



The position of compulsory licensing in China

As China waits for its first compulsory licence to be granted, **Jason Ma** examines the mechanisms behind the procedure, highlighting the grounds under which one can be approved

When the Patent Law was enacted in 1985, it created a mechanism for the grant of a compulsory licence. The mechanism has been adjusted to provide more grounds for granting compulsory licences with the amendments to the Patent Law. The State Intellectual Property Office ("SIPO") has also issued specific regulations implementing the provisions of the Patent Law on compulsory patent licensing. However, China has never granted any compulsory licence, nor does it seem likely that it will in the near future. But, on 3 February 2010, at a SIPO press conference regarding the announcement of the new Implementing Regulations for the Patent Law, a SIPO spokesperson stated that, if China were to begin granting compulsory licences, it would likely start with pharmaceutical patents relating to public health.

The establishment and development of the compulsory patent licensing mechanism

The first Patent Law of the People's Republic of China came into force in 1985 and was supplemented by implementing regulations later that year. The 1985 Patent Law was amended in

1992, 2000 and 2008 (the amendments became effective in 1993, 2001 and 2009, respectively, hereafter referred to as "1993 Patent Law", "2001 Patent Law" and "2009 Patent Law") and each amendment was followed by revised implementing regulations, which became effective in 1993, 2001 and 2010, respectively (hereafter referred to as "1993 Implementing Regulations", "2001 Implementing Regulations" and "2010 Implementing Regulations"). Additionally, the SIPO issued specific regulations on compulsory patent licensing in 2003 and 2006.

The 1985 Patent Law provided that compulsory licences could be granted under two circumstances, namely where there was non-exploitation until a lapse of three years from the date when the patent was granted, and/or where a subsequent patent which is involved in technical advance is dependent on an earlier patent. The amendments to the patent law and the corresponding implementing regulations, have adjusted the requirements for these grounds and have brought new grounds for compulsory licensing.

In 2003, the SIPO issued specific regulations on the grant of compulsory licences, the Measures for Compulsory Patent Licensing ("2003 Measures"), which provide detailed procedural requirements. After, the World

Trade Organization (WTO) agreed to take actions to implement paragraph six of the Doha Declaration related to the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreement and public health, which could allow WTO members to issue compulsory licences to export generic versions of patented drugs to countries with insufficient or no manufacturing capacity in the pharmaceutical sector. In 2006, the SIPO issued the Measures on Compulsory Patent Licensing Involving Public Health Issues ("2006 Measures"). It seems that both the 2003 Measures and the 2006 Measures remain in force and have not been superseded by either the 2009 Patent Law or the 2010 Implementing Regulations.¹ Although it was reported in 2009 that the SIPO would revise the specific regulations on compulsory licensing, it seems that there has been no significant progress on this proposal.

Therefore, the Chinese compulsory patent licensing mechanism is shaped by the 2003 Measures, the 2006 Measures the relevant provisions in the 2009 Patent Law, and the 2010 Implementing Regulations, which provide detailed provisions on the grounds for compulsory licensing, the procedural requirements, adjudication of compensation, judicial review of the SIPO's decisions and other relevant issues.

Grounds for the grant of a compulsory licence

In China, a compulsory licence may be granted under one of the following five grounds:

1. For production and export of patented pharmaceuticals to foreign countries or regions for dealing with public health problems

The 2009 Patent Law permits the SIPO, "for the purpose of public health", to grant a compulsory licence for the production of a "patented pharmaceutical", and export such products to a country or region that conforms to the provisions of the relevant international treaties to which the People's Republic of China has acceded.² Prior to the 2009 Patent Law coming into force, the 2006 Measures already created this ground. However, the SIPO, as an administrative government agency, should not have the legal authority to create new grounds for compulsory licensing under Chinese law. The 2010 Implementing Regulations define the term "patented pharmaceutical" as "any patented product, or product directly obtained according to a patented process, of the pharmaceutical sector needed to address public health problems, including patented active ingredients necessary for manufacture of the product and diagnostic supplies needed for use of the product."³ The 2010 Implementing Regulations also clarify that the SIPO decisions under Article 50 of the 2009 Patent Law must "be in conformity with the provision of the international treaties China has concluded or acceded to regarding granting a compulsory licence for resolving a public health problem, except for those China has made its reservations."⁴

2. For combating monopolistic behaviour

The 2009 Patent Law authorises the SIPO to grant a compulsory licence when the patentee's act of exercising the patent rights has been determined as monopolistic behaviour by a competent authority in accordance with the law.⁵ The SIPO can grant such a compulsory licence only "to eliminate or reduce the adverse consequences of such monopolistic behaviour on competition", and the SIPO may grant a compulsory licence only upon the request of an entity or person who can demonstrate the capability to exploit the invention which is the subject-matter of the granted patent.⁶ A compulsory licence granted under this situation is *not* limited to use "predominantly for the supply of the domestic market".⁷

3. For combating non-exploitation of patents

The 2009 Patent Law gives the SIPO the power

to grant a non-exclusive compulsory licence if the patentee, after the lapse of three full years from the date when the patent is granted *and* after the lapse of four full years from the date when the patent application is filed, fails to exploit or fails to sufficiently exploit its or his patent without any justifiable reason.⁸

To be granted a compulsory licence under this provision, the person requesting a compulsory licence must prove both that he/she has the capability to exploit the patent, and has requested a licence from the patentee on "reasonable terms and conditions" but has not been able to get a licence from the patentee "within a reasonable timeframe".⁹

A compulsory licence issued under this provision must be "predominantly for supplying the domestic market"¹⁰.

In China, importation is included within the concept of exploitation, and a patentee may exploit a patent when no patented product is manufactured in China.¹¹

The 2010 Implementing Regulations provide that a patentee "fails to sufficiently exploit" its patent when "the patentee and its licensee exploit the patent in a manner or scale that cannot satisfy the domestic demand for the patented product or patented process."¹² However, it is unclear how the SIPO will determine that a patentee or licensee "cannot satisfy the domestic demand". In addition, there is no guidance on what might constitute a "justifiable reason" for failure to exploit or failure to sufficiently exploit a patent.

4. For dealing with "national emergency", "extraordinary state of affairs" or the situation under which the "public interest requires" a compulsory licence

The 2009 Patent Law provides that the SIPO can grant a compulsory licence "where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires."¹³ A compulsory licence issued under this provision must be "predominantly for supplying the domestic market"¹⁴.

The 2009 Patent Law and the 2010 Implementing Regulations do not provide interpretation of the terms "national emergency" and "public interest". The 2006 Measures specify that a "national emergency" as used in the Patent Law includes a "public health crisis" caused by the occurrence and spread of AIDS, tuberculosis, malaria, or other epidemic diseases specified in the Law on the Prevention and Treatment of Epidemic Diseases. The 2006 Measures also specify that prevention and control of epidemic diseases can be a situation under which "public interest so requires".

5. For the exploitation of a dependent patent

The 2009 Patent Law allows the owner of a

subsequent patent, the owner of which cannot use the subsequent patent without exploiting an earlier patent, to apply to the SIPO for a compulsory licence to exploit the earlier patent, provided that the subsequent patent involves an "important technical advance of considerable economic significance" in relation to the invention claimed in the earlier patent.¹⁵

In this situation, the person requesting the compulsory licence must prove that the person has made efforts to obtain authorisation from the patentee of the earlier patent on "reasonable terms and conditions", and that such efforts have not been successful within a "reasonable period of time".¹⁶

A compulsory licence issued under this provision must be "predominantly for supplying the domestic market."¹⁷ Article 51 also permits the holder of the patent subject to the compulsory licence to apply to the SIPO to obtain a cross-licence for the dependent patent.¹⁸

The compulsory licence shall always be a non-exclusive licence, it cannot be reassigned to another person. In the case, that the compulsory licence is for a patent regarding a semi-conductor technology, such a compulsory licence may be granted only when (i) the purpose is for public interest, or (ii) the purpose is for combating monopolistic behaviour.¹⁹

How an application for a compulsory licence is processed

It is the SIPO that has the authority to decide whether a compulsory licence should be granted. This is the case even if the grounds for a compulsory licence is for dealing with a "national emergency", an "extraordinary state of affairs", or the situation under which the "public interest requires" a compulsory licence.

The applicant may be a government department or a private company, depending on the grounds for the compulsory licence. An applicant for a compulsory licence should submit a request to the SIPO, including a statement of the reasons for the compulsory licence, "relevant supporting documents"²⁰ and pay an official fee for the request. The fee must be paid within 30 calendar days²¹ (if the applicant is a government department, the official fee shall be waived). The SIPO will send a copy of the application to the patentee, and the patentee must then "state his or its opinions within the time limit specified" by the SIPO.²² The patentee's failure to respond will not influence the SIPO's decision on whether to issue a compulsory licence.²³

The SIPO must not reject an application unless it has: (i) provided notice to the applicant of the reasons why it proposes to reject the application; and (ii) afforded the applicant a chance to provide further information, or otherwise to take steps to address the reasons stated in the notice. The SIPO must not grant a compulsory licence unless it has

given notice to the patentee of the reasons why it proposes to grant a compulsory licence.²⁴

Both parties (applicant and patentee) have the right to request a hearing.²⁵ Hearings for compulsory licences must be open to the public unless the proceeding involves state secret, trade secret or personal privacy. Notice of a hearing must be given to the applicant, patentee and other stakeholders. The applicant, patentee and stakeholders have the right to make pleadings and cross-examine. Hearing transcripts must be checked and signed by the participants. For those applications which are considered as a "national emergency", "extraordinary state of affairs" or for the circumstance under which the "public interest so requires", the above requirements for hearing will not apply.

Both the applicant and the patentee have a right to apply for a judicial review of the SIPO's decision within three months from the date of receipt of the SIPO's decision.

A compulsory licence will lapse on the expiry of its duration. Also, the patentee may seek termination of a compulsory licence by filing a request to the SIPO if the patentee thinks that the circumstances have changed, and that the grounds for the requested compulsory licence no longer exist. The SIPO shall review the request in a similar way to how it reviews an application for the grant of a compulsory licence and then make a decision. Both the patentee and the licensee have a right for judicial review.

A new provision in the 2010 Implementing Regulations requires the SIPO to notify both the applicant and the patentee of the SIPO's prospective decision, including the reason, before the decision is finalised. The 2010 Implementing Regulations do not provide additional details regarding the level of specificity in this notice.

The 2003 Measures requires grants to be listed in the patent register, published in the *China Patent Gazette*, and posted on the SIPO website.

The adjudication of compensation

The 2009 Patent Law provides that the licensee(s) of the compulsory licence shall pay "reasonable compensation" to the owner of the patent, or deal with the compensation issue according to the provisions of the relevant international treaties to which the People's Republic of China has acceded. Where the licensee(s) should pay the patentee compensation for the compulsory licence, the parties shall determine the terms of compensation through mutual consultation. If the parties cannot agree, any party may apply to the SIPO for adjudication of the terms of compensation. The applicant must submit documents to the SIPO showing

that the parties have been unable to come to agreement on the terms of payment of compensation. The SIPO will adjudicate the issue within three months.

Judicial review

As discussed earlier, the SIPO has the power to determine, upon request from a party, whether a compulsory licence should be granted, terminated (prior to expiry of the granted duration), and what the terms for payment of compensation should be. If a party disagrees with a decision made by the SIPO, the party can seek judicial review of such decisions within three months from the date of receipt of the SIPO's decision.

Analysis

China has established a mechanism for the grant of compulsory patent licensing and there have been detailed provisions also.

China has referred to the provisions of international treaties to which the People's Republic of China has acceded when relevant provisions were drafted. The 2010 Implementing Regulations expressly require that the SIPO decisions under Article 50 of the 2009 Patent Law must "be in conformity with the provision of the international treaties China has concluded or acceded to regarding granting a compulsory licence for resolving a public health problem, except for those China has made its reservations." However, the Chinese regulations do have certain deviations from the international standards. For example, the Chinese regulations do not provide that the patentee is entitled to "adequate compensation", as Article 31(h) of TRIPS requires, although Article 74 of the 2009 Patent Law does provide that the patentee may seek "reasonable compensation" when a compulsory licence is imposed.

The 2009 Patent Law and the 2010 Implementing Regulations have brought certain amendments to the mechanism for compulsory patent licensing. On 12 October 2011, the SIPO published a draft of new measure on patent compulsory licensing for public comments. According to the SIPO, the new measure will supersede the 2003 Measures and the 2006 Measures.

Although compulsory licensing has been available under People's Republic of China Patent Law since 1985 and the mechanism for the grant of compulsory licences has been well developed in China, China has not granted any compulsory licence to date and the Chinese government has been very cautious about giving any official comments whether it is the time to grant the first compulsory licence.

Recently, Gilead Sciences announced it had granted medicine patent pool licences for four AIDS medicines to be supplied in more than 100 countries, but the scheme does not include China.

Certain Chinese media sources have called on the Chinese government to consider compulsory licences for these medicines in China, but the Chinese government has kept silent on this and it is not certain if its position will change.

As the SIPO spokesperson stated on 3 February 2010, if China were to begin granting compulsory licences, it would likely start with pharmaceutical patents relating to public health.

Footnotes

1. Under Chinese law, if there is any conflict between the 2009 Patent Law/2010 Implementing Regulations and the 2003 Measures/2006 Measures, the 2009 Patent Law/2010 Implementing Regulations will prevail.
2. The 2009 Patent Law, Art 50.
3. The 2010 Implementing Regulations, Art 73
4. *id* Art. 74.
5. *id* Art. 48.
6. *id*.
7. *id* Art. 53.
8. *id* Art. 48.
9. *id* Art. 54.
10. *id* Art. 53.
11. *id* Art. 11.
12. The 2010 Implementing Regulations, Art 73.
13. The 2009 Patent Law, Art 49.
14. *id* Art. 53.
15. *id* Art. 51.
16. *id* Art. 54.
17. *id* Art. 51.
18. *id* Art. 51.
19. *id* Art. 52.
20. The 2010 Implementing Regulations, Art. 74.
21. The official fee for an application for compulsory license is insignificant because the fee for invention patent is RMB300 (about \$47) and that for utility model patent is RMB200 (about \$30).
22. The 2010 Implementing Regulations, Art 74.
23. *id*.
24. The 2010 Implementing Regulations, Art 74.
25. The 2003 Measures, Art 12.

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