

CHAPTER 9

INDIA

NATIONAL TREATMENT

LOCAL CONTENT REQUIREMENTS ON DOMESTICALLY MANUFACTURED ELECTRONIC PRODUCTS

Refer to pages 107-108 of the 2018 Report on Compliance by Major Trading Partners with Trade Agreements - WTO, FTA/EPA and IIA-.

QUANTITATIVE RESTRICTIONS

(1) 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 equipped with refrigerants.

<PROBLEMS UNDER INTERNATIONAL RULES>

This measure prohibits the importation of air conditioners equipped with refrigerants and is likely to be in violation of Article XI:1 of GATT (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 Article XX (b) of GATT (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 refrigerants that are 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.

(2) LICENSING REGIME ON PC AND TABLET IMPORTS

<OUTLINE OF THE MEASURES>

In August 2023, the Indian government announced that some PC-

related products falling under HS code 8471 category (including laptops, tablets, all-in-one PCs, servers, and ultra-small form factor devices) would be added to the "import restriction list" under the category of "Restricted" and would require an import license. Although the government subsequently announced a relaxation of the regulation regarding this measure in October of the same year, it came into effect in November of the same year. As a result of this measure, the relevant PC-related products have become subject to an import licensing regime based on the discretion of the authorities, as well as the Actual User Condition (which means a condition that only actual users of the relevant products can import them).

<PROBLEMS UNDER INTERNATIONAL RULES>

This measure imposes discretionary licensing restrictions on the import of certain PC-related products, and is likely to be in violation of Article XI:1 of GATT (General Elimination of Quantitative Restrictions) which prohibits import restrictions in principle. Although the Indian government claimed, in response to the questions from the United States at the meeting of the Committee on Import Licensing of the WTO, that it is an automatic license, the license is not automatically granted under the relevant laws and it has actually not confirmed at the moment that such situation exists. In addition, this measure may conflict with the Agreement on Import Licensing Procedures due to the fact that the application procedure has not undergone a public announcement process and lacks a notification to the WTO.

<RECENT DEVELOPMENTS>

In October 2023, Japan raised the problems under the international rules as discussed above with the Indian government at the Committee on Import Licensing in 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. For the definitions of tariff, tariff rate, binding coverage, and bound tariff rate, see Chapter 5.1.

<OUTLINE OF THE MEASURES>

The Customs Tariff Act specifies the basic customs duty 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, etc. 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 export.

From fiscal year 2003, the Indian government continued to

implement reductions of the basic customs duty rates, setting forth the objectives of (1) reducing the basic customs duty 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 customs duty rates on automobile parts, electrical parts and machinery parts to 7.5%. In addition, in March 2007, the government reduced the maximum basic customs duty rates on essentially all bound items excluding agricultural products from 12.5% to 10%, in principle.

However, since 2014, in order to promote domestic manufacturing, the Indian government, under its “Make In India” initiative, has introduced tariff increase measures through the Finance Bill (subsequently, the Finance Act) and the domestic notification, which have resulted in increases in the basic customs duty on various products.

The binding coverage on non-agricultural products in 2022 was 70.1% in India, and the simple average bound tariff rate for non-agricultural products was high at 36.0%. Unbound items include high-tariff items such as passenger cars (125%), motorcycles (100%) and clothing (20%), and the tariff rate on textile products is high considering the competitiveness of Indian products and the international standard. The simple average applied tariff rate for non-agricultural products in 2022 was 14.7%.

<CONCERNS>

As long as the high tariff itself does not exceed the bound tariff rate, there is no problem in terms of the WTO Agreements, but in light of the spirit of the WTO Agreements that promotes free trade and enhances economic welfare, it is desirable to reduce tariffs as much as possible.

A low binding coverage 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 the WTO Agreements, but since they make it possible for authorities to set arbitrary applied tariff rates and tariff increase measures have been actually taken since 2014, 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 Indian government has taken tariff increase measures for the following items in the immediate three years:

2021: chemicals; plastics; auto parts; electrical and electronic parts (compressors, printed-circuit boards, tempered glass for automobiles); etc.

2022: semiconductor components; medical X-ray equipment and specified parts; etc.

2023: automobiles; knocked-down vehicles; bicycles; toys; etc.

(2) GOODS AND SERVICES TAX

<OUTLINE OF THE MEASURES>

The Indian government introduced the Goods and Services Tax

(GST) in July 2017 to unify indirect taxes such as countervailing duties, the additional customs duties, value added tax, and the central sales tax that had been collected at the time of import at customs clearance, except for certain items. As a result, the basic customs duty, education tax, GST, and GST compensation cess (additional tax on high-quality goods and services) would be imposed on imported goods and services.

In addition, in February 2018, the education tax (3%) imposed on the basic customs duty was abolished, and instead, the social welfare surcharge was introduced.

<PROBLEMS UNDER INTERNATIONAL RULES>

This basic customs duty, so long as it is below the bound tariff rate for individual items, is consistent with Article II of GATT. On the other hand, GST, GST compensation cess, and the social welfare surcharge are considered to come under the category of “ordinary customs duty” or “other duties or charges” as provided for in Article II:1(b) of GATT. If these tariffs come under the former, then they exceed the concession commitment at least for products for which a commitment to remove tariffs was made 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, GST, GST compensation cess, and the social welfare surcharge are likely to be in violation of Article II of GATT regardless of the category they fall under.

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 public notice by the government. If GST were to be imposed, regarding these items, in addition to the violation of Article II of GATT for the social welfare surcharge, GST and GST compensation cess may be in violation of Articles II, and III of GATT, in terms of double taxation.

(3) INCREASE IN TARIFFS ON ICT PRODUCTS

<OUTLINE OF THE MEASURES>

For ICT (Information and Communication Technology) products such as ITA items, the Indian government has also implemented tariff increase measures through the Finance Bill (and subsequently the Finance Act) and the domestic notification.

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 were also increased. In April 2018, the

tariff rate on mobile phone printed circuit board assemblies (PCBA) was increased to 10%.

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 continued, 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 Agreements. However, it is raising the tariff rates on these products through the Finance Bill (and subsequently the Finance Act) and the domestic notification. These tariffs increase measures are highly likely to violate Article II of GATT, which provides that tariffs shall not be in excess of the 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 promptly. However, no improvement was seen.

Among these series of tariff increase measures, tariffs on some ICT products are highly likely to violate Article II of GATT, 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 Article II of GATT. However, the consultation with India did not solve the problem.

In February 2020, the Indian government further 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).

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 established in July of the same year (DS584).

In February 2021, the Indian government raised tariff rates on cell phone charger parts, refrigerator and air conditioner compressors, and solar conversion circuits, etc.

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 applied tariff rate schedule² (*2 in Figure I-10-1). In February 2022, the Indian government also raised tariff rates on semiconductor components.

On April 17, 2023, the panel largely accepted Japan's allegations and found that the measure taken by India is inconsistent with the WTO Agreements, and the Panel report was issued to recommend correction of the measure.

On May 17, 2023, the Indian government filed an appeal before the Appellate Body against the Panel report. However, the appeal before the Appellate Body remains pending without being heard as the Appellate Body is currently non-functioning (i.e., appeal into the void) (see the column of Part II, Chapter 17 “Issues Concerning the WTO Appellate Body”). Japan will continue to pursue the proceedings in order to ensure that this case is resolved properly in accordance with the WTO rules.

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% (*2)

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

For *1 and *2, the tariff rates for certain items were raised to 20% after the request for panel establishment.

¹ In December 2019, mobile phones (HS8517.1210 and 8517.1290) were reclassified to HS8517.1211, 8517.1219, and 8517.1290, following the revision of the tariff rate schedule of India.

² In the revision of the applied tariff rate schedule in January 2022, 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%).

(4) EPA, ENHANCED RULES OF ORIGIN PROCEDURES

<OUTLINE OF THE MEASURES>

In August 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 in September. 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 EPA, 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 EPA 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 EPA.

In addition, under the Japan-India EPA, 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 EPA 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 EPA 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 EPA 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 operation of CAROTAR 2020, the Central Board of Indirect Taxes and Customs issued a notice in August 2021 that customs officials should request verification only when there are justifiable reasons, by specifically indicating such reasons, and within the time limits specified in CAROTAR 2020.

SUBSIDIES

NATIONAL FOOD SECURITY ACT

<OUTLINE OF THE MEASURES>

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.

A total of 18.5 trillion rupees in food subsidies have been distributed over the past nine years. The Indian government has promised to continue providing free food grains to the approximately 800 million beneficiaries under the National Food Security Act for one year from January 1, 2023 to December 31, 2023.

In order to further enhance food distributions in India, One Nation One Ration Card (ONORC) scheme has been implemented with the objective of ensuring that beneficiaries, particularly migrant workers and marginalized communities, can easily access food across the country regardless of their locations.

<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 WTO 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 Agriculture Agreement, WTO 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 would be continued to the special meeting of the Agricultural Affairs Committee at the 10th WTO Ministerial Conference in December 2015. Nonetheless, there was still no progress at the 13th WTO Ministerial Conference in February 2024. 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 MEASURES>

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 tariff 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 Agreements.

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 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 Agreements. However, since progress for revoking the measure was not evident, Japan requested consultations with India based on the WTO Agreements 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 the Panel report which represented a ruling, upholding most of Japan’s claims, that this measure was inconsistent with the WTO Agreements 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 Article XIX:1(a) of GATT), (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.

STANDARDS AND CONFORMITY ASSESSMENT SYSTEMS

In recent years, the Indian government has introduced technical regulations in a wide range of fields, including steel products, electrical and electronic equipment, footwear, screws (bolts and nuts), copper ingots, aluminum and aluminum alloys. For those products subject to the technical regulations there is an accelerating trend where manufacturers are required to obtain Indian Industrial Standards ("IS") for products imported to or distributed in India and to ensure that the products conform to the standards after the enforcement date. However, there are several cases where the certification process is not commenced or is delayed for factories outside of India even though the interval between the issuance of the notification on the requirement of certification and its implementation is short. Given the absence of sufficient time frame for certification of the IS, concerns have been raised particularly about the potential impact on Japanese companies with factories in third countries.

(1) TECHNICAL REGULATIONS FOR STEEL PRODUCTS

<OUTLINE OF THE MEASURES>

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 IS for steel products imported to India and to ensure conformance with the standards for steel products. 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>

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. Moreover, when new types of steel were added at the update of the IS for steel products subject to mandatory standards, there was a notice period of only about three months.

Japan has requested the Indian government to improve this matter in discussions with the Ministry of Steel of India in November 2023 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 MEASURES>

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 were obligated to obtain network security approvals from inspection authorities in India when purchasing telecommunications equipment from foreign telecommunications equipment manufacturers.

In December 2020, the Indian government approved the National Security Directive on the Telecommunication Sector to prevent the use of insecure equipment within the network, and from June 2021, a policy of using trusted sources and trusted equipment came into effect. Under this directive, the authority designated by the Indian government formulated a plan to create a list of "trusted sources" and "trusted equipment", and measures for procurement and guidance on effective management supervision will be issued.

<PROBLEMS UNDER INTERNATIONAL RULES>

Although the contents of the notification issued in 2010 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 the national treatment obligation under Article III:4 of GATT and Article 2.1 of the TBT Agreement.

<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 MEASURES>

In September 2012, the Indian government (Ministry of Communication and Information Technology) announced legislation to obligate 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 would 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 79 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, were 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. Under the Mandatory Testing and Certification of Telecom Equipment (MTCTE) of the Indian government TEC

(Telecommunication Engineering Center), Phase-I products became mandatory in October 2019, Phase-II products became mandatory in October 2020, Phase-III products and Phase-IV products will become mandatory in January or April 2024, and Phase-V products will become mandatory in July 2024. This regulation is intended for telecom equipment, but the safety requirement covered by the “Regulation on electronic and information technology devices 2012 (mandatory registration duties)” and the wireless requirement covered by the WPC wireless authentication are already included in the items to be tested for the acquisition of certification. This is considered to be a double regulation.

(4) STRENGTHENING OF RESTRICTIONS ON RECYCLING AND DISPOSAL OF PLASTIC WASTES

<OUTLINE OF THE MEASURES AND CONCERNS>

The Plastic Waste Rules (“PWM”) 2016, introduced in March 2016 and stipulate recycling and disposal of plastic wastes, require that the thickness of sheet plastic packaging be at least 50 microns. The revision in October 2023 introduced additional requirement to display the name, registration number, and thickness information of the brand owner on plastic packaging, and the revision in March 2024 introduced additional requirement to bear the label of percentage of recycled materials, among other things, on plastic products and plastic packaging using recycled materials, and both of these revisions came into effect immediately.

<PROBLEMS UNDER INTERNATIONAL RULES>

These regulations may be in violation of Article 2.9 and Article 2.12 of the TBT Agreement in that no public consultation was conducted through TBT notification at the time of the revision, and that no sufficient preparatory period was given to business operators, respectively.

<RECENT DEVELOPMENTS>

Revisions made in October 2023 and March 2024 were adopted with immediate effect without TBT notification. Despite requests from Japan and local industries for a review of the requirements, they have not been accepted. It is desirable that realistic and effective regulations be considered before deciding on the details of the regulations, by seeking opinions in accordance with the TBT rules and giving due consideration to the opinions of stakeholders.

(5) STRENGTHENING OF REGULATIONS ON RECYCLING, DISPOSITION AND RESTRICTIONS ON CHEMICALS CONTAINED IN E-WASTES

<OUTLINE OF THE MEASURES AND CONCERNS>

The E-waste Management Rules (EWM) 2016 (enforced in October 2016), which is the revised version of the E-waste Management Rules (EWM) 2011 which were introduced in May 2011 to stipulate recycling, disposition and restrictions on chemicals contained in E-wastes, were further revised to E-waste Management Rules (EWM) 2022 in November 2022. As a result of this revision, the number of products subject to these rules has been significantly expanded. In addition to the products previously subject to these rules such as personal computers, mobile phones, and televisions, numerous new electrical and electronic products have now been included. Furthermore, requirements to display the

conformity declarations regarding the reduction of hazardous substances and to provide detailed information, which had been required for some time, have been significantly expanded to the newly added product categories. Even though this revision requires redesign of numerous newly added produce categories, the preparation period was only about five months from the announcement of the regulation in November 2022 to the enforcement date in April 2023. Moreover, there were several revisions in the regulation without prior notice, including partial revision in the regulation made in January 2023, which was shortly before the regulation was enforced, as well as revision made in July 2023, which was after the enforcement, to postpone the enforcement date retroactively for two years. These revisions were implemented without soliciting opinions from stakeholders, which resulted in significant confusion among business operators and caused excessive burden on them.

<PROBLEMS UNDER INTERNATIONAL RULES>

Since no opinion was solicited through TBT notification upon the revisions in 2022, January 2023 and July 2023, these regulations may be in violation of Article 2.9 and Article 5.6 of the TBT Agreement, which stipulate that a notification shall be made to other Members through the WTO Secretariat on proposal of the revision to standards/certification system and allow other Members to make comments. In addition, repeated and sudden revisions in the regulation and allowing short preparatory period before enforcement may be in violation of Article 2.12 and Article 5.9 of the TBT Agreement which stipulate that Members shall not enforce a law without allowing economic operators sufficient time.

<RECENT DEVELOPMENTS>

As discussed above, there were several revisions in the regulation, including the revision of a part of the regulation made in January 2023, which was shortly before the enforcement, and the revision to postpone the enforcement date for two years made in July 2023, which was after the enforcement. These revisions are presumed to have been made in response to comments submitted by related industries after the revision of EWM2022. However, several revisions made after the revision of EWM2022 could have been unnecessary if realistic and effective regulations had been considered after soliciting opinions in accordance with the TBT rules and fully taking into account the opinions of stakeholders at the time of deciding the detailed regulations upon revisions of the EWM2022.

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) (currently, the Department for Promotion of Industry and Internal Trade (DPIIT)) of the Ministry of Commerce and Industry published a new Consolidated Foreign Direct

Investment Policy that consolidates policies concerning inward direct investment by foreign enterprises (the latest revision made on October 15, 2020). Under this Consolidated Foreign Direct Investment 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. (prior government approval route) were provided in a negative list. In addition, 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.

(1) FINANCIAL SERVICES SECTORS

(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 Foreign Direct Investment 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. Furthermore, in 2021, insurance laws were amended and the ceiling on permissible foreign investment in insurance companies was raised from 49% to 74%.

(2) DISTRIBUTION SERVICES SECTORS

In Indian foreign investment regulations, retail trading is broadly divided into single-brand retail trading, multi-brand retail trading, and duty-free shops. Among these, 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).

(3) BROADCASTING SECTORS

In the broadcasting sector, including cable networks and mobile TV, the foreign direct investment of up to 100% is permitted under the automatic route (which automatically allows investments

without prior government approvals). On the other hand, the direct investment in FM radio and “news and current affairs” TV channels must be up to 49% and government approvals and compliance with prescribed guidelines are required. Moreover, the streaming of news and current affairs through digital media requires government approvals, with the foreign direct investment cap of 26%. However, this 26% cap under the foreign direct investment policy is not applicable if OTT (services of broadcasting programs and content over the Internet) platform serves as host for digital broadcast of a TV station.

<CONCERNS>

Although the WTO Agreements have 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) DIGITAL PERSONAL DATA PROTECTION ACT

<OUTLINE OF THE MEASURES>

In India, the “Digital Personal Data Protection Act”, which was released for public consultation in November 2022, was enacted in August 2023. This act stipulates that the Indian government may issue a notification on the scope of the “Significant Data Fiduciary” and that the Significant Data Fiduciary is mandated to appoint a Data Protection Officer and undertake Data Protection Impact Assessments. Moreover, this act also stipulates that the Indian government may restrict the transfer of personal data to countries or territories outside India by issuing a notification. In certain cases, this act also applies to the processing of personal data outside India.

<PROBLEMS UNDER INTERNATIONAL RULES>

As stated above, the Indian government can restrict the Data Fiduciary’s transfer of personal data to certain countries and territories by issuing a notification. However, the notification of the Indian government to restrict the countries/territories to which personal data is transferred has never been issued as at the timing this Report is written and the details of restrictions on transfer of the personal data outside India are not clear. There is a concern that foreign business operators may be treated unjustly depending on the operation of this act. If this act is operated in a manner that affects the provision of services and treats services and service providers of WTO member countries less favorably than those of India, it may violate the national treatment obligation in Article 17 of the GATS.

In addition, depending on how this act is operated, there is a concern that foreign business operators of specified countries may be treated more or less favorably than other foreign business operators, which may constitute a violation of the obligation of most-favored-nation treatment in Article 2 of the GATS.

<RECENT DEVELOPMENTS>

We will continue to work with the industry to closely monitor future operation 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

<OUTLINE OF THE MEASURES>

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 WTO 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>

The average time required for a civil, criminal, or administrative remedy for an infringement to be given remains unpublished. In addition, with regard to remedies by the customs authorities, it is possible to obtain protection by methods such as confiscations and import suspensions by making an application to the customs authorities. It is required by law that the decision on such application shall be made within 30 business days from the receipt of the application. However, some investigations indicate that it takes about 6 to 7 months on average for a remedy to be actually provided.

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 MEASURES>

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-.

<PROBLEMS UNDER INTERNATIONAL RULES>

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. In June 2022, the Kerala High Court directed the Ministry of Commerce and Industry and the Department of Pharmaceuticals to submit their opinions on the establishment of the compulsory licensing of breast cancer drugs.

In addition, in October 2020, India and South Africa submitted a proposal regarding COVID-19 to the TRIPS Council to decide at the general council meeting to waive certain obligations under the TRIPS Agreement (obligation to protect copyrights, designs, patents and undisclosed information, and obligations related to enforcement thereof) for the time being for the purposes of the prevention, containment, and treatment of COVID-19 with a view to providing timely access to COVID-19 related medical supplies (including therapeutic, vaccines, diagnostic kits, masks and ventilators) (the TRIPS Waiver Proposal; see 1. (4) (ix) of Chapter 13 of Part II for details).

With respect to the discussions in India in association with the TRIPS Waiver Proposal, in July 2021, the Indian Parliamentary Committee on Commerce recommended the temporary waiver of the patent rights on the production of medicines and vaccines for the treatment of COVID-19 and the grant of compulsory licenses related to the patents. In April 2022, the Committee recommended consideration of the possibility of grant compulsory licenses if COVID-19 causes a serious threat to lives. However, no

compulsory license has been granted at present.

As there are requests from industries in Japan to enhance the transparency in the system and operation of compulsory licenses, it is necessary to keep an eye on the consistency with international rules such as the Paris Convention and the TRIPS Agreement.

