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Effects of the TPP on Vietnam's Pharmaceutical Industry

On February 4, 2016, Vietnam and 11 other countries signed the Trans-Pacific Partnership (TPP). The TPP includes Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, the United States, Vietnam, and Singapore—countries which represent 36 percent of global GDP and more than 25 percent of world trade. Though the prospects of a quick and smooth ratification of the treaty have dimmed considerably, thanks to election-year politicization in the United States, if and when the TPP is finally ratified by its various participants, it will have a major impact on business in Vietnam—including the pharmaceutical industry.

The TPP will affect the pharmaceutical industry largely through its investment protections and intellectual property regime. Like other free-trade agreements, the TPP promotes foreign investment by requiring its member states to provide protections over investments originating from other TPP member countries. Importantly, intellectual property rights are considered a "covered investment" under the TPP. In other words, Vietnam is obligated to protect a pharmaceutical company's IP rights in accordance with the TPP. In addition to these investment protections, the TPP also contains an entire subchapter dedicated to the pharmaceutical industry, including the treatment of patents.

Investment Protections

While most of the investment protection under the TPP would apply to all companies equally, pharmaceutical companies should pay particular attention to the following.

National Treatment and Most-Favored Nation Treatment. The TPP requires Vietnam to treat investors from other TPP member states (TPP Investors) the same way it would treat domestic investors in similar circumstances. In other words, Vietnam is required to give "national treatment" to TPP Investors. In addition, Vietnam must treat such covered investments the same way it would treat locally owned projects. The TPP also requires Vietnam not to discriminate against any foreign investor. For example, if an American pharmaceutical company owns a patent in Vietnam, that patent must be treated the same way as if a Vietnamese party held the patent.

Expropriation. The TPP prohibits member states from expropriating investments. In other words, Vietnam would generally be prohibited from expropriating or nationalizing a pharmaceutical company's IP rights. However, expropriation is allowed if it is for a "public purpose," such as compulsory patent licensing in a public health emergency. In such case, Vietnam must promptly provide compensation to the investor that is equivalent to market value. The TPP further mandates that any expropriation must be done without discrimination.

Performance Requirements. The TPP prohibits Vietnam from requiring an investment project to use or implement certain "preferred" commitments or content. For example, Vietnam cannot enact legislation requiring a foreign pharmaceutical company to use only locally sourced materials or technology in its toll manufacturing, or to export a specific percentage of goods. Other prohibitions include forcing an investor to adopt a specific royalty rate under a license contract or a specific term of a license contract.

Important exceptions to this provision exist. The license restrictions do not apply to license agreements between a foreign investor and the Vietnamese government. In addition, the government is allowed to mandate performance requirements with regard to government procurement, certain investment privileges and benefits, and preferential tariffs or quotas. Other general exceptions also apply, such as legislation to protect human and environmental health.

Patents

Under Article 5.3 of Vietnam's Law on Intellectual Property, if a regulation in an international convention of which Vietnam is a member differs from the respective regulation of the IP law, then the regulation in the convention would apply. Based on this, the Law on Intellectual Property will likely be adjusted to be consistent with the TPP. The following articles in the current regulations are not consistent with the respective regulations of the TPP:

Patentable Subject Matter. Under the TPP, patents are available for "use inventions," that is, those claiming at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A member state may limit those new processes to those that do not claim the use of the product. Currently, the Vietnam Patent Office rejects use inventions in general, though it lacks convincing legal grounds. In light of the TPP, Vietnam's Patent Office should change its treatment of use inventions. However, it is unclear—even with the change—whether new indications or new methods, such as new dosing, will be patentable.

Patent Term Adjustment for Patent Office Delays. According to the TPP, a patent term can be adjusted to compensate for unreasonable delays in a member state's issuance of patents. The transition period is five years, which can be extended for up to one additional year, meaning that it could become effective in 2023 or 2024. This issue is not addressed in Vietnam's current regulations.

Data Protection for Drugs. The provisions of the TPP on data protection for drugs differ from current Vietnamese law. Under the current regulations, within five years from the date of marketing authorization of the data-protected drug, no marketing authorization can be granted for other dossiers referring to the protected trial data. The TPP also provides a period of at least five years from the date of marketing authorization during which a third party cannot market a product on the basis of: (1) protected data; or (2) the marketing approval granted. Therefore, there could be some adjustments in the applicable laws of Vietnam related to data protection for drugs to make the data protection more reliable in practice. The transition period is ten years, which can be extended for up to two additional years, meaning that it could become effective in 2028 or 2030.

Outlook

The TPP is expected to create new business opportunities in Vietnam for pharmaceutical companies. The investment protections will reduce risk and increase confidence, which will add to investment inflows. Pharmaceutical companies would also have increased predictability and protections with respect to their IP rights. Both Vietnam and pharmaceutical firms will benefit.

This article was written by John Frangos, consultant, and Chuyen Hong Huu Le, attorney-at-law, at Tilleke & Gibbins. This summary is designed to provide general information only and is not offered as specific advice on any particular matter.

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