

CHAPTER 10

INDIA

NATIONAL TREATMENT

Local Content Requirements on Domestically Manufactured Electronic Products

Refer to pages 113-114 of the 2018 Report on Compliance by Major Trading Partners with Trade Agreements - WTO, FTA/EPA and IIA-.

QUANTITATIVE RESTRICTIONS

IMPORT BAN ON AIR CONDITIONERS

<OUTLINE OF THE MEASURES>

In October 2020, the Indian government announced an import ban on air conditioners, which came into effect immediately without any transitional measures. Products subject to this measure are limited to those with equipped with refrigerant.

<PROBLEMS UNDER INTERNATIONAL RULES>

This measure prohibits the importation of air conditioners equipped with refrigerant, and is likely to be in violation of GATT Article 11.1 (general elimination of quantitative restrictions) and TRIMs Agreement Article 2.1 (national treatment and quantitative restrictions). While India has explained that this measure is consistent with its obligations under the Montreal Protocol in the TPR of India. The question is whether it can be justified under GATT Article 20(b) (measures necessary for the maintenance of human life and health) or (g) (measures relating to the conservation of exhaustible natural resources), etc. This measure lacks necessity and is unreasonable, and therefore does not satisfy the requirements for justification because it regulates air conditioners using refrigerant that is not subject to India's reduction and elimination obligations under the Montreal Protocol or to India's regulation of ozone-depleting CFC gases under its domestic law.

<RECENT DEVELOPMENTS>

Japan has expressed its concerns to the Indian Government bilaterally regarding the above issue under

international rules, and has raised the issue at the TRIMs Committee, the Council for Trade in Goods, and the Market Access Committee (MA Committee) at the WTO.

TARIFFS

(1) HIGH TARIFF PRODUCTS

* This particular case was included in light of the following concerns despite it being a trade or investment policy or measure that does not expressly violate the WTO Agreements or other international rules.

<OUTLINE OF THE MEASURES>

The Customs Tariff Act specifies basic tariff and special duties (e.g., countervailing duties, anti-dumping duties, safeguard duties, etc.). MFN or EPA (the Japan-India Comprehensive Economic Partnership Agreement (Japan-India EPA)) tariff rates are applied to products imported from Japan. In addition, tariff exemption measures (e.g., tariff refunds) are applied to raw materials and parts intended for reexport.

In 2020, the simple average bound rate for non-agricultural products is high at 36.0%. And the simple average of applied tariff rate of non-agricultural products in 2020 was 11.9%.

Since fiscal year 2003, the Indian Government has continued to implement reductions of the basic tariff rates, setting forth the objectives of (1) reducing the basic tariff rate (applied tariff rate) to the ASEAN level, and (2) shifting to a tariff system that applies 10% tariff rates to finished products and 5%-7.5% tariff rates to raw materials and parts. The government implemented a tariff reduction on specific capital goods and some parts and raw materials in January 2007, and reduced the basic tariff rates on automobile parts, electrical parts and machinery parts to 7.5%. In addition, in March 2007, the government reduced the maximum basic tariff rates on essentially all bound items excluding agricultural products from 12.5% to 10%, in principle.

On the other hand, the binding coverage on non-agricultural products in 2020 is 70.1% and unbound items include high-tariff items such as passenger cars (60%), motorcycles (100%) and clothing (10%). The tariff rate on textile products is high considering the competitiveness of Indian products and the international standard.

<CONCERNS>

As long as the high tariff itself does not exceed the bound rate, there is no problem in terms of the WTO Agreements, but in light of the spirit of the WTO Agreements that promote free trade and enhance economic welfare, it is desirable to reduce tariffs as much as possible and eliminate the tariff peaks (see “Tariff Rates” in 1. (1) (iii) of Chapter 5, Part II) described above.

A low binding ratio and the existence of a gap between the applied tariff rates and the bound tariff rates with the applied tariff rates being lower are not a problem under WTO Agreements, but since they make it possible for authorities to set arbitrary applied tariff rates, it is desirable from the point of view of increasing predictability that unbound products be bound and the bound tariff rates be lowered.

<RECENT DEVELOPMENTS>

As Japan-India EPA came into effect in August 2011, tariffs on automobile parts for manufacturing and steel products imported from Japan were removed in the following 5 to 10 years, and thus the market access has been improved.

In addition, the following measures were taken in 2021 in response to the spread of the COVID-19:

- a. Temporary exemption from import tariffs
< From April 20 to October 31, 2021 >
(i) Remdesivir Active Pharmaceutical Ingredients (API), (ii) beta-cyclodextrin (SBEB CD) used in the manufacture of Remdesivir, provided that the importer follows the procedures set forth in Customs (Import of Goods at the Concessional Rate of Duty) Rules, 2017; (iii) Remdesivir for injection
< From April 24 to July 31, 2021 >
COVID-19 countermeasure products, such as COVID-19 vaccines, oxygen concentrators, medical oxygen, oxygen cylinders, oxygen filling equipment, oxygen storage tanks, oxygen generators, ISO containers for transporting oxygen, oxygen cylinders including cryogenic cylinders and tanks, and ventilators.
< From April 30, 2021 - >
Inflammation diagnostic (marker) kit (IL6, D-dimer, CRP (C-Reactive Protein), LDH (Lactate De-Hydrogenase), ferritin, procalcitonin (PCT), blood gas reagents)
- b. Temporary reduction of Integrated Goods and Services Tax (IGST)
< From May 1 to June 30, 2021: reduced to 12% >
Oxygen concentrators imported for personal use
< From May 3 to June 30, 2021: Tax exemption are applied if the following conditions are met >
(i) The goods are imported into India free of charge for the purpose of anti-COVID-19 measures by the State Government or any body, relief agency or statutory organization authorized by the State

Government.

(ii) The goods are received from abroad for the purpose of free distribution in India and anti-COVID-19 measures.

(iii) Following the prescribed procedures.

(2) SPECIAL ADDITIONAL TARIFFS

<OUTLINE OF THE MEASURES>

In India, customs duties comprising the basic tariff (whose rates were claimed to be applied tariff rates), countervailing duties, additional customs duties, special additional customs duties, and the education tax were collected by the customs authorities upon customs clearance. The rate of all these taxes put together was higher than the applied tariff rates that the Indian Government presented at the international negotiations such as the WTO.

The Indian Government introduced (GST) on July 1, 2017 to unify indirect taxes such as countervailing duties, the additional customs duties, value added tax and the central sales tax. As a result, the basic custom duty, educational tax, GST, and GST additional tax (additional tax on high-quality goods and services) are imposed on imported goods and services.

In addition, on February 2, 2018, the education tax (3%) imposed on the basic customs duties were abolished, and instead, the social welfare surcharge has been introduced.

<Problems under International Rules>

This basic tariff rate, so long as it is below the bound rate for individual items, is consistent with GATT Article II. On the other hand, the additional customs duty and previously imposed education tax are considered to come under the category of “ordinary customs duty” or “other duties or charges” as provided for in GATT Article II, paragraph 1(b). If these tariffs come under the former, then the tariffs imposed exceed the concession commitment regarding products for which a commitment was made to remove tariffs under ITA (Information Technology Agreement). If these tariffs come under the latter, they are in violation of the same concession commitment because they are not actually stated in India’s concession schedule (as they are required to be). For this reason, the additional customs duty and the education tax are likely to be in violation of GATT Article II regardless of the category they fall under.

The social welfare surcharge that was introduced to replace the education tax may continue to violate GATT Article II as the education tax used to.

In addition, the government continues to impose the former countervailing duties, additional customs duties, the special additional customs duties, value added tax and the central sale tax upon crude oil, high-speed diesel oil, gasoline, natural gas, and aviation turbine fuel at present. However, GST will be imposed on these products from the date of the notice by the government. If GST were to

be imposed, regarding to these items, in addition to the violation of GATT Article II for the social welfare surcharge, the additional customs duty may be in violation of GATT Article II, and Article III, in terms of double taxation.

(3) INCREASE IN TARIFFS ON ICT PRODUCTS

<OUTLINE OF THE MEASURES>

For some ICT (Information and Communication Technology) products that are classified as being exempt from tariffs (0%) in India's concession schedule under the WTO Agreement, to promote the production in India, the Indian Government introduced tariff increase measures through the Finance Bill (and subsequently the Finance Act) and the domestic notification. The government is repeatedly increasing tariffs on various products since 2014.

Specifically, in July 2014, the tariff rate was raised to 10% for some items of telecommunication equipment (HS8517.6290 and 8517.6990).

In July 2017, the tariff rates were raised to 10% for some items of the following categories: ink cartridges (HS8443.9951 and 8443.9952), other printers (HS8443.3290), mobile phones (HS8517.1210 and 8517.1290), base stations (HS8517.6100), and parts of telephone and telecommunication equipment (HS8517.7090). In December 2017, the tariff rate on mobile phones was increased to 15%.

In February 2018, the Indian Government increased the tariff rates on some items of the category of mobile phones and telecommunication equipment (HS8517.6290) to 20%. The tariff rates for TV LCDs, food, perfume, automobile parts, footwear, jewelry, furniture, watches, toys, etc., were also increased.

In April 2018, the tariff rate on mobile phone printed circuit board assemblies (PCBA) was increased to 10%.

In July and August 2018, the tariff rate on several textile products was raised, and in September 2018, the tariff rates on consumer electronics, footwear, and jewelry were also raised.

In October 2018, the tariff rates for some items of base stations and parts of telephone and telecommunication equipment (HS8517.7090) were raised to 20%, and the tariff rate for some printed circuit board assemblies (PCBA) (HS8517.7010) was raised to 10%.

In April 2016, as the above tariff increase measures continue, Japan, the EU and the US submitted a joint questionnaire regarding the measures to increase tariffs on ICT products. At the meetings of the WTO Committee on Market Access, the ITA Committee and the Council

for Trade in Goods, Japan requested the Indian Government to give a detailed explanation. However, India explained that "those products have been developed with new technologies and are not subject to the scope of tariff elimination to which India committed under the ITA."

<PROBLEMS UNDER INTERNATIONAL RULES>

The Indian Government sets bound tariff rates for some ICT products at zero (0%) in its concession schedule under the WTO Agreement. However, it is raising the tariff rates on these products through the Finance Bill (and subsequently the Finance Act) and the domestic notification. These tariff increase measures are highly likely to violate GATT Article II, which provides that tariffs shall not be in excess of bound tariff rates.

<RECENT DEVELOPMENTS>

As the Indian Government is repeatedly raising the tariffs, Japan repeatedly expressed concerns at the meetings of the WTO Committee on Market Access, the ITA Committee and the Council for Trade in Goods through the Japanese embassy. In the fall of 2018, several administrative-level meetings were held and Japan requested the Indian Government to give a detailed explanation and withdraw the tariff measures. However, no improvement was seen.

Among these series of tariff increase measures, tariffs on some ICT products are highly likely to violate GATT Article II, which provides that tariffs shall not be in excess of the rates stated in the concession schedule with respect to products imported from other countries. For instance, mobile phones (HS8517.1211, 8517.1219, and 8517.1290)¹, base stations (HS8517.6100), telecommunication equipment (HS8517.6290), printed circuit board assemblies (PCBA) (HS8517.7010), and telephone/telecommunication equipment parts (HS8517.7090) are classified as being exempt from tariffs (0%) at six-digit HS codes (HS8517.12, 8517.61, 8517.62, and 8517.70) in India's Concession Schedule (as of December 2019)².

In May 2019, to enhance the effectiveness of the discussion between the two countries, Japan requested for a consultation based on the WTO Dispute Settlement Understanding regarding the items that may violate GATT Article II. However, the consultation with India did not solve the problem.

In February 2020, the Indian Government raised the tariff rate on mobile phone printed circuit board assemblies (PCBA), which are the items subject to the consultation, to 20% (*1 in Figure I-10-1) (effective as of April 2020). It also raised tariff rates on footwear, furniture, etc.

Following Japan's request for the establishment of a panel against the Indian Government in March 2020 (see <Figure I-10-1> for specific items), the panel was

¹ Mobile phones fell under HS8517.1211, 8517.1219, and 8517.1290 following the revision of the applied tariff rate schedule in December 2019.

² In the January 2022 revision of the applied tariff rate schedule, the following reclassification was made: mobile phones (HS8517.12) to HS8517.1300 (smart phones, tariff rate 20%) and HS8517.1400 (other mobile phones, tariff rate 20%); printed circuit board assemblies (PCBA) (HS8517.7010) to HS8517.7910 (PCBA, tariff rate 20%); and telephone/telecommunication equipment parts (HS8517.7090) to HS8517.7100 (antenna reflectors and parts thereof, tariff rate 20%) and HS8517.7990 (other parts, tariff rate 15%).

established in July of the same year. Panel proceeding on the case is underway. The panel for the EU and Taiwan case were established in June and July 2020, respectively. Japan will continue to advance the procedures so that the case will be solved appropriately in accordance with the

In January 2022, the Indian Government further raised the tariff rates from 15% to 20% on some telephone/telecommunication equipment parts subject to the dispute settlement consultation, in the revision of the

WTO rules.

In February 2021, the Indian Government raised tariff rates such as on chemicals, plastics, machinery, auto parts, cell phone charger parts, refrigerator and air conditioner compressors, and solar conversion circuits. applied tariff rate schedule² (*2 in Figure I-10-1). In February 2022, the Indian Government also raised tariff rates on semiconductor components.

<Figure I-10-1> Main Products and Tariff Rates at the Time of Panel Establishment Request (March 2020)

Main products	India HS No.	Tariff rates
Smart phones	8517.1211	Raised from 0% to 20%
Feature phones	8517.1219	Raised from 0% to 20%
Mobile phone base stations	8517.6100	Raised from 0% to 20%
Digital microwave communication devices	8517.6290	Raised from 0% to 20%
Mobile phone printed circuit board assemblies	8517.7010	Raised from 0% to 10% (*1)
Smart phone LCD modules	8517.7090	Raised from 0% to 15% (20% in some cases) (*2)

Note: All the rates in India's Concession Schedule under the WTO Agreement are 0%.

Items in *1 and *2 are those for which tariff rates were raised after the request for panel establishment.

(4) EPA, ENHANCED RULES OF ORIGIN PROCEDURES

<OUTLINE OF THE MEASURES>

On August 21, 2020, the Department of Revenue, Ministry of Finance, India, published in the official gazette the new rules for determination of origin under trade agreements (CAROTAR 2020: the Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020), which came into effect on September 21. CAROTAR was supposed to be a measure to address the misuse, such as roundabout trade, in which goods are imported through countries that are members of free trade agreements (FTAs) and some provisions could be interpreted as requiring the importer to maintain confidential information, such as the exporter's cost information and production process, when requested by customs officials.

In addition, Rule 5.5(b) states that customs may deny an application for preferential tariff treatment without further verification if it is demonstrated, based on the information and materials submitted by the importer, that the origin criteria are not met. As well, Rules 4.(a) and 5.(1) and (2) impose on the importer the obligation to maintain relevant information showing that the origin criteria are met, and to provide such information upon request of the customs of the importing country.

<PROBLEMS UNDER INTERNATIONAL RULES>

Under the Japan-India Comprehensive Economic Partnership Agreement (Japan-India CEPA), if the information provided by the importer to customs does not meet the origin criteria, the application of the agreement can be denied. Meanwhile, if there is any doubt about the content of the certificate of origin, including insufficient or unavailable information on whether or not the goods meet the origin criteria, the customs of the importing country can request the government of the exporting country to verify the certificate, and then deny the preferential tariff application (Japan-India CEPA Annex 3, Sections 6 and 8). As a result of the implementation of CAROTAR, if there is any doubt about the origin of the goods, and the application for preferential tariff is denied without going through the verification process with the government of the exporting country, it may cause consistency issues with these provisions of the Japan-India CEPA.

In addition, under the Japan-India CEPA, detailed information and certification documents concerning the fulfillment of the origin criteria are to be kept by the certificate issuing authority or the exporter or producer (Japan-India CEPA Annex 3, Section 5). Meanwhile, there is no obligation on the importer to retain such information. Furthermore, Chapter 4 (Customs Procedures) of the Japan-India CEPA stipulates the obligation of each party to simplify customs procedures for the prompt clearance of goods traded between the two parties, and there are concerns that CAROTAR may conflict with these obligations depending on its

implementation.

Since the implementation of CAROTAR, Indian customs offices have instructed importers to provide excessive amounts of information, including confidential information (e.g., cost information of the exporter), which cannot be provided to importers for commercial reasons, and as a result, there have been many cases where importers have been unable to clear their goods at preferential tariff rates. In some cases, due to the strict screening process at customs for CAROTAR enforcement, the products could not be cleared while waiting for up to 15 days for the response of customs authorities, and therefore some importers gave up using EPA and chose to the customs clearance at the most-favored-nation (MFN) rate. This implementation of CAROTAR has resulted in the loss of the tariff benefits promised by the Japan-India CEPA that would otherwise have been enjoyed, and Japanese companies have been faced with additional costs.

In response to these issues, and as a result of repeated efforts by the Japanese government through the Japanese Embassy in India and other organizations, on October 8, 2020, the Indian Government released explanatory materials that included responses to our requests. In addition, on December 17, 2020, the Ministry of Finance of India issued a notice to the Chief Commissioners of Customs and other related agencies requesting proper enforcement of CAROTAR. As a result of these measures, the confusion is being resolved, but it will be necessary to continue to monitor the future implementation of CAROTAR.

<RECENT DEVELOPMENTS>

For the purpose of improving the implementation of CAROTAR 2020, the Central Board of Indirect Taxes and Customs issued a notice dated August 17, 2021, stating that a proper officer may communicate a verification only when there are justifiable reasons, by specifically indicating such reasons, and within the prescribed timeline of specified in CAROTAR 2020.

ANTI-DUMPING MEASURES

(1) AD MEASURES ON JAPANESE HOT-ROLLED STEEL SHEETS AND THICK PLATES; AD MEASURES ON JAPANESE COLD-ROLLED STEEL SHEETS

In May 2017, the Indian government made a final decision on Japanese hot-rolled steel sheets and thick plates and Japanese cold-rolled steel sheets. In these final decisions, it is not specifically considered to which same kinds of domestic products the various products to be surveyed having different purposes and price ranges gave dosage effect and price effect when injury was

determined. In addition, the AD duties will be imposed as a difference between the reference price and the export price of the products to be surveyed. However, the basis for the calculation of the reference price is not clarified, which raises doubts on the consistency with the AD Agreements. Until the final decision was made, the Japanese government had pointed out the above at the public hearing and the AD Committee and sought improvement by submitting a government opinion. However, the final decision was made although there was still a concern for the consistency with the WTO Agreements. For details of the original decision of this matter, refer to page 117 of the 2018 Report on Compliance by Major Trading Partners with Trade Agreements - WTO, FTA/EPA and IIA.

In March 2021, the Indian Government began an AD sunset review. Although the Indian Ministry of Commerce and Industry proposed an extension in September of the same year, in January 2022, the Indian Ministry of Finance decided not to extend the taxation measures on hot-rolled steel sheets, thick plates, and cold-rolled steel sheets.

At the AD Committee meeting in October 2021, Japan had also requested the early termination of this taxation not to improperly continue for a long period. Japan appreciates that India decided not to continue the AD measures considering the issues raised by Japan regarding the consistency with the agreement.

(2) AD MEASURES ON JAPANESE RESORCINOL

<OUTLINE OF THE MEASURES>

In January 2018, the Indian government decided to take AD taxation measures against Japanese Resorcinol. In this decision, no reasonable basis has been shown for the calculation of the damping margins, cumulative assessment, and price effect, and the analysis of the effect of the import of the target products on the domestic industries is insufficient. Thus, the AD agreement may be violated in terms of determination of injury. Until the final decision was made, the Japanese government had pointed out the above by submitting a government opinion. However, the final decision was made although there was still a concern for the consistency with the WTO Agreements. For details, refer to page 117 of the, 2018 Report on Compliance by Major Trading Partners with Trade Agreements - WTO, FTA/EPA and IIA-.

<RECENT DEVELOPMENTS>

In February and December 2017, Japan submitted a government opinion to the Indian Government and pointed out the issues in the aforementioned international rules. Japan was closely monitoring the operation of the AD system by the Indian Government.

In March 2021, when the taxable period expired, the

Indian Government did not make a decision to continue the taxation and this measures were terminated.

SUBSIDIES

NATIONAL FOOD SECURITY ACT

<OUTLINE OF THE MEASURE>

In India, the National Food Security Act, a program in which the government distributes grain that it bought from producers to the poor at low price, was enacted in September 2013. The act aims to stabilize the food supply to the poor, enabling people to buy rice, wheat, and cereals at 3 rupees/kg, 2 rupees/kg, and 1 rupee/kg, respectively, up to 5 kg every month, and approximately 63% of the total population (approximately 75% in rural areas and 50% in urban areas) is eligible for this measure. According to the Indian Government, the necessary grain amount under the former distribution program was 56.37 million tons (as of 2012), whereas the amount under current system is 61.00 million tons. Thus, the Domestic Support has increased.

<PROBLEMS UNDER INTERNATIONAL RULES>

In expansion of the distribution program by the National Food Security Act, when necessary grain is purchased at an administrative price, it will be regarded as a price support policy for producers in the Agriculture Agreement and corresponds to the Domestic Support that is subject to reduction. In September 2014, India notified the agricultural committee of the Domestic Support of FY2004 to FY2010, which is provided in Article 18 of the Agriculture Agreement. During that period, the expenses related to the public stock system increased from 5.7 billion to 13.8 billion US dollars. The amount of grain purchased by the government also increased from 24.7 million to 34.2 million tons (rice) and 16.8 million to 22.5 million tons (wheat). The Domestic Support related to such measures is within the range of de minimis (10% of the agricultural production) until FY2010; therefore, the aggregate measurement of support (AMS) is zero but there is a concern that the Domestic Support amount may further increase through the enforcement of the act. It is important to monitor the details of the future domestic support notification and the relationship with the commitment level with the WTO.

<RECENT DEVELOPMENTS>

At the 9th WTO Ministerial Conference in December 2013, in the case of public stockpiling systems for food security purposes by developing countries, even if their domestic support violates their domestic support reduction obligation under the WTO Agricultural Agreement, member countries agreed as a provisional measure to refrain from taking the matter to dispute

settlement. In response to the request by India, at the WTO General Council meeting on November 27, 2014, we agreed that the provisional measure continues until a permanent solution is adopted and that maximum effort will be made so that the solution will be adopted by the end of 2015. However, there is no progress in the discussion for the adoption of this solution, and it was confirmed that the discussion will be continued to the special meeting of the Agricultural Affairs Committee at the 10th WTO Ministerial Conference in December 2015. It is necessary to carefully observe how the discussion for the permanent solution influences the regulation of the Domestic Support.

SAFEGUARDS

(1) SAFEGUARD MEASURE ON HOT-ROLLED FLAT PRODUCTS

<OUTLINE OF THE MEASURE>

The Indian government initiated a safeguard investigation of hot-rolled flat products on September 7, 2015. On September 9, 2015, the government decided to impose provisional safeguard measures, and started to impose the provisional safeguard measures (20%) for 200 days from September 14, 2015.

On March 15, 2016, the head office of Safeguards of the India, Ministry of Commerce and Trade published a final report finding an increase in imports of hot-rolled flat products, and threat of serious injury to the domestic industry. In response, the Indian Ministry of Finance published a notice in the official gazette on March 29, 2016 to the effect that the safeguard measures would be imposed for two years and six months from the commencement of the provisional measures.

<PROBLEMS UNDER INTERNATIONAL RULES>

The increased import of products subject to the measure must be “as a result of ... the effect of the obligations incurred by a contracting party under this Agreement, including tariff concessions” as prescribed in Article XIX: 1(a) of GATT. However, while India’s final report describes that the India’s bound rate under GATT is 40%, it does not appropriately find that the imports have increased as a result of the effect of India’s obligations under GATT.

Japan and India concluded the Japan-India Comprehensive Economic Partnership Agreement (Japan-India CEPA), under which tariffs on the relevant items have been reduced. However, the tariff concession obligation under the Japan-India CEPA is not the above-mentioned obligation incurred under GATT as prescribed in Article XIX: 1(a) of GATT. Therefore, increased imports that have occurred as a result of the effect of the tariff concession under the Japan-India CEPA should not

be taken into account in an investigation for imposing safeguard measures under the WTO Agreement.

Furthermore, India's investigation report finds facts such as the excess of capacity of steel products in China and increased demand in India to be unforeseen developments as prescribed in Article XIX: 1(a) of GATT. However, the excess of production capacity falls under the scope of anticipation as such excess results from a mere change of supply and demand. In addition, such "unforeseen developments" are interpreted as developments that create a change in the competitive relationship between domestic and imported goods to the detriment of domestic goods only. However, the described facts triggered by excess production capacity does not detrimentally affect only to the domestically produced goods. Thus, Japan believes the circumstances explained in the report do not meet the "unforeseen developments" criteria under Article XIX: 1(a) of the GATT.

As above, the Indian authority has not appropriately determined the above-mentioned requirement for the imposition of safeguard measures, so the measure may be inconsistent with the WTO Agreements including Article XIX: 1(a) of GATT.

<RECENT DEVELOPMENTS>

Since the investigation was initiated in September 2015, Japan has submitted written comments, participated in public hearings and taken other opportunities to point out that the measures taken by India may violate the WTO Agreement. However, since progress for revoking the measure was not evident, Japan requested consultations with India based on the WTO Agreement in December 2016 (DS518). Based on the results of the consultations, Japan requested the WTO to conduct a panel hearing on March 9, 2017 and the panel was established on April 3, 2017.

On 6th November, 2018, the panel circulated a panel report which represented a ruling, upholding most of Japan's claims, that this measure was inconsistent with the WTO Agreement for the following reasons: (1) India failed to sufficiently prove the fact that there was a logical connection between the unforeseen development of the events and the increase in imports based on objective evidence (SG Agreement Articles 2.1, 4.2(a) and GATT Article XIX: 1(a)), (2) India failed to appropriately examine the injury factors (i.e., price and profitability) of the domestic industry in determining the "serious injury" to the domestic industry and also failed to determine the injury based on any objective data (SG Agreement Article 4.2(a)). (3) India failed to make reasoned findings in its determination as to the causal link between the increase in imports and the serious injury to the domestic industry (SG Agreement Article 4.2(b)). Further, the panel recommended India to make the safeguard measure consistent with the Agreements to the extent that the measure continues to have any effects, while the measure

had been already expired.

India appealed against the panel's judgment on December 14, 2018; however, the Appellate Body cannot judge the case currently (refer to the column "Problems of WTO Appellate Body" in Chapter 17, Part II).

Japan will proceed with necessary procedures subject to the WTO rules so that the case will be resolved in an appropriate manner.

(2) BILATERAL SAFEGUARD MEASURES UNDER THE JAPAN-INDIA CEPA FOR PVC SUSPENSION GRADE RESIN

<OUTLINE OF THE MEASURES>

On September 8, 2020, the Indian Government initiated a bilateral safeguard investigation into PVC suspension grade resin under the Japan-India Comprehensive Economic Partnership Agreement (Japan-India CEPA). (The current tariff rate on this item is 0.7%, and the WTO bound tariff rate is 10%.)

<PROBLEMS UNDER INTERNATIONAL RULES>

There was no bilateral written notification of the above-mentioned announcement in the official gazette, which is required under the Japan-India CEPA (the Indian government issued a bilateral notification to the Japanese government in response to a request from the Embassy of Japan in India on September 22 of the same year).

In addition, India's production of PVC suspension grade resin (1.4 million tons) is far short of India's growing domestic demand (more than 3.5 million tons), and the capacity utilization of domestic manufacturers is more than 98% and they are forced to rely on imports, which casts doubts on the allegation of injury to the domestic industry due to increased imports. In addition, the three Indian applicants in this safeguard investigation account for only about 25% of India's domestic production. With the increasing volume of imports from other countries, it is questionable whether they can "demonstrate on the basis of objective evidence" (Article 23.3(d) of the Japan-India CEPA) the causal relationship between the damage to the domestic industry and imports of Japanese products.

<RECENT DEVELOPMENTS>

In October 2020, the Embassy of Japan in India held a video conference with the Directorate General of Foreign Trade, Ministry of Commerce and Industry, India, expressing concern and requesting holding consultation for compensation (Article 23.4(c) of the Japan-India CEPA). In the same month, the Embassy of Japan in India and the industry notified the Indian Ministry of Commerce and Industry of their registration of interested parties, and the Japanese government submitted a government opinion.

Subsequently, the investigation procedure was

delayed due to the COVID-19 pandemic, but in July 2021, the investigation was terminated due to the withdrawal of the application by the applicant company, and the measure was not invoked.

STANDARDS AND CONFORMITY ASSESSMENT SYSTEMS

(1) TECHNICAL REGULATIONS FOR STEEL PRODUCTS

<OUTLINE OF THE MEASURE>

In September 2008, the Indian government announced that it would introduce technical standards for steel products. After the enforcement date, steel manufacturers were required to acquire Indian Industrial Standards (“IS Standard”, IS = Indian Standards) for steel products exported to India and to ensure conformance with the standards. Currently, IS is in place as mandatory standards for a total of 145 steel products.

<Problems under International Rules>

The Indian government has explained that the policy objectives are to ensure the safety and quality of products and to protect the environment. However, these objectives cannot be achieved through regulations of intermediate goods such as steel products but instead should be achieved through safety regulations of final products; thus, Japan deems the regulation unnecessary. Therefore, the regulation is suspected of being more trade-restrictive than necessary in light of the policy objective and may violate Article 2.2 of the TBT Agreement.

<RECENT DEVELOPMENTS>

On-site audits of production plants are required for certification to the standards, but due to the spread of the COVID-19, on-site audits have been extremely difficult to conduct. In addition, in allowing imports for non-certified cases on an exceptional basis, India has imposed conditions such as the submission of a future plan for switching to local procurement. In this regard, the Indian Government stated at the TBT Committee meetings in June 2021 and November 2021 that it was considering the introduction of virtual remote audits as an alternative to local audits.

Japan has requested the Indian government to improve this matter in discussions with the Ministry of Steel and in the TPR of India in January 2021. Japan will continue to closely monitor the operation of this system and, if necessary, seek the proper operation of the system through continued discussions between the two countries

and through the TBT Committee.

(2) STRENGTHENING OF RESTRICTIONS ON CONDITIONS FOR LICENSING TELECOMMUNICATIONS CARRIERS

<OUTLINE OF THE MEASURE>

In March 2010, the Indian government published a notification titled “Ensuring Security and Safety before Purchase of Telecommunications Equipment from Foreign Companies” and published regulations on procurement of telecommunications equipment in India for the purpose of ensuring security in information and telecommunications. The content of the regulations was partially relaxed in May 2011, but Indian carriers are obligated to obtain network security approvals from inspection authorities in India when purchasing telecommunications equipment from foreign telecommunications equipment manufacturers. The date of implementation for this system was scheduled for July, 2014 but it was postponed many times thereafter. However, details regarding the measures such as security requirements are not clear.

<PROBLEMS UNDER INTERNATIONAL RULES>

Although the contents of these notifications are unclear, if inspections by domestic inspection authorities, etc. require telecommunications equipment to have specific security features, they may be de facto compulsory conformity assessments of the equipment by the government, etc. Therefore, the Indian government may assume the obligation to notify the WTO.

The requirement that only equipment which is approved by domestic inspection authorities are allowed to be included in the network will cause discriminatory treatment of foreign products. Therefore, it may violate national treatment under GATT Article III: 4 and Article 2.1 of the TBT Agreements.

<RECENT DEVELOPMENTS>

Since 2010, industrial groups in Japan, the United States and Europe have been expressing their concerns to the Indian government. In October, Japanese industrial circles (four groups) issued a letter expressing their concerns again to the Indian government. As Japanese government, on the occasion of the ASEAN plus 6 Economic Ministers’ Meeting in August 2010 (in Viet Nam) and the East Asia Summit meeting in October (in Viet Nam), the Minister of Economy, Trade and Industry of Japan expressed Japan’s concerns to the Minister of Commerce and Industry of India. Also at the India-Japan Ministerial-Level Economic Dialogue in April 2012, Japan requested the Indian government to take adequate measures to address this problem.

Japan will continue to request details of these regulations and consistency with international IT security

regulations.

(3) INTRODUCTION OF TECHNICAL REGULATION ON ELECTRONIC AND INFORMATION TECHNOLOGY DEVICES

<OUTLINE OF THE MEASURE>

In September 2012, the Indian government (Ministry of Communication and Information Technology) announced legislation to oblige the registration of electronic and information technology devices, the “Regulation on electronic and information technology devices 2012 (mandatory registration duties)” (notification to the TBT Committee was made in October of the same year). Preliminary registration and labeling in accordance with domestic safety standards on 15 items of electric home appliances and electronic devices became obligatory (projectors were newly added to the subject items in July 2013). This regulation was fully enforced in January 2014.

In November 2014, the Indian government published official gazette stating that it will newly make 15 items subject to the system. Since then, mandatory items have been added several times, and currently the regulation is fully enforced on 63 items. At present, a very large number of applications for testing are being made for both domestic and foreign products, but a large number of documents are required for application, and thus many applications for registration have not been completed. As a result, there has been a confused situation where exports of subject items are delayed.

<Problems under International Rules>

Article 5.1.2 of the TBT Agreement stipulates that “conformity assessment procedures shall not be more trade-restrictive than necessary.” However, registration procedures of this regulation require excessive procedures such as submission of a large number of documents, and no reasonable explanations or reasons for the necessity of such excessive procedures have been given by India. Therefore, this regulation is suspected of being conformity assessment procedures that are more trade-restrictive than necessary in light of the policy objectives of the regulation, and may violate Article 5.1.2 of the TBT Agreement.

<RECENT DEVELOPMENTS>

The Government of India issued a revised market audit document, “Market Surveillance Policy May 2018 (v1)” on May 20, 2018 and BIS Conformity Assessment Regulations 2018 on June 4 of the same year. The operation of the market audit has been documented but the provisions for prepaid costs by the manufacturer and cancellation measure of registration are unreasonable and unclear. Further, additional requests, such as displaying

BIS website information (URL) on equipment and packaging, are also added.

In July 2018, a new standard for secondary batteries IS16046 (Part1) and (Part2) was announced. It is necessary to test and register batteries again based on the new standard and to change the indications on the batteries. Since a drastic solution is required regarding newly added items subject to the standard and a transitional period for revising technical standards, Japan will continue to request the Indian government to improve the system.

TRADE IN SERVICES

(1) FOREIGN INVESTMENT RESTRICTIONS, ETC.

* This particular case was included in light of the following concerns despite it being a trade or investment policy or measure that does not expressly violate the WTO Agreements or other international rules.

<OUTLINE OF THE MEASURES>

In March 2010, the Department of Industrial Policy and Promotion (DIPP) of the Ministry of Commerce and Industry published a new Consolidated FDI Policy that consolidates policies concerning inward direct investment by foreign enterprises (the latest revision made on October 15, 2020). Under this Consolidated FDI Policy, business types/forms for which foreign direct investment was prohibited/restricted, business types with upper limits on the foreign investment ratios, and business types requiring individual approval by the Foreign Investment Promotion Board (FIPB), etc. were provided in a negative list. Business types for which foreign direct investment was prohibited included eight areas, e.g., nuclear energy and rail ways that have not been opened to private companies, real estate businesses or construction of farming businesses, lotteries, gambling including casinos, and tobacco production.

In May 2014, the Bharatiya Janata Party (BJP, Prime Minister Narendra Modi), which became the ruling party after the general election, relaxed foreign investment regulations in certain sectors. In August of the same year, the upper limit of the foreign investment ratio in the defense sector was raised from 26% to 49% and the ratios for high-speed railway, urban railway corridor, and designated cargo railway businesses, through PPP, were raised to 100%. In addition, the requirements for investment in foreign real estate/construction businesses were relaxed in October of the same year. The Cabinet decided to reduce the minimum scale (area) of properties as to which investment is allowed from 50,000m² to 20,000m². An overview of foreign investment

regulations on financial services and distribution services sectors, etc. is given below.

(i) FINANCIAL SERVICES

(a) BANKS

Regarding relaxed restrictions on foreign investment in private banks, foreign banks have become able to establish wholly-owned subsidiaries in India, provided that they (1) are under the jurisdiction of the competent authorities of their home countries, and (2) meet approval requirements of the Reserve Bank of India (RBI), which is India's central bank. These points are also provided for in the Consolidated FDI Policy. On the other hand, for domestic private banks, foreign direct investment is allowed up to 74%. As for non-banks, foreign investment up to 100 percent was permitted in 18 sectors, including commercial banks such as designated merchant banks and home financing. Since October 2016, the scope of sectors has been expanded to include "other financial services." However, minimum capital requirements are prescribed according to investment ratios. In this case, it is also required to follow the guidelines of the RBI.

The Japan-India Comprehensive Economic Partnership Agreement (Japan-India CEPA) entered into force in August 2011. As an achievement in the financial field, Japan acquired special treatment. Specifically, India will give positive consideration to Japanese banks' applications for the establishment of up to 10 branches in four years, though there is a quantitative restriction stipulating that no more than 20 branches of foreign banks can be established annually within India. However, the authorities' approval for the establishment of branches is still taking a long time.

In November 2013, RBI announced measures to promote conversion of branches to subsidiaries by allowing foreign banks to receive administrative treatment similar to that given to domestic banks.

(b) INSURANCE

In the field of insurance, a bill proposing to raise the ceiling on permissible foreign investments in insurance companies from 26% to 49% was approved at a Cabinet meeting in July 2014 after the Modi administration came into office. Since the bill was not deliberated at the budget session or the winter session of Parliament in 2014 due to opposition by the opposition parties, the government issued a Presidential Decree at the end of December of the same year as a provisional measure to raise the foreign investment ratio. In March 2015, a bill for amending insurance laws passed the Parliament, and foreign investments of up to 49% became allowed.

(ii) DISTRIBUTIONS SERVICES

With the relaxation of regulations concerning foreign investment of 2012, the upper limit on foreign capital investment for single-brand retailers was raised from 51% to 100% under certain conditions (enforced in

January 2012). Additional regulatory relaxations took place at the same time with the subsequent relaxation of regulations on multi-brand retailers. Major conditions for the regulatory relaxation are as follows.

- Products must be single-brand.
- In cases where foreign capital is over 51%, retailers must make efforts to procure 30% on average of their goods from medium and small-scale domestic suppliers, villages, etc., for five years after establishing a store.

Furthermore, as for products that are developed with state-of-the-art or cutting-edge technologies and cannot be procured domestically in India, retailers are to be exempted from the above goal for three years after the first branch store is opened; the exemption is to cease in the fourth year and is scheduled to be enforced in June 2016.

In contrast, regulations on multi-brand retailers for which foreign entry was previously prohibited were relaxed to allow up to 51% of foreign capital investment (enforced in September 2012), and further relaxation was decided by the Cabinet (in August 2013). Major conditions for the regulatory relaxation are as follows, which practically impose entry barriers.

- Minimum investment is 100 million US dollars.
- A minimum of 50% of the invested amount shall be directed at infrastructure other than land purchase or rent (backend infrastructure such as manufacture, packaging, distribution, and storage, etc.) within three years of initial investment.
- 30% of products procured shall be from domestic small-size industries (with investment in buildings and facilities of 2 million US dollars or less). This needs to be achieved in terms of the average of total product procurement for the first five years, and then achieved every year thereafter.
- Applies only to the states that have approved the relaxation of the restriction (as of December 2013, 11 states expressed their acceptance).

<CONCERNS>

Although the WTO Agreement has no general rules on investment, the GATS disciplines service trade activities through investment. The restrictions on foreign investment described above do not violate the WTO Agreements so long as the restrictions do not contravene India's GATS commitments. However, it is desirable that liberalization efforts be made in accordance with the spirit of the WTO and the GATS in mind.

<RECENT DEVELOPMENTS>

Bharatiya Janata Party (BJP), which became the ruling party after the general election in May 2014, had expressed its position of being cautious about relaxing foreign investment regulations on general retail businesses after the election. After the establishment of the new administration, the Minister of Commerce and

Industry again expressed opposition to the relaxation of foreign investment regulations on general retail businesses. Although developments relating to relaxing the above regulations were observed in June and October 2016, Japan will continue to monitor the trends of amended laws related to the reinforcement of restrictions on foreign investment and is working on the relaxation of such restrictions through bilateral policy dialogues and other occasions.

(2) PERSONAL INFORMATION PROTECTION BILL

<OUTLINE OF THE MEASURE>

In June 2018, a committee of experts of the Indian government submitted a report on data protection and the draft of the “Personal Data Protection Bill” to the Ministry of Electronics and Information Technology (MeitY). In July 2018, the bill (hereinafter referred to as the “2018 Bill”) was made public. Although the bill had not been enacted, the Indian government accordingly published the Personal Information Protection Amendment Bill (hereinafter referred to as the “2019 Bill”) in December 2019 reflecting the public comments collected with regard to the 2018 Bill. Basically, the 2019 Bill follows the contents of the 2018 Bill, while several changes were made. Still, the 2019 Bill includes (1) the obligation to store the “sensitive personal data, including financial, health, and biometric data” in India when such data is transferred outside India (Article 33, Paragraph 1); (2) the obligation to process data designated by the central government as “critical personal data” in India (Article 33, Paragraph 2); and (3) provisions related to cross-border transfer of “sensitive personal data” and “critical personal data” outside India (Article 34). The 2019 Bill has also new provisions such as exemption of the central government acting in the interest of security and public order (Article 35), and obligations to provide non-personal data to the central government (Article 91, Paragraph 2). While the Bill has certain similarities to the EU’s General Data Protection Regulation (GDPR), some provisions, such as the obligation to obtain the explicit consent of the data holder as a prerequisite for cross-border transfer of “sensitive personal data,” are unique to India.

<PROBLEMS UNDER INTERNATIONAL RULES>

The 2019 Bill also stipulates that the “critical personal data” shall be processed in India. It is concerned that the definition of the “critical personal data” subject to the obligation under the bill is unclear. In addition, while the scope of the “sensitive personal data” is limited in comparison with the 2018 Bill, the obligation to store the “sensitive personal data” in India is still existent. Under these obligations, there are concerns that foreign operators may be treated less favorably in high probability than domestic operators. It is necessary to

keep an eye to avoid excessive data localization requirements.

Regarding cross-border data transfer, compared with the 2018 Bill, standard contract articles and conditions that are considered as approval standards of cross-border data transfer scheme within group companies are clearly articulated. However, the scope of the data subject to the bill is still unclear. Furthermore, regarding cross-border transfer of the “sensitive personal data,” requirements seem to be excessive in that the bill requires an explicit consent by the data holder even if the transfer is based on standard contract articles approved by the authorities and the cross-border data transfer scheme within group companies. For foreign businesses that have consolidated and managed employee data of their offices located in various countries outside India, these restrictions on cross-border data transfer may cause security concerns and additional costs for storing such data in India as well as further concerns for foreign businesses that consider entering the Indian market or continuing their business in India. At the same time, these regulations would place foreign businesses at de facto less competitive conditions compared to service providers in India who have consolidated and managed data in India. In this sense, the regulations may violate the national treatment obligation stipulated in Article 17 of the GATS. In addition, a report proposing amendments to the Bill was submitted to the National Assembly in December 2021, stating that non-personal data should be also included in the scope of the Bill, about which the industry has expressed concerns.

It is necessary to keep paying attention to these aspects during the legislation processes and establishing relevant regulations.

<RECENT DEVELOPMENTS>

In February 2020, the Japanese government submitted its comments on the 2019 Bill. The bill was submitted to the lower house of Indian Parliament in December 2019 and is now under consideration. We will continue to work with the industry to closely monitor future legislation processes and relevant regulations to avoid unjustifiable infringement on free flow of information and rights of foreign operators.

PROTECTION OF INTELLECTUAL PROPERTY

(1) ISSUES RELATED TO COUNTERFEIT, PIRATED AND OTHER INFRINGING PRODUCTS

<CURRENT STATE>

According to the investigation into the situation of damage caused by counterfeit, pirated, and other

infringing products in India conducted in June 2021 by the Authentication Solution Providers' Association, a non-profit organization that works to combat counterfeit goods in India based on various authentication methods, the amount of damage caused by counterfeit products in India is more than 1 trillion rupees (about 1.4 trillion yen) every year. As well, according to the FICCI CASCADE (Committee against Smuggling and Counterfeiting Activities Destroying the Economy), about 30% of the products in the automobile parts market are counterfeit products.

On the other hand, India is not sufficiently cracking down on counterfeit products that are spreading. A survey reveals it takes on average 7 to 10 years from disclosure to criminal punishment. It has been reported that counterfeit products in the market are not decreasing because the substantial deterrent effect on the infringement is insufficient.

<CONCERNS>

One of the serious issues shared by emerging/developing countries concerning intellectual property is that there are many cases of intellectual property infringements occurring in these countries through manufacturing/distribution of counterfeit, pirated and other infringing products and that the effectiveness of exercising rights to eliminate such intellectual property infringements is not fully ensured.

Rights are not fully protected just by developing actual regulations concerning intellectual property and creating and improving the relevant systems. For the full protection of rights, the following measures are indispensable: appropriate and effective management of bodies that grant and register rights in terms of acquisition of rights; and effective and prompt handling of right infringements through relief measures by judicial proceedings, border measures by customs, and criminal regulations and sanctions in terms of enforcement of rights against infringements.

Substantial part (from Article 41 to Article 61) of the TRIPS Agreement is set aside for regulations concerning enforcement of such rights, requiring member countries to ensure their domestic legal systems which enable effective and prompt measures (Article 41).

Also, in order to secure the efficient operation of the system related to the protection of intellectual property, Japan-India Comprehensive Economic Partnership Agreement (Japan-India CEPA) obligates taking appropriate measures for simplifying the domestic administrative procedures related to intellectual property (Article 103).

In light of the above regulations, cases where effective and prompt enforcement of rights is not ensured may violate obligations stipulated in these agreements.

<RECENT DEVELOPMENTS>

In recent years, in order to shorten the examination period of patent applications, the Indian government is

working on approaches such as “Patent Prosecution Highway” and increasing the number of examiners. (The Patent Prosecution Highway started between Japan and India in December 2019).

In addition, the Indian government states that the enforcement of the rights is one of the pillars in the “National Intellectual Property Rights Policy” compiled in 2016 and “Intellectual Property Rights System of India - Initiative by Government” published in 2019.

In addition, on-line counterfeit products are increasing with the rapid growth of the e-commerce market. In 2019, the Department for Promotion of Industry and Internal Trade of India of the Ministry of Commerce and Industry published an E-Commerce Policy and the Department of Consumer Affairs of the Ministry of Consumer Affairs, Food & Public Distribution published 2019 Guidelines for Consumer Protection (E-Commerce). With these developments, guidelines for the e-commerce market are being discussed.

Since the spread of the novel coronavirus infection, local reports indicate that the demand for products related to the novel coronavirus, such as disinfectant solutions, masks, and testing reagents, has increased, which has led to an increase in counterfeit products of these products. For example, there has been an increase in the distribution in the local market of counterfeit disinfectants that bore the product labels of well-known pharmaceutical companies and were advertised as having a disinfectant effect when, in fact, they did not. In March 2020, in response to a report from a citizen, the factory of a manufacturer of counterfeit disinfectants was shut down and counterfeit disinfectants in the possession of the distributor were seized in a raid. Raids are conducted by the police to round up stores in a local market suspected of selling counterfeit goods, arrest the sellers of counterfeit goods, and seize the counterfeit goods, with the aim of eradicating the sale of counterfeit goods in the local market. Imports of counterfeit medicines, test kits, respirators, masks, and other items related to the novel coronavirus are also on the rise, and Indian Customs is actively implementing border control measures against the importation of these items.

It is necessary to focus on the Indian government's approaches against effective and quick right execution.

(2) PROTECTION OF PATENTS IN RELATION TO PHARMACEUTICALS, ETC.

<OUTLINE OF THE MEASURE>

India did not recognize drug substances patents in the 1970 Patent Law but in December 2004, ahead of the January 2005 deadline (expiration), the revised 2004 Patent Law (Presidential Decree) including the introduction of the substance patent system was promulgated. After that, the Parliament deliberated and adopted the 2005 Amendment Act (3rd), promulgated in April 2005 and it was implemented retroactively as effective from January of the same year excluding some

articles. The points of the 2005 revised law included (1) Introduction of substance patent system (Deletion of Patent Act Article 5) (2) Introduction of definitions of medicinal substances (Article 2 (ta)), (3) Deletion of exclusive sales rights (EMR) provisions (Article 24A-F), (4) Restrictions on rights of patentees, etc. related to mailbox applications (Article 11A (7)) and (5) Introduction of compulsory license (manufacturing and export) for the export of pharmaceuticals under certain exceptional circumstances (Article 92A), etc.

Since the enforcement of the revised law in 2005, patents have been granted for pharmaceutical-related inventions. However, pharmaceutical-related inventions that have been patented in major countries are sometimes rejected in India under Article 3 (d) of the Patent Law, which denies patentability of “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” as “not an invention”. In reality, in April 2013, the Supreme Court decided that patent applications relating to anticancer drugs of foreign pharmaceutical manufacturers should not be approved under Article 3 (d) of the Patent Act.

Further, there is a movement to activate compulsory licenses for pharmaceutical-related inventions. In March 2012, the Office of the Controller General of Patents, Designs & Trade Marks, based on the application of a generic manufacturer in India, found that “a foreign drug manufacturer did not set an appropriate price and did not supply a sufficient amount of medicine at a reasonable price in India”. A compulsory license was set for pharmaceutical-related patents owned by the foreign pharmaceutical manufacturer based on one of the conditions for invoking compulsory licenses: “the patented invention is not available to the public at a reasonably affordable price” (Patent Act Article 84, Paragraph 1 (b)).

Regarding the establishment of this compulsory license, in May 2012, the foreign pharmaceutical manufacturer was dissatisfied with the decision by the Office of the Controller General of Patents, Designs & Trade Marks and an appeal was filed with the Indian Intellectual Property Appeals Board. However, it was rejected in March, 2013. In May of the same year, the foreign pharmaceutical manufacturer filed a complaint with the Mumbai High Court, but it was rejected in July 2014. In correspondence to that, a special permission application was made to the Supreme Court, but it was rejected in December 2014. Other applications for setting compulsory licenses that have been made, have been rejected by the Office of the Controller General of Patents, Designs & Trade Marks.

Regarding other background history, see Page 170 of the 2017 Report on Compliance by Major Trading Partners with Trade Agreements -WTO, FTA/EPA and IIA-.

It can be appreciated that a substance patent system has been introduced and the obligations under the TRIPS Agreement have been fulfilled. However, Article 3 (d) of the Patent Law states that “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” is not patentable. Therefore, it may be inconsistent with Article 27 (1) of the TRIPS Agreement, which prohibits discrimination in the technical field, as it establishes stricter criteria that allow patenting for the technical field of chemical substances and pharmaceuticals.

<RECENT DEVELOPMENTS>

In March 2018, 60 health organizations submitted a letter to Prime Minister Modi about two types of anti-TB drugs, seeking the establishment of a compulsory license (Article 92 of the Patent Law) based on a notification from the central government, but it has not been actually invoked. There is a request from the Japanese industry to improve transparency regarding the system and operation of compulsory licenses and even hereafter, it will be necessary to keep an eye on the consistency with international rules such as the Paris Convention and TRIPS Agreement

<PROBLEMS UNDER INTERNATIONAL RULES>

