Patent Considerations for India and China
What to Know Before Beginning to Target Business Opportunities in These Regions

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Patent protection of pharmaceutical products is recognized as a necessary mechanism to prevent competitor copycat products. Sheer population alone makes China and India attractive markets for sale of products.

When intending to market a pharmaceutical product in these countries, a company typically files a patent application with the intent to secure granted patent claims to the product. There are, however, several considerations a patent practitioner should be aware of when advising a company whether to file in India or China and when preparing patent applications for filing in the countries. These considerations are addressed in this article. First, patent rules in the U.S. and Europe are provided to give context to the considerations in India and China.

Like most countries, China and India follow a patent “examination system”, whereby a patent application is examined by a patent examiner at the national patent office to ascertain whether the claims presented in the application satisfy the country’s legal standards for patentability. The patent examiner will issue a written report outlining any basis found for a lack of patentability.

The patent applicant has an opportunity to respond to the written report, which may include amending the claims in a way that is supported in the application as originally filed. The written exchanges between the examiner and the patent applicant can continue multiple rounds, typically until claims are found to be patentable (allowable) or the examiner issues a final rejection, which can be appealed by the applicant.

In the U.S., claims recognized as eligible for patent protection are to:

- a new drug compound,
- a new composition or formulation comprising a new drug or a known drug,
- methods of treatment using the compound or composition, and
- a new dosage regimen.

Typically a company with a pharmaceutical product will seek all types of claims, unless, of course, the product is based on a known drug, in which case claims to the drug compound are not sought.

In Europe, claims to a new drug compound, to a new composition with a new or a known drug, and to a dosage regimen are permitted. For policy reasons, Europe does not permit claims to methods of treatment, although claims to a “use” of a compound or composition (such as for making a medicine) are permissible. These “use” type of claims are termed first medical use and second medical use or “Swiss” claims.

India

India, however, under its law, does not permit claims to a method of medical treatment nor claims presented in first or second medical-use format. Moreover, claims to a modified drug compound, such as an ester of a known compound, are prohibited from patentability unless the modified compound significantly improves the medicine’s efficacy.

Claims to a pharmaceutical composition containing two or more active components may be permitted, provided all the active components and their concentrations are set forth in the claim, with support for an unexpected synergistic effect or with comparative in vivo assay data provided to corroborate an enhanced efficacy of the claimed composition in comparison to known compositions.

When determining whether to seek patent protection in India for a pharmaceutical product, an important consideration is whether the product is a new use of a known drug or composition, i.e., the invention is a new method of treatment based on a known drug; without a significant improvement or synergism, seeking patent protection in India would not be a fruitful endeavor and a waste of a company’s money.

For patent applications in India claiming a compound or composition, data supporting improved efficacy or synergistic effect are necessary to ensure patentability, and a company should be aware of this requirement and attempt to secure the supporting data prior to the deadlines for filing in India.
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China

Whether to seek patent protection for a pharmaceutical product in China presents a different set of considerations. China permits claims to compounds, compositions, and methods of treatment. One challenge in securing patent protection for any of these types of claims in China lies in proper drafting of the patent application.

Because it is common in China for the patent examiner to reject the claims on the grounds of undue breadth, and to insist that the scope of the claims be limited to the scope of the working examples, the examples set forth in the application as filed become critically important to the breadth of allowable claim scope. A patent practitioner should, at the time of drafting the patent application, carefully consider how best to present the data in support of the invention in various working examples.

Determining whether to file for patent protection in India and China for a pharmaceutical product presents considerations different from those in other countries, like the U.S. and Europe. A patent practitioner should be aware of the limitations on permissible types of claims and on the requirements posed under national laws for an examiner to find the claims allowable prior to actually incurring the costs of filing in a given country.

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