Trouble looms in amendments to Patent Act

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The proposed amendment

The draft amendment to the Patent Act proposed by the Department of Intellectual Property (DIP) includes several reforms and new additions to the current law. One of the most prominent changes which would directly affect research-based pharmaceutical companies is the new provisions on pharmaceutical compulsory licenses. These new provisions are to be added to the current law under which the procedure for issuance of compulsory licenses by government departments remains ambiguous. The proposed amendment not only fails to address the existing ambiguity in the law but could potentially adds a new set of issues with respect to imports and exports of products manufactured under compulsory licenses.

In particular, the proposed amendment provides the following:

Importation of products manufactured under CL

Section 52/1 states that any persons who wish to import pharmaceutical products which are used for treatment of diseases prescribed by the Minister of Commerce may apply to the Director General (DG) of DIP for a compulsory license if it appears at the time when the application is filed that Thailand has insufficient or no manufacturing capacities for the product in question. The applicant must also demonstrate either that;

- there is no product produced under the patent or under the patented process for sale in any domestic market or, if there is, it is sold at an unreasonably high price or does not meet the public demand; or
- the product is required to resolve public health problems.

In any event, the applicant is required to negotiate a voluntary license with the patent owner prior to applying for a CL. Particularly, the applicant must show that it has made an effort to obtain a license form the patentee by proposing conditions and royalties reasonable under the circumstance but no agreement could be reached within 30 days. The applicant is required to pay royalties to the patent owner in accordance with the rules prescribed by the DG of DIP, unless remuneration is already paid in the exporting country. Lastly, Section 52/1 provides that the application for a compulsory license will be governed by the ministerial regulations to be enacted by the Ministry of Commerce.

Section 52/2 states that in the event that Thailand has insufficient or no manufacturing capacities for pharmaceutical products, and to resolve public health problems or alleviate a shortage of pharmaceutical products used for treatment of diseases prescribed by the Minister of Commerce, government departments, themselves or through others, may exploit the rights under such pharmaceutical patents in order to import the products in question. As in the case of a private applicant for CL, the government department is required to pay royalties to the patent owner in accordance with the rules prescribed by the DG of DIP, unless remuneration is paid in the exporting country.

The government department is also required to inform the patent owner without delay. The proposed Act simply provides that the application for a compulsory license under this section will be governed by the ministerial regulations.

Section 52/3 grants the Prime Minister, with an approval of the Cabinet, the power to issue a compulsory license to import pharmaceutical products which are used for treatment of diseases prescribed by the Minister of Commerce, in the event of national emergencies and Thailand has insufficient or no manufacturing capacities for the pharmaceutical products in question.

A remuneration must be paid to the patent owner in accordance with the rules prescribed by the DG of DIP, unless remuneration is paid in the exporting country. The exploitation of the patent rights shall be in accordance with the forms, rules and procedures prescribed in the ministerial regulations.

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