license has requested that the relevant right holder grant a license but the request ended in failure. Members first determine the propriety of granting a license for each application for license and then grant a non-exclusive, non-assignable compulsory license. In such case, the relevant right holder shall be paid adequate remuneration. However, prior efforts to obtain authorization are not required in the case of a national emergency or for public non-commercial use. But since there are various views on the interpretation of what constitutes a national emergency or public non-commercial use as well as those who have authority to adopt the interpretation thereof, there was the possibility that the Members would be accused of violating obligations by other Members in terms of grant of compulsory licenses. The possibility turned to reality in this case in which the United States issued a complaint against the Brazilian system of compulsory licenses. Under the DSU, the complaint was withdrawn since the United States and Brazil agreed to a mutually satisfactory solution through bilateral consultations.

Article 68 of Brazil's 1996 Industrial Property Law states that the patent holder shall be subject to getting the patent licensed on a compulsory basis if his acts are recognized as abusive exercises of his rights by a judicial or administrative decision. Article 68 (1) provides that non-exploitation within the country or insufficient commercialization of the subject matter of patent rights would also be subject to compulsory license. On the other hand, the same law establishes the exemption provisions stipulating that the following cases are excluded from being subject to compulsory license: cases where this is not economically feasible when importation shall be permitted, where the non-use is based on legitimate reasons, where serious and effective preparations for exploitation are proceeding, and where there is an obstacle of a legal nature in terms of the failure to manufacture or to market. Therefore, even if Brazil had continued the DSU procedure, the panel was unlikely to determine that the said law breached the obligations under the TRIPS Agreement. Rather, there was an option for Brazil to continue

(*5) The request for consultation made by the United States is WT/DS199/1, 8 June 2000. The request for the establishment of the panel is WT/DS199/3, 9 January 2001. The notification to the DSB of a mutually satisfactory agreement between the United States and Brazil is WT/DS199/4, 19 July 2001.

the DSU procedure in order to obtain authorization by the panel on the consistency of the said law with the TRIPS Agreement. However, the DSU aims to contribute to clarifying the interpretation of the provisions in the WTO Agreement and to form an agreement between the parties concerned regardless of contents and process. Therefore, the interpretation of Article 31 has not been made detailed and clear through this case.

### (4) TRIPS Agreement and Protection of Public Health—Doha Declaration—

The results of intensive discussion on problems regarding the protection of pharmaceutical inventions by patent rights that were left behind through the above cases is the "Declaration on the TRIPS Agreement and Public Health" adopted by the Doha Ministerial Conference. First examining the process of adoption that is the records of negotiation on the said Declaration, the following is the fundamental problem with the relationship between the protection of pharmaceutical inventions by patent rights under the TRIPS Agreement and the management of the public health problem: Under the current TRIPS Agreement, when a WTO Member intends to take measures such as the grant of compulsory licenses and parallel import for the purpose of enabling the supply of urgently needed and important pharmaceutical products, it is not clear whether these measures constitute violation of the obligations under the Agreement, and these measures are liable to be exposed to pressure from the relevant trading partners, including complaints under the DSU. The factors of the TRIPS Agreement that create this situation are as follows: (1) There is no clear definition of the scope of exceptions and limitations to the exclusive rights conferred by a patent right as provided under Article 30; (2) It is unclear what constitutes an emergency or public non-commercial use that does not require the prior authorization of the patent holder, as referred to in Article 31 (b); (3) Members recognize international exhaustion differently as it relates to parallel import; (4) When Members lacking the ability to manufacture pharmaceutical products import lower-priced generic pharmaceuticals manufactured under a compulsory license from other Members since there are no domestic pharmaceutical companies to which a compulsory license can be granted, the products manufactured under the compulsory license may conflict with Article 31 (f)—products manufactured under a compulsory license are "predominantly" for the supply of the domestic market.

Contrary to this, paragraphs 4 and 5 of the Ministerial Declaration set the principle of interpreting each provision of the TRIPS Agreement in light of the provisions of the object and purpose of the Agreement or in a manner supportive to the protection of the public health of the Members, and it clearly specifies that Members have the discretion to grant a compulsory license and to establish their own regime for international exhaustion. Paragraph 6 instructs the TRIPS Council to find a solution to improve access to pharmaceutical products for Members lacking the ability to manufacture pharmaceutical products. In this way, the said Declaration is considered to have solved the above-mentioned problems with the TRIPS Agreement to a certain extent and to include the contents that give important suggestions to future interpretation.

Then, evaluating the legal nature of the Declaration in light of the rules of interpretation under the Vienna Convention on the Law of Treaties, the Declaration falls under "subsequent agreement" among Members that possesses an authority extremely close to the authoritative interpretation of the WTO, and also falls under "subsequent practice" and a declaration of political intentions. Therefore, the Declaration is a document that can be cited by Members, the panel or the Appellate Body in the DSU proceedings, and thus can be evaluated as having the possibility of greatly influencing the future implementation of the TRIPS Agreement.

Lastly examined is the reach of the discussions on the protection of pharmaceutical inventions by patent rights through the implementation of the Declaration. The TRIPS Council made decisions on the extension of the transition period for least-developed country Members and the establishment of a new system to confirm the compliance of developed country Members with obligations regarding the provision of incentives to promote the transfer of technology.(*6) In addition, regarding the difficulties that Members lacking the ability to manufacture pharmaceutical products are facing in respect to Article 31 (f), which is stated in Paragraph 6 of the Declaration, the TRIPS Council discussed a transitional plan,(*7) which is the formation of a pipeline for the export and import of specific generic pharmaceuticals in which information is

(*6) The decision to extend the transitional period for LDC is the *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain obligations with Respect to Pharmaceutical Products*, IP/C/25, June 2002. In addition, the decision regarding the promotion of transfer of technology is the *Implementation of Article 66.2 of the TRIPS Agreement: Decision of the Council for TRIPS of 19 February 2003*, IP/C/28, 20 February 2003.

(*7) *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health -- Note from the Chairman*, JOB (02)/217, 16 December 2002.

concentrated on the WTO, on the assumption of the amendment of Article 31 (f). The discussion again paused interpretative questions as follows: whether the Declaration covers only countermeasures against infectious diseases taken by Members lacking the ability to manufacture pharmaceutical products or also more generally covers measures necessary for the protection of public health taken by all Members and if so to what extent, and how the provisions of the object and purpose of the TRIPS Agreement are specifically applied. Regarding the scope of the subject of the Declaration, from the wording of the Declaration and the records of negotiation, Members are clearly considered to have been oriented toward a more general reference of the scope, but it requires further examination in consideration of the effects on the pharmaceutical industry.

## Ⅳ Conclusion

The interpretation of the TRIPS Agreement is in the process of progressive development, and the WTO Members are proceeding with finding a balance between the protection of pharmaceutical inventions by patent rights and the social need to use inventions, on the international plane called the TRIPS Agreement. There is the possibility that the Agreement will progressively develop its interpretations based on agreements between Members with the Doha Declaration as a turning point and will form an international system that is different from the one expected when the Agreement was concluded. However, this is only a possibility, and it is important to verify the effectiveness of each agreement and practice from the standpoint of international law.