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Chinese patent prosecution recently made worldwide headlines when the press announced that the Chinese Patent Office (SIPO) rejected a Gilead Sovaldi prodrug patent. Sovaldi (sofosbuvir) is a breakthrough drug used to treat chronic hepatitis C virus (HCV) infection. Hepatitis C is a viral disease that causes inflammation of the liver which may lead to diminished liver function, and eventually in some cases, liver failure. In clinical trials, Sovaldi was the “first drug to demonstrate safety and effectiveness in treating certain types of HCV infection without co-administration of interferon.” Sovaldi, in combination with other anti-HCV medication(s), proved particularly effective, reducing viral loads below the lower limit of quantitation for a vast majority of patients at the end of a 12-week treatment. Sovaldi’s price has also been controversial. For example, its U.S. price has been quoted in the media as ranging from $84,000 to $168,000 for a 12-week course of treatment. Clearly, Sovaldi is an important drug, and the rejection of Gilead’s prodrug patent raises issues worthy of consideration for companies seeking pharmaceutical patent protection in China.

China Is Becoming an Increasingly Important Pharmaceutical Market

China is the world’s most populous nation. Additionally, in 2015, China overtook the United States to become the world’s largest economy. These and other factors, including the availability of pharmaceutical patents, make China an increasingly attractive pharmaceutical market.

Broad Pharmaceutical Patent Claims Are Traditionally Difficult to Obtain in China

China, for historical, economic, and policy reasons, has been reluctant to grant broad pharmaceutical patent claims. Initially, when patent law came into force in 1984, pharmaceuticals and chemical products were excluded from patent eligible subject matter. In part, this was because of a concern that patents might preclude a portion of China’s population from obtaining medications. Also, the then weakness of China’s domestic pharmaceutical and chemical industries did not incentivize China to grant patent protection to pharmaceuticals. After the 1992 amendment to Chinese patent law, pharmaceutical patent protection became possible—if requirements specific to Chinese patent law were met. Additionally, the growing strength of China’s domestic pharmaceutical and chemical industries, and the burgeoning wealth of China’s population, are driving increasing acceptance of pharmaceutical patents.

Chinese Pharmaceutical Patent Protection Starts with Application Drafting

Patent protection starts with drafting of a patent application. Traditionally, applications have been drafted to meet the specific requirements of the United States (e.g., patent eligible subject matter), and Europe (e.g., written description), which combined, make up a significant portion of the world’s pharmaceutical market. With the increasing importance of China, applications should also be drafted with an eye to meeting Chinese patent requirements, which are constantly evolving. Knowledge of nuanced Chinese patent law is critical, especially regarding e.g.,

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1 A prodrug is an inactive form of a drug that the body, after administration, metabolically converts into the biologically active drug.
4 Id.
6 The rejection can still be appealed, and Gilead has at least one other issued Chinese patent covering Sovaldi.

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i) How to make and use the invention (enablement): Post-application filing data cannot generally be used to support enablement in China. Thus, it is important to include sufficient enabling disclosure in the application at the time of filing. In addition, to meet the sufficient disclosure requirement, it is also vital to clearly describe what has been made and used. China is stricter in this regard (enablement) than, e.g., the U.S.

ii) A recommended practice is to include a plethora of actual (not prophetic) examples in the application. These examples support enablement and can result in broader allowed claim scope. When in doubt, more is better. This recommendation is generally applicable regardless of jurisdiction.

iii) Post-application filing data, however, can be used to address inventive-step (obviousness) rejections if the application otherwise provides support for an argument favoring patentability (e.g., a superior and unexpected result). Thus, a recommended practice is to consider including written description for secondary considerations which favor patentability, even if data is not yet available to fully support these. China, in this instance, is similar to Japan.

iv) Another suggested practice is to draft the application to address China’s stringent new matter criteria. It can be very difficult to enter a claim whose embodiment has not been clearly recited in the application. China is similar in this regard to Europe.

v) Finally, knowledge and inclusion of features which may convey patentability are keys to successful Chinese patent application prosecution. For example, in some jurisdictions, dosage amounts or ranges, alone or in combination, may convey patentability. These features, presented in a ‘Swiss style’ claim in China, are unlikely to advance prosecution. In this instance, China is different than, e.g., the U.S.

**Prosecution Skills Are Also Critical**

Successful patent prosecution can make the difference: i) between getting or not getting a patent; and ii) getting the broadest possible claim or getting something significantly reduced in scope. In this regard, both knowledge of Chinese patent law, and good working relationships and communication with Chinese examiners, are critical.

**Conclusion**

China is becoming an increasingly important pharmaceutical market as evidenced, e.g., by the worldwide reporting of a Sovaldi prodrug patent rejection in the SIPO. Chinese pharmaceutical patent protection requires top-tier prosecutors who can optimize a patent application for entry into China, effectively communicate with Chinese examiners, and efficiently guide the prosecution of the patent application to gain broadest possible claim scope allowance.

For more information on patent protection in China, please contact: Vern Norviel, Karen Wong, or any intellectual property professional at Wilson Sonsini Goodrich & Rosati.

Charles Andres, Lou Lieto, Cheng Zhang, and Ming Zhong contributed to the preparation of this WSGR Alert.

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9 Since October 2013, SIPO would consider supplemental data filed as evidence to support results or effects already described in the application as filed.

10 In this respect, China’s Supreme Court issued a decision in May 2015, invalidating the patent ZL96195564.3, which is associated with Pfizer’s drug Lipitor. The reason for invalidation was lack of sufficient disclosure.

11 See Supreme Court Decision (2012) Zhixingzi No.75.
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