Hope or Nope – Impacts of TPP on Taiwan IP Industry

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Background of Trans-Pacific Partnership (TPP) Agreement

The Trans-Pacific Partnership (TPP) Agreement is an economic agreement of partnership around twelve countries in the pacific ring, including Brunei, Chile, New Zealand, Singapore, the United States, Australia, Peru, Vietnam, Malaysia, Mexico, Canada, and Japan. The first round of negotiations has been completed on October 4, 2015. Currently, Taiwan and Korea are also seeking to take part in the second round of negotiations.

The TPP Agreement propagates high qualities and high standards, and covers almost every business, such as goods market, agriculture, textiles and clothing, cross-border service trades, financial services, telecommunications, government procurement, transparency of medicine and medical equipment, rules of origin, customs administration, trade facilitation, food safety and inspection, sanitary and phytosanitary measures (SPS), technical barrier to trade (TBT), investment, labor, intellectual properties, etc. The subject matters involved are far beyond those covered in the World Trade Organization (WTO).

Since TPP members accounts for 36% of the GDP in the world, and the trade volume thereof also exceeds 30% of the global trade volume. Once joining the TPP, a country will be able to enjoy mutual customs duty exemption and open service sector and investment market, along with investment protection, in multiple countries all at once. This is why Taiwan has also been trying to participate in TPP negotiations.

In view of the significance of the TPP Agreement, the following paragraphs of this article will be devoted to discussions concerning patent-related provisions in the TPP Agreement, which received most attention of the constructing states and were hotly debated in the first ground of negotiations.

Patent-related Clauses in TPP Agreement

The coverage of the TPP Agreement is very broad. The intellectual property (IP) rights are also included as one of the subject matters in the TPP Agreement and have become one of the main focuses in the negotiations.

Under the strategy of over-protection to its own pharmaceutical industries, the United States proposed several IP-related measures in the TPP Agreement that are very different from the IP right protection standard expected by other member states, including **issues in connection with patent applications such as extending patent/data exclusivity protection, providing applicants with multiple opportunities of amendments, and patent term compensation**. For a better understanding about the changes and impacts on patent applications (particularly **pharmaceutical** patent applications) brought by the TPP Agreement, the crucial provisions are discussed in the following based on the text of TPP after the first round of negotiations.

I. Patent Linkage System

The TPP Agreement requests the member states to implement the "patent linkage system". Such system is set up for pharmaceutical patents and aims at providing a linkage mechanism between patent rights and drug market entry licenses to clarify patent disputes before generic drugs enter the market.

To be more specific, the member states must link the examination and registration procedures for market entry applications of drugs with the statuses of relevant patents. When a pharmaceutical manufacturer files a drug market entry application with the authorities, it must also disclose patent information as requested in the relevant provisions in connection with the drug and registers the same in the patent linkage system. Thus, during the term of its patent, the patentee will be informed when a generic drug maker declares that the patent has expired or will soon expire, and be aware of the risk of infringement immediately. The system also ensures the patentee enough time to take legal or administrative actions as well as remedy measures such as provisional injunction, thereby assist the patentee in settling patent validity or infringement disputes in proper time.

II. Extending Patent/Data Exclusivity Protection

In the TPP Agreement, the member states also agree to extend the exclusive right of test-related data submitted for market entry applications of agricultural chemical products and pharmaceutical products. Details of the terms are as follows:

"Regarding to the test-related data submitted for market entry applications of agricultural chemical products or pharmaceutical products, the TPP mandates that data exclusivity protection be furnished. During the protection, a third party shall not be granted to cite the data to apply for a same or similar agricultural chemical product or pharmaceutical product without the consent of the original data provider. The protection periods for respective products are as follows:

1. For new chemical agricultural products, at least 10 years of data exclusivity protection shall be furnished.

2. For new pharmaceutical products with new ingredients, at least five years of date exclusivity protection shall be furnished.

3. For new clinical data for new indications, formulations, or methods of administration of a known pharmaceutical product, at least three years of data exclusivity protection shall be furnished.

4. For new biologics, at least eight years of effective market protection or at least five years of protection alongside other effective market protection mechanisms shall be furnished."

The protection of "data exclusivity" is implemented in consideration of the complicated and time/cost-consuming clinical experimentss required for drug market entry applications. If the experiment records and data for which the pharmaceutical companies devote significant amount of time and money are laid open at will, the time required for generic drug makers to manufacture generic drugs will be shorten, and the advantageous position and competitiveness of the advanced countries or countries with advanced pharmaceutical industries will be weakened. Thus, the pharmaceutical companies are granted a specific period of protection during which the data shall neither be laid open at will nor be used by other parties.

The period of "data exclusivity" is different from the period of patent right protection. For example, if a "new pharmaceutical product with new ingredients" is granted a 20-year patent right, the protection period of data exclusivity does not start counting until the patent right expires. Thus, the period of non-disclosure of relevant data concerning the "new pharmaceutical product with new ingredients" becomes 25 (20+5) years.

Since relevant data cannot be disclosed at will during the protection period of data exclusivity and others cannot use these data, the generic drug makers will have to devote money and efforts into clinical experiments if they consider 25 years too long to wait and wish to register the generic drugs during the data exclusivity period. However, this will **significantly increase the cost of generic drugs**, which is disadvantageous to countries having a higher demand to generic drugs but nevertheless maintains the advantage of the countries with advanced pharmaceutical industries. Alternatively if the generic drug makers are unwilling to make efforts in drug development, they will have to wait 25 years to start manufacturing generic drugs. Thus, for countries having a higher demand to generic drugs, **the availability of generic drugs will be delayed**. Accordingly, in view of the provisions on data exclusivity in the TPP Agreement, relevant industries should develop responding strategies soonest possible.

III. Inclusion of Surgical and Therapeutic Methods for Human Beings into Patentable Subject Matters

The TPP Agreement stipulates "methods or manufacturing processes meeting conditions such as novelty, non-obviousness and industrial utility are **eligible** for patent protection, but **therapeutic methods for human beings** are exceptions to which patent protection does not apply".

Regarding the provisions above, the United States proposed in the first round of negotiations to include therapeutic methods for human beings into patentable subject matters. However, after lengthy discussions and considering that practitioners may forbid others from using some therapeutic methods or request licensing fees, which will hold back the pharmaceutical industries from providing therapeutic services, the agreement specifically excludes therapeutic and diagnosis methods for human beings from the patentable subject matters.

IV. Providing Applicants with Multiple Opportunities of Amendments

The TPP Agreement after the first round of negotiations stipulates "regarding the procedures, the constructing states shall be dedicated to lay open the technical contents of patent applications within **18 months after the filing dates of the patent applications** for public retrieval. In addition, **an applicant shall be granted opportunities to make amendments and corrections** to obtain or maintain a patent right after the amendments/corrections".

The provisions above suggest that the version of TPP Agreement proposed by the United States advocates more applicant-friendly measures, including loosening up patent examination procedures, adopting patent examination procedures favoring the applicants, and providing the applicants with the right of having multiple opportunities to amend the claim scopes. Such measures will certainly increase the chance of grant of pharmaceutical patents and give additional protection to advanced countries or countries with advanced pharmaceutical industries.

V. Terms of Pharmaceutical Patents Extended Covertly

The TPP Agreement stipulates "the examination is unreasonably delayed if an applicant filed an invention application and is not granted a patent right since the later of **five years from the filing date or three years after requesting substantive examination**, and **the term of the patent right shall be compensated**. However, the period of time that is not attributable to the authority may be excluded from the patent term compensation".

The provisions on patent term compensation are stipulated in view of the longer the examination time for grant of a pharmaceutical patent than other patents, which makes the profitable time of the pharmaceutical patent available to the patentee shorter. Therefore, the provisions are set forth to compensate the patentee for the patent term. However, such provisions also covertly extend the patent terms of pharmaceutical patents.

Since there is a significant gap between the prices of brand name drugs and generic drugs, the time for generic drugs to enter the market will be significantly affected by the extended terms of pharmaceutical patents, and the time of using brand

name drugs will consequently be lengthened. Thus, such extension will have drastic impacts on the costs for drugs and health insurance plans in the member states, making the extension a delicate issue to handle.

Impacts of TPP Agreement

Regarding the patent-related provisions in the TPP Agreement, even though many changes have been made to the original version proposed by the United States in the first round of negations, a framework of strict protection, which **particularly favors patent applicants and pharmaceutical industries**, is still adopted for intellectual properties. Therefore, the TPP Agreement will certainly bring influence on the Asian markets, particularly to the pharmaceutical industries. Thus, to face the upcoming challenges and be adaptable to the trends going forward, relevant industries should come up with responding strategies and make suitable adjustments as soon as possible.

[Reference Documents]

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