Hogan Lovells

New draft rules setting out procedure for compulsory patent licensing include monopolistic conduct and public health concerns

On 12 October 2011, the Legal Affairs Office of the State Council of China and the State Intellectual Property Office ("**SIPO**") published a consultation paper regarding SIPO's draft Amendments to Measures for Compulsory Licensing of Patents (the "**Draft Measures**"). The consultation paper seeks comments from the public by 13 November 2011.

The Measures

The purpose of the amendments is to implement the relevant provisions of the PRC Patent Law (effective 1 October 2009) and the Implementing Regulations to the Patent Law (effective 1 February 2010), and to consolidate the contents of the current 2003 Measures for Compulsory Licensing of Patents (the "**Current Measures**") and the 2005 Measures for Compulsory Licensing of Patents concerning Public Health.

The Current Measures have five chapters and 39 articles, while the Draft Measures have six chapters and 42 articles. Many of the proposed changes are to make the measures consistent with changes in substantive patent law. For example, Article 7 of the Draft Measures provides for a compulsory license for manufacturing and exporting of drugs to underdeveloped countries and regions recognized by the UN and certain developed or developing members of the WTO, which is already foreseen by Article 50 of the Patent Law. Monopolistic conduct held to be contrary to the Anti-Monopoly Law and other laws or regulations with antitrust provisions (such as the PRC Contract Law and its implementing measures) may also lead to compulsory licenses being granted.

The application procedure for a compulsory license remains largely unchanged. For instance, SIPO remains the approving authority and parties are entitled to appeal to the court against decisions of SIPO concerning the grant of compulsory licenses. Having said that, there are some changes worth noting as highlighted below:

1. **Grounds for granting compulsory licenses expanded**

   Articles 5 to 8 of the Draft Measures basically recite Articles 48 to 51 of the current Patent Law and expand the grounds for granting compulsory license under the Current Measures. A comparison of the grounds under the Draft Measures and Current Measures follows:

	The Draft Measures	The Current Measures
1	Where a patentee fails to exploit or fully exploit a patent without justification either 3 years after the date of grant or 4 years after the date of filing (Art 5 following Art 48(1) of the Patent Law).	Where a patentee fails to grant a licence upon request on reasonable terms and conditions and within a reasonable period of time (Art 4)
2	Where a patentee's exercise of its patent rights is determined in accordance with the law to be monopolistic conduct so as to eliminate or reduce the adverse effects of such conduct on competition (Art 5 following Art 48(2) of the Patent Law).	Absent
3	In case of national emergency or any extraordinary state of affairs or where the public interest so requires (Art 6 following Art 49 of the Patent Law).	No change
4	For the purposes of public health to allow the manufacture of pharmaceuticals patented in China and to export the same to the following countries or regions: • the most underdeveloped countries or regions recognized by the United Nations • - those members of developed or developing members of the WTO which have notified the WTO that they wish to import such pharmaceuticals (Art 7 following Art 50 of the Patent Law)	Absent

5	Where a patented invention or utility model involves an important technical advance with considerable economic significance in comparison to a previous patented invention or utility model, and the exploitation of the same is dependent on the exploitation of the previous patented invention/utility model. The patentee of the previous patent may also apply for a compulsory license to use the later patent (Art 8 following Art 51 of the Patent Law).	No change

2. **Burden of proof greater for individual entities than for government bodies**

   The Draft Measures place the burden of proof on individual entities wishing to obtain a compulsory license. Article 11 of the Draft Measures provides that an applicant for a compulsory license under Article 48(1) or 51 of the Patent Law must furnish proof that it has requested the patentee for a license on reasonable terms and conditions but is unable to secure a license within a reasonable period of time.

   Specifically, under Article 48(2) of the Patent Law, an entity or individual can apply for a compulsory license where the patent holder has been engaged in monopolistic conduct. However, in order to avoid adverse effects caused to the competition, an applicant cannot simply assert that the patent holder's conduct is anti-competitive, but instead must furnish proof that a legally effective judgment or decision has been issued by a court with antitrust enforcement authority (in particular, the National Development and Reform Commission and the State Administration of Industry and Commerce).

   Also, Article 12 of the Draft Measures proposes that, where a government body under the State Council requests a compulsory license under Article 49 of the Patent Law, it need only "state" (as opposed to "prove") certain factors where the application is based on any national emergency, extraordinary state of affairs or public interest. It appears that a government body may simply request a compulsory license and SIPO will be bound to grant the license even if there is no evidence provided by the government to justify such a grant. This matter remains to be clarified.

3. **SIPO is required to notify parties of its decision before it hands down a decision and the parties can make further submissions**

   Article 16 of the Draft Measures follows the contents of Article 10 of the Current Measures as regards the parties' right to present their cases, allowing patentees to receive a copy of an application for a compulsory license and to file a response within a prescribed period of time. Articles 19, 21 and 38 of the Draft Measures further propose that SIPO shall notify the parties of its decision as well as the relevant grounds before it hands down the decision, and that the parties may file further submissions within a prescribed period upon receipt of that notice. This provision is welcome as it provides an additional opportunity for the parties to present submissions before SIPO makes a final decision.

4. **Patentees do not have a right to call for a hearing if an application for a compulsory license is made under Article 49 or 50 of the Patent Law**

   According to Article 18 of the Draft Measures, both the applicant and the patentee may, as under the Current Measures, request SIPO to hold a hearing, though this is not applicable to cases, which fall under Article 49 (national emergency, etc.). Article 18 also proposes that the exception to the patentee's right to a hearing should also apply to cases under Article 50 (entities wishing to manufacture and export pharmaceuticals to qualified countries). This provision, together with the proposed Article 12, which only requires a government body to *state*, rather than *prove*, the existence of a national emergency, etc., may lead to a non-transparent and arbitrary approach to the operation of the compulsory license system by government bodies and jeopardize the patentee's legitimate right to be protected under the patent system. The patentee's right to request a hearing should apply to each and every case where a

compulsory license is applied for.

5. **SIPO's decision must set out requirements for any compulsory license granted under Article 50 of the Patent Law**

   Where a compulsory license is granted pursuant to Article 50 of the Patent Law, Article 22 of the Draft Measures imposes on SIPO to set out certain requirements in its decision, namely:

   - the quantity of pharmaceuticals produced shall not exceed the necessary amount required by the importer;
   - all the pharmaceuticals so produced shall be exported and sold to the importer;
   - special features, labeling, coloring or shape of the products are required to identify that the products were produced under a compulsory licence;
   - the licensee must publish the above quantities and special features on its website or the relevant WTO website.

   Article 23 of the Draft Measures further requires any relevant government department to report details of such compulsory licenses to the WTO, including the name and address of the licensee, the name and amount of the pharmaceuticals to be exported, etc. These requirements are helpful to limit products reaching unauthorized markets, ensuring that pharmaceuticals produced under a compulsory license strictly serve the needs of the relevant qualified countries and are in compliance with the relevant provisions of the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health[1]. However, the Draft Measures do not set out the consequences of a breach of these requirements and should therefore be amended to include legal sanctions.

Conclusion

Although many countries such as the US and UK have similar legislation that allows the government to grant compulsory licenses, China's regime is somewhat broader and more favorable to potential licensees. In particular as it concerns Article 51 of the Patent Law, according to which in some cases a later patentee may request a grant for a compulsory license to exploit an earlier invention or utility model; and an earlier patentee may request a license to exploit a later invention or utility model.[2] Moreover, the provisions with regard to monopolistic conduct are lacking in detail. The fact that the Draft Measures allow for court judgments to be provided as the basis of an application for a compulsory license might have the effect of leading to an increase in antitrust litigation in China.

Foreign patent owners in particular remain concerned as to how the Chinese government and courts will handle compulsory licensing issues in practice. Although there have not been any published reports on compulsory licenses granted to date, it is an area that attracts much attention and will no doubt continue to do so.

Hogan Lovells is current preparing a commentary paper to be submitted to SIPO. Stakeholders are invited to provide input to Hogan Lovells.

[1] http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm

[2] Article 51 of the Patent Law states: "Where the invention or utility model for which the patent right has been granted constitutes important technical advance of considerable economic significance compared with another invention or utility model for which a patent right has been granted earlier and the exploitation of the later invention or utility model depends on the exploitation of the earlier invention or utility model, the patent administrative department under the State Council may, upon the request of the later patentee, grant a compulsory license to exploit the earlier invention or utility model.

Where, according to the preceding paragraph, a compulsory license is granted, the patent administrative department under the State Council may, upon the request of the earlier patentee, also grant a compulsory license to exploit the later invention or utility model."

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