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Compulsory Licensing of Patent Rights for Inventions Relating to Covid-19 Vaccines under the IP Law of Vietnam

In the context of the Covid-19 pandemic's renewed spread, several proposals for the temporary waiver of patent rights for inventions relating to Covid-19 vaccines have been made by a number of countries, including South Africa and India. This is so that poor and developing countries may more conveniently access the vaccine, and more effectively respond to the health challenges. Such proposal has been supported by the Directors of the WTO and the WHO, as well as Mr. Joe Biden, the President of the United States, but most countries in the European Union still strongly oppose such a waver based on the view that the temporary waiver of patent rights may reduce vaccine manufacturers' profits and therefore, discourages technology innovation and creation.

The proposal for temporary waiver of patent rights is based on the Doha Declaration on TRIPS Agreement and Public Health which reaffirmed flexibility of the TRIPS member states in circumventing patent rights for better access to essential medicines by developing countries with insufficient, or no manufacturing capacity in the pharmaceutical sector. In the TRIPS Agreement (the Agreement on Trade-Related Aspects of Intellectual Property Rights), provisions relating to the compulsory licensing of patent rights are provided in Article 30 *(Exceptions to Rights Conferred)* and 31 *(Other Use Without Authorization of the Right Holder)* thereof. The 2005 Intellectual Property Law of Vietnam, as amended in 2009 and 2019 (the "**IP Law**"), and its guiding regulations, have included certain provisions which conform with Article 31 of the TRIPS Agreement of which Vietnam is a member state.

With the controversy surrounding patent rights and a much sought vaccine, this article will offer a brief summary of the laws and regulations directed to compulsory licensing of patent rights in Vietnam.

Under the Vietnam's IP Law, patent owners are obliged to use their patented inventions, i.e. must

manufacture protected products or apply protected processes in their invention, to satisfy the requirements of national defence and security, disease prevention, and treatment and nutrition of the people or to meet other social urgent needs (Article 136.1, the IP Law). In addition, patent owners may also be compelled to grant rights to their patent for eligible dependent inventions at a reasonably commercial price and conditions. A dependent invention is defined as an invention which is created based on other invention (the "**principal invention**"), and may only be used on condition that the principal invention is also used, wherein an eligible dependent invention is one that makes an important technical advance as compared with the principal invention and has great economic significance as proved by its owner (Article 137, the IP Law). Failure to comply with these requirements may result in action by the state to compel the rights owner to grant the relevant rights.

In case of licensing of the right to use a principal invention, a license on reasonable terms in respect of the dependent invention must be granted to the owner of the principal invention, and the licensee of the right to use the principal invention must not assign such right, except where the assignment is effected together with all rights to the dependent inventions.

Non-compliance with the obligations of using of the patented invention or licensing patent rights to owner of the dependent invention may be the grounds for the State to grant compulsory patent licenses in the second and third instances mentioned below without the consent or agreement of the owner of the patent rights. Under Article 145 of the IP Law, there are four instances in which this may occur as follows:

1. where the patented invention is used for public and non-commercial purposes, serving national defence and security, disease prevention, and treatment and nutrition of people or other urgent social needs;

2. where the holder of the exclusive rights to use the patented invention fails to fulfill the obligations of using the patented invention to satisfy the needs of national defence and security, disease prevention, and treatment and nutrition of the people, or other social urgent needs, and with the condition that the time limit of four years from the date of filing the respective patent application and three years as from the date of granting the patent for invention has passed;

3. where a person who wishes to use the patent fails to reach a patent license agreement with the holder of the exclusive rights to use the patented invention, irrespective of efforts made within a reasonable time in negotiating a mutually acceptable price and reasonable conditions. The case of licensing the rights to use of principal invention to the owner of the dependent invention may be included in this circumstance; and

4. where the holder of the patent rights is deemed to perform anti-competitive practices prohibited by the law on competition. Pursuant to Article 27 of the 2018 Competition Law of Vietnam (the "**Competition Law**"), relating prohibited anti-competitive practices may be the abuse of a monopoly position of an enterprise, which includes, inter alia: (i) imposing

irrational buying or selling prices of goods or services or establishing minimum resale price maintenance (RPM), which causes or possibly causes damage to customers; (ii) restricting production and distribution of goods, services, limiting markets, preventing technical and technological development, which causes or possibly causes damage to customers; (iii) applying dissimilar commercial conditions in similar transactions, which leads to or possibly leads to prevention of other enterprises from market entry or expansion or exclusion of other enterprises; (iv) imposing conditions on other enterprises to conclude goods or services purchase or sale contracts or requesting customers to accept obligations which have no direct connection with subjects of such contracts, which leads to or possibly leads to prevention of other enterprises from market entry/expansion or exclusion of other enterprises; (v) preventing other enterprises from market entry or expansion; (vi) imposing unfavorable conditions on customers; and (vii) taking advantage of the monopoly position to unilaterally modify or cancel the contract already signed without justifiable reasons. In this connection, Article 24 of the Competition Law provides that an enterprise shall be considered to hold the monopoly position if there is no enterprise competing on the goods or services dealt in by such enterprise on the relevant market.

Where the patented invention is used for public and non-commercial purposes, serving national defence and security, disease prevention, and treatment and nutrition of people or other urgent social needs as in the case of Item (1) above, the invention will be used on behalf of the State as provided in Article 133.1 of the IP Law, and the competent authorities for issuing the decisions on the grant of compulsory licensing comprise the Ministries and ministerial equivalent bodies, subject to their management domains. The competent authority in respect of items (2), (3) and (4) is the Ministry of Science and Technology (the "**MOST**"). Upon grant of compulsory licensing, the competent authorities must inform the holder of exclusive right to use the invention and the National Office of Intellectual Property (the "**NOIP**") of such grant.

Per Article 146 of the IP Law, the compulsory licensing of patent rights granted under decisions of the competent authorities must comply with the following conditions:

- the granted rights to use the patented invention must be non-exclusive;
- the scope of license must be limited to the extent and duration sufficient to achieve the licensing objectives, and basically for the domestic market, except for the case as mentioned above in which the holder of the patent rights fails to use the rights for the public benefit after the passing of the statutory limits, and for an invention in semi-conducting technology, the licensing shall be only for public and non-commercial purposes or for dealing with anti-competitive practices prohibited by the law on competition;
- the licensee must neither assign nor sub-license their licensed right to others, except where the assignment is effected together with the transfer of the licensee's establishment; and

- the licensee must pay the holder of the patent rights a satisfactory compensation depending on the economic value of such licensed right in each particular case, and compliant with the compensation framework stipulated by the Government. In this connection, so far, there has been no such compensation framework provided by the Government.

The holder of the exclusive right to use the patented invention shall have the right to request termination of the granted license when the prescribed grounds for the compulsory licensing no longer exist and are unlikely to recur, provided that such termination shall not be prejudicial to the related licensee.

There has only been one case relating to compulsory licensing of patent rights in Vietnam, which occurred in 2005 when Vietnam was faced with a critical shortage of the drug in a bird flu pandemic caused by H5N1 virus. In that urgent situation and in accordance with the warning of the WHO, the Vietnamese Government approached Roche - a Swiss pharmaceutical company for a big volume of TAMIFLU®, and negotiated with it on a license for producing TAMIFLU® by a Vietnamese company for meeting the emergency needs of disease prevention. It was an intention of the Ministry of Health (the "MOH"), that in case no license agreement had been reached with Roche, the MOH would have suspended the patent rights in question of Roche, and authorized one or more Vietnamese companies to manufacture the drug for non-commercial purpose based on Article 802 of the 1995 Civil Code and Article 51 of Decree No. 63/ND-CP of the Government dated 24 October 1996. Fortunately, the Roche agreed with the MOH to grant such a license to a Vietnamese company selected by itself for manufacturing TAMIFLU® in Vietnam, and the efficacy of the provisions for compulsory licensing remains untested.

In light of these provisions, it is possible for the Vietnam's Government, if it deems necessary, to either suspend or compel the licensing of Covid-19 vaccines for the emergency needs of disease prevention. The practicality, however, is less certain as the technology to produce the vaccines remains in the hands of foreign entities who can largely choose to ignore a request or order of the Government. What is more likely is the possibility that once the Vietnamese locally developed vaccines are approved the Government could order their creators to allow for the compulsory licensing of such vaccine in order to accelerate the distribution of vaccines to its citizens. Hopefully, neither case will become necessary and the Government's goals of vaccinating the population will be met with voluntarily provided intellectual property rights.

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