Selected Intellectual Property Issues under the TPP and Japan-EU EPA

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I. Introduction

As the former Director of the Intellectual Property Affairs Division of the Ministry of Foreign Affairs (MOFA) and the former negotiator of the Japanese Government's Trans-Pacific Partnership (TPP) Headquarters at the Cabinet Secretariat Office, I was involved in discussions and negotiations in multilateral/regional fora such as the World Trade Organization (WTO)/Council for the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), World Intellectual Property Organization (WIPO) and Asia-Pacific Economic Cooperation (APEC). I also led the Japanese delegation in the field of intellectual property (IP) in the negotiations for several mega Free Trade Agreements (FTAs), including the TPP/the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), the Japan-EU Economic Partnership Agreement (EPA) and the Regional Comprehensive Economic Partnership (RCEP). In addition, I conducted intensive discussions with colleagues from other governments, such as the U.S. Trade Representative (USTR), on IP and related issues found in third countries with the aim of abolishing/amending regulations inconsistent with international obligations or harmful to IP rights holders.

Based on my experience from the foregoing, I would like to discuss three IP issues in this article, namely: (a) data protection of undisclosed test or other data on biologics under the TPP, (b) the *ex officio* authority for criminal enforcement related to copyright or related rights under the TPP, and (c) the protection of geographical indications pursuant to international agreements under the TPP and Japan-EU EPA.[1]

II. Data Protection of Undisclosed Test or Other Data on Biologics

Data protection of undisclosed test or other data concerning safety and efficacy for a new pharmaceutical product, which data is submitted to the competent authority as a requirement for obtaining marketing approval, was one of the most difficult issues in the TPP negotiations. In particular, data protection for new biologics was so controversial because it was new to certain TPP participants, which did not specifically provide for such data protection for biologics, and the term was expected to be longer than that for low molecular drugs due to the nature of biologics, thereby

1. Texts of the TPP are available at the website of the Department of Foreign Affairs & Trade of New Zealand (https://www.mfat.govt.nz/en/about-us/who-we-are/treaties/trans-pacific-partnership-agreement-tpp/text-of-the-trans-pacific-partnership), texts of the CPTPP are available at the website of the same Department (https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text-and-resources/), and texts of the Japan-EU EPA are available at the MOFA's website (https://www.mofa.go.jp/ecm/ie/page4e_000875.html).

making this issue highly politically sensitive for them.

Article 18.50.1 of the TPP requires the TPP Parties (as defined in the TPP) to provide at least five years of data protection for new pharmaceutical products (i.e., new low molecular drugs).[2] Further, Article 18.51.1 sets forth the period of data protection for new biologics as follows: (a) eight years from the date of the first marketing approval of the product in the Party, or (b) (i) at least five years, (ii) through other measures, and (iii) recognizing that market circumstances also contribute to effective market protection, to deliver a comparable outcome in the market.[3]

The period of protection under item (b) above seems quite ambiguous such that there is some room for interpretation, in particular, on the meaning of "other measures" and "a comparable outcome in the market." What do "other measures" mean? What do the "market circumstances" indicate? Does "a comparable outcome in the market" mean eight years or less? Some TPP participants that have adopted a national health care insurance system might interpret "other measures" to include the procedure of a national health insurance price listing/reimbursement, which may take one to two years for a relevant pharmaceutical company to prepare and file. Some TPP participants may consider that the patent term extension (Article 18.48) or patent linkage system (Article 18.53) could work for that purpose. There is no consensus as to whether the comparable outcome means eight years. As this provision was a result of a political agreement, this ambiguity was unavoidable.

In Japan, clinical data for a pharmaceutical product with a new active substance, whether biologic or non-biologic, receives at least eight years of data protection through the "re-examination period" in its pharmaceutical regulatory system.[4] The re-examination period is the period between the date on which an applicant obtains marketing approval and the end of the eighth year, after which the Japanese government will then re-examine the efficacy and safety of the said product. The re-examination is based on additional data collected by the originator pharmaceutical company from individual patients during the said period. During the re-examination period, generic or biosimilar manufacturers cannot rely on the clinical data submitted by the said originator company to the competent authority for obtaining the first marketing approval. If a product is designated as an orphan drug, then the period should be extended to 10 years.[5] Accordingly, Japan is in compliance with Articles 18.50.1 and 18.51.1 of the TPP. Please note, however, that Articles 18.50 and 18.51 have been suspended in the CPTPP.[6]

III. *Ex Officio* Authority for Criminal Enforcement of Copyright or Related Rights

With respect to criminal enforcement against willful copyright or related rights piracy on a commercial scale, each TPP Party must provide under Article 18.77.6 (g) of the TPP that its competent authorities may act upon their own initiative to commence legal action without need for a formal complaint by a third person or right holder. However, footnote 135 of the said provision states that *"[W]ith respect to copyright and related rights piracy*

2. A new pharmaceutical product for the purpose of Article 18.50.1 of the TPP means a pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party (TPP, art. 18.52).
3. Article 18.51.2 of the TPP provides that each Party shall apply Article 18.51 (Biologics) to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.
4. The Pharmaceuticals and Medical Device Act, art. 14, and Notification No. 16 issued by the Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (August 31, 2020).
5. *Id.*
6. Article 14.37.1 of the Japan-EU EPA stipulates that each Party shall provide for no less than six years of data protection for undisclosed test or other data submitted to its competent authority by the first applicant for obtaining marketing approval for pharmaceutical products which utilize new pharmaceutical ingredients.

[provided for under paragraph 1], a Party may limit application of this subparagraph to the cases in which there is an impact on the right holder's ability to exploit the work, performance or phonogram in the market."

The language of the footnote seems ambiguous, but the intent thereof is that if a certain copyright or related rights piracy work does not compete with the genuine work in the market, then the TPP Parties may not need to implement the above obligation. We interpret this footnote as follows: if there is a certain causation or link, such as when a person who purchases a pirated work, such as a counterfeit copy of a DVD or of a book as a whole, will not purchase the genuine work because the former may already be used as a substitute for the latter, then both works are actually competing in the market, and thus, there is an impact on the right holder's ability to exploit the work. On the other hand, if a person who purchases a derivative work of, for instance, a *manga* created by an amateur or a fan will also purchase the original *manga* work that is for sale or when it is published, then there may not be an impact on the right holder's ability to exploit the work.

The Japanese Copyright Act sets forth penalties under Articles 119 through 122bis thereof, which require that a formal complaint be filed by a right holder in accordance with Article 123.1 thereof (with some exceptions such as in cases involving the circumvention of technological protection measures and infringement of moral rights). To comply with the obligations set forth in the abovementioned Article 18.77.6 (g) of the TPP, and in light of the flexibilities given by the above footnote, Japan amended the Copyright Act to add a new Article 123.2, which became effective on December 30, 2018 when the CPTPP entered into force among its six Parties.

The new Article 123.2 of the Japanese Copyright Act stipulates that the above Article 123.1 does not apply to the offense referred to in Article 119.1 (penalties for a person who infringes a copyright, print right or neighboring right), which offense a person commits by committing one of the acts set forth in the following items, either for the purpose of gaining a financial benefit in consideration of such act, or for the purpose of harming the profit that the owner of the copyright, etc., is expected to gain by making available or presenting a fee-based work, etc.:[7]

(a) transferring copies of an unaltered original fee-based work, etc., to the public, or transmitting an unaltered original fee-based work, etc., to the public, or

(b) reproducing a fee-based work, etc., for the purpose of transferring copies of the unaltered original fee-based work, etc., to the public, or for the purpose of transmitting the unaltered original fee-based work, etc., to the public,

but only if the profit that the owner of the copyright, etc., is expected to gain by making available or presenting its fee-based work, etc., would be unreasonably harmed (in light of the nature or purpose of the fee-based work, etc., the number of copies that would be reproduced, the circumstances of its reproduction, or any other conditions).

The Agency for Cultural Affairs has illustrated the following typical cases where the *ex officio* authority for criminal enforcement is allowed to be exercised under the new Article 123.2:

(a) Infringing activities subject to *ex officio* authority

-selling a counterfeit copy of a *manga* or novel on sale, or

-distribution of pirated motion picture works on the Web.

7. Article 123.3 of the Copyright Act defines the term "a fee-based work, etc." as a work or performance, etc. (limited to one that is the subject of a copyright, print right or neighboring right) made available or presented to the public for value (other than through an action that infringes a copyright, print right or neighboring right (for a work made available or presented abroad, this means an action that would constitute copyright infringement if it took place in Japan)).

(b) Infringing activities not subject to *ex officio* authority
-selling fan fiction *manga* and the like at a comic market, or
-contributing a parody of a *manga* to a blog on the Internet.

IV. Protection of Geographical Indications in the TPP and Japan-EU EPA

The protection of geographical indications (GIs) was one of the serious issues during the TPP negotiations where TPP participants were so divided. Certain "new-world" participants provide GI protection through a trademark system that applies the principle of "first-to-file, first-in-right." They are critical of the EU's aggressive move to expand its GI protection to agricultural products and foodstuffs at the level of Article 23 of the TRIPS Agreement,[8] through the *sui generis* system where, in particular, GIs can co-exist with prior trademarks. On the other hand, the EU has strongly requested its trading partners through the FTA/EPA negotiations to protect the GIs of the EU, some of which are generic terms for the above TPP participants, such as "Feta," "Asiago," "Fontina," and "Gorgonzola." "Parmigiano Reggiano" is an Italian GI protected in the EU, while "parmesan" is treated as a generic term in the U.S. Moreover, "Chablis" and "Champagne" are French GIs protected in the EU though such terms can still be used by certain persons or their successors in interest in the U.S. under the U.S.-EU Wine Agreement (grandfathering). Now, both are fighting in the field of FTA/EPA negotiations on this matter with the aim of establishing a *de facto* standard.

As a background, the U.S. and Australia filed a complaint against the EU before the WTO panel claiming that the EU's GI protection system was not consistent with the TRIPS' obligations, namely, on national treatment (Article 3) and the exclusive right of trademarks (Article 16) in connection with co-existing subsequent GIs. The WTO panel found that the EU's system was not in compliance with Articles 3 and 16, however, Article 17 (exception to the exclusive right of trademarks) justified the inconsistency of the latter (co-existence of the subsequent GIs).[9] Since then, the U.S. has put more stress on the importance of, in particular, "due process" or "transparency" for GI protection, including opposition and cancellation procedures, and the "first-to-file, first-in-right" principle, while the EU has aggressively moved forward to mutually protect GIs pursuant to FTAs/EPAs. Among others, one serious issue is the protection of GIs pursuant to international agreements where the real interested persons and countries are not normally involved before both Parties decide to protect the GIs.

With respect to GI protection pursuant to an international agreement between TPP Parties, or between a TPP Party and a non-Party, Article 18.36 of the TPP obliges that the TPP Party(ies) provide interested persons with sufficient opposition opportunities,[10] including:

(a) making information available to allow the general public to obtain guidance on GI protection and allow interested persons to ascertain the status of requests for protection;

(b) making available to the public, through the Internet, details regarding the terms to be protected (including specifying whether the protection is being

8. Article 22 of the TRIPS Agreement obliges Members to provide the legal means for interested parties to prevent: (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than its true place of origin in a manner that misleads the public as to the geographical origin of the good, and (b) any use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention (1967). On the other hand, Article 23 of the TRIPS Agreement provides for additional or absolute protection of GIs on wines and spirits such that the use of a GI identifying a wine or spirit not originating from the place indicated by the GI in question shall be prevented, even where the true origin of the good is indicated or the GI is used in a translation or accompanied with expressions such as "kind," "type," "style," "imitation" or the like. The said Article also provides that the registration of a trademark for wines or sprits which contains or consists of GIs identifying wines or sprits shall be refused or invalidated, with respect to such wines or spirits not having this origin.

9. WT/DS174/R (March 15, 2005).

considered for any translations or transliterations of those terms, and with respect to multi-component terms, specifying the components, if any, for which protection is being considered, or the components that are disclaimed);
(c) providing a reasonable period of time for interested persons to oppose the protection (that period shall provide a meaningful opportunity for interested persons to participate in an opposition process); and
(d) informing the other TPP Parties of the opportunity to oppose before the commencement of such opposition period.

When Japan negotiated with the EU on the protection of GIs pursuant to the Japan-EU EPA, though the TPP/CPTPP was not applicable at the time, Japan nevertheless followed the above procedure, and received opinions and oppositions from interested persons and countries. After all things were considered, the authorities (i.e., Ministry of Agriculture, Forestry and Fisheries for agricultural, forestry and fishery products and foodstuffs ("agricultural products"), and the National Tax Agency for alcohol beverages) determined the protection of the GIs of the EU under the Japan-EU EPA.[11] Japan agreed to protect 210 GI products of the EU (139 alcohol beverages, and 71 agricultural products), and the EU agreed to protect 56 GI products of Japan (eight alcohol beverages, and 48 agricultural products) under the Japan-EU EPA.[12]

There are certain compromises on the protection of the EU's GIs, taking into consideration the opinions and oppositions submitted by interested persons and countries.[13]

Since authorities will publish the GIs to be protected on the Internet in advance for opposition when they are considering the protection thereof under their domestic systems or pursuant to an international agreement, it is advisable to check such information if you or your clients have a specific interest in a certain term or its translation and transliteration.

10. The applicable opposition grounds set forth under Article 18.32.1 of the TPP include, at least, the following: (a) the GI is likely to cause confusion with a trademark that is the subject of a pre-existing good faith pending application or registration in the territory of the Party, (b) the GI is likely to cause confusion with a pre-existing trademark, the rights to which have been acquired in accordance with the Party's law, and (c) the GI is a term customary in common language as the common name for the relevant good in the territory of the Party.
11. The following are the relevant Japanese laws and regulations on the protection of GIs: (a) The Act on Securing of Liquor Tax and on Liquor Business Associations (Law No. 7 of 1953) and the Notice on Establishing Indication Standards Concerning Geographical Indications for Liquor (National Tax Agency Notice No. 19 of 2015, last amended on March 31, 2017) issued under the Act, and (b) The Act on Protection of the Names of Specific Agricultural, Forestry and Fishery Products and Foodstuffs (Law No. 84 of 2014, last amended on February 1, 2019).
12. The results of the mutual protection of GIs under the Japan-EU EPA are available at https://www.nta.go.jp/english/taxes/liquor_administration/geographical/02.htm (alcohol beverages) and https://www.maff.go.jp/e/policies/intel/gi_act/designation2.html (agricultural products). In February 2021, 28 GIs of Japan and the EU were added to the GI lists of the Japan-EU EPA. These GIs were also published on the Internet for opposition before they were added to the GI lists of the said treaty.
13. The following are some examples: (a) "Parmigiano Reggiano" is protected but the GI provisions of the treaty shall in no way prejudice the right of any person to use or register in Japan a trademark containing or consisting of the term "parmesan" in respect of hard cheeses, (b) "Camembert de Normandie" is protected while "camembert" can be used, (c) "Emmental de Savoie" is protected while "emmental" can be used, (d) "Mozzarella di Bufala Campana" is protected while "mozzarella" and/or "mozzarella di bufala" can be used, (e) "Grana Padano" is protected while "Grana" can be used, and (f) "Pecorino Romano" and "Pecorino Toscano" are protected while "Pecorino" and/or "Romano" can be used.

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