ALLEN & OVERY

IMPORTANCE OF PATENTS IN CHINESE PHARMACEUTICAL TENDERING

China has a complicated and unique tendering system for drugs – and patents play an important role in almost every tender. What adds to the complexity is that tendering rules vary between provinces. Providing necessary patent advice has become increasingly crucial to differentiating between competitors and winning tenders in China.

THE DRUG TENDERING SYSTEM IN CHINA

The main pharmaceutical market for multinational companies (**MNCs**) in China is the government tendering market, where government-owned hospitals procure drugs through the provincial tendering process. Each province calls for manufacturers to participate in its tendering process. These tenders are carried out for a one-to-two-year tender cycle. A company must win tenders to sell its various drugs to public hospitals within a province.

The tendering criteria mostly concern quality and price. In essence, the quality of a drug determines the tier within which a company is allowed to compete, and the lowest price bid within a tier wins.

WHY ARE PATENTS IMPORTANT?

The provincial tendering document sets out the quality criteria for tendered drugs. Under the government's overarching policy of promoting innovation, a typical tender for a particular drug (i.e. under the same generic name) is divided into separate tiers according to its patent status (or lack thereof) and other quality criteria. Generally, a "patented" drug is categorised within a tier that is different from the corresponding "generic" tier.

The overall net result is that "patented" products do not compete with "generics". Therefore, it is vital for a company to prove its "patented" status for a particular product even if there are corresponding generics on the market.

Further, "patented" status in this context is very different from the conventional sense of a patent-protected product under the patent law. Each province in China has its own rules for determining the "patented" status, and the rules have evolved over time. For example, in almost all of the provinces, an expired patent can be used to indicate "patented" status. Foreign patents may also be used as evidence. In effect, off-patent originators tender separately from generics

and are able to obtain a large price premium over local generic drugs and win tenders regardless of the existence of competing generics.

Lastly, drugs achieving "patented" status are scored differently depending on the types of corresponding patents. Most provinces consider compound patents to be of the highest quality and score these most favourably. Yet the definition of "compound" patents varies between the provinces. The prevalent definition is that a compound patent is directed to a new chemical entity according to the patent document issued by the State Intellectual Property Office (**SIPO**) or a foreign patent office. Each tendering office has more detailed guidance on what constitutes a "compound" patent on an active pharmaceutical ingredient (**API**). For example, we have seen it defined as a patent which does not derive its novelty from acid or salt counter ion. In addition to compound patents, formulation patents and process patents also count, but they are likely to be assigned a lower score.

As such, patents could be a determinative factor in deciding the tier within which a drug belongs. Failure to be accepted within a preferred tier means that a company may have to cut the drug's price so as to win a tender, or otherwise face losing the tender altogether.

CHALLENGES FACED BY MNCS' LOCAL BUSINESS

At MNCs, the local commercial team manages the tendering in each province. Without assistance from patent counsel, its members are responsible for compiling patent information and supporting documents for a tendered drug. The tendering officers who review the patent information normally do not have any patent expertise. Consequently, they may not read a patent correctly in light of the tendering rules, thus leading to an erroneous conclusion as to the tier ranking or potential score for a tendered drug.

While the commercial team does have an opportunity to rebut any negative findings made by a tendering officer, the time allowed for a response is quite tight (a few days). In addition, the reasoning behind the tendering officer's decision will usually not be provided. This renders it even more difficult for the commercial team to prepare a proper and effective response.

BEST PRACTICES

To assist the overall success in drug tendering by a pharmaceutical business in China, there are a few things that can be immediately done by way of preparation:

Patent review

Review by the patent lawyers of all the relevant patents and identification by them of the patents that may be submitted for a tendered drug.

Document preparation

Preparation of a set of proof documents in Chinese, including the following:

i) Good Chinese translation of foreign patents.

ii) Summary of the patent(s) at issue to make technical details accessible by the commercial team/tendering officer.

iii) Chain of title documentation from the headquarters to confirm: (i) patent ownership; (ii) the link between the patent(s) and the tendered product; and (iii) that the Chinese entity is entitled to the benefits of the relevant patent(s) for tendering purposes.

Response to negative findings

Tendering officers accept appropriate responses and materials from the companies to overcome a negative finding concerning their patents. Yet such a response is best prepared by a patent lawyer after reviewing the relevant provincial rules and the patent at issue. The response is usually in the form of a letter to the tendering officer, which by its nature needs to be concise and on point. The written response could also serve as a communication tool for the commercial team or its local agents when discussing the matter with the tendering officers. From time to time, it is more effective for a patent lawyer to appear before the tendering authority to present the argument in person.

Challenge a competitor's alleged patent portfolios

Many local competitors take advantage of such "patented" drug status by submitting their own patents. As part of their offensive strategy toward success, it is important to point out the weaknesses or defects in their patent documentation and arguments. For instance, it is rare for the local competitors to come up with a genuine compound patent. However, many local companies routinely submit "compound" patent documents even though their products are generics; the MNC's lawyers need to point this out to the tendering officers and put such competing drugs in the "generic" category where they belong.

CONCLUSION

Winning a tender is the only way to sell the majority of drugs in China. While this process in itself is nuanced and vastly complex, the patent aspect can be managed early and effectively. The involvement of lawyers in the process may also be necessary to thwart competitors' attempts to "game the system". Further, as drug tendering is constantly evolving in China, patent advice needs to be tailored to and updated for each province in each cycle.

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