Tilleke & Gibbins
Vol. 7 No. 3 August 2016

Informed Counsel

Analysis of Recent Legal Developments in Southeast Asia

contents

Indonesia's Amended Patent Law 2016: New Requirements and Expanded Provisions

Left | **Melinda Ambrizal** — IP Consultant – melinda.a@tilleke.com
Right | **Wongrat Ratanaprayul** — Attorney-at-Law – wongrat.r@tilleke.com

On July 28, 2016, proposed amendments to Indonesia's Patent Law were passed. The amendments will come into effect on August 28, and will bring with them a raft of changes to clarify uncertainties in the existing law. In this article, we discuss the key changes to Indonesia's Patent Law under the amendments.

Exemptions from Pharmaceutical Patent Infringement

A number of exemptions from pharmaceutical patent infringement have been introduced under the amendments, including:

- importation of a pharmaceutical product which is patented in Indonesia, and the product is legally marketed in another country without the permission of the patent owner; and
- manufacturing of a pharmaceutical product which is patented in Indonesia within five years before the patent protection expires, for the purpose of licensing and marketing after the patent protection of the patent expires.

The exemption on the importation of pharmaceutical products is intended, according to the authorities, to help ensure that pharmaceutical products are reasonably priced, and access to pharmaceutical products is widened. This provision can be exercised if it is proven that the price of a certain pharmaceutical product in Indonesia is very high compared to the price of an identical product in the international market. The provision is strictly limited to "pharmaceutical products," and it does not allow parallel imports of non-pharmaceutical products. The authorities may face challenges in determining what a fair price is, and it is hoped that they would involve patent holders/licensees in discussions before importation.

As to the exemption on the manufacturing of pharmaceutical products to acquire a license, also known as a "Bolar Provision," this should help ensure that pharmaceutical products will be made available by another party after patent protection expires. The five-year period before patent protection expires has been extended from two years, which allows a longer time to manufacture a pharmaceutical product before the patent expires for the purpose of marketing and applying for licenses at BPOM, Indonesia's National Agency of Drug and Food Control.

However, unless BPOM's regulations are updated to align with the five-year period, producers of generic drugs will not be able to use this new provision in practice.

Second Use or Second Medical Use Claims

The amendments clearly prohibit protection against second use or "second medical use" of an existing patent. Before the amendments, the addition of claims providing a second use or second medical use of an existing patent was allowed. The amended law aligns with other jurisdictions such as India and Vietnam.

Continued on page 2

Indonesia's Amended Patent Law (from page 1)

Compulsory Licenses

The amendments allow compulsory licenses to be granted if a developing country or least developed country requires a pharmaceutical product which is patented in Indonesia for the treatment of an endemic disease. The pharmaceutical product can be manufactured in Indonesia and then exported to the country.

If the pharmaceutical product has not been manufactured in Indonesia, a compulsory license would be granted to the government to import procurement of a pharmaceutical product for the treatment of an endemic disease. As this relies heavily on the government's discretion, it would be interesting to see how the government would exercise its discretion in enforcing this provision.

Appeal Commission Authority Expanded

Prior to the amendment, the Patent Appeal Commission only examined appeal petitions of rejected patent applications. Under the amendments, however, the Commission has the authority to receive, examine, and decide on the appeal petitions of:

1. a refused application;
2. a correction of the patent specification, claims, and/or drawings after the application has been granted; and
3. notice of a grant decision with respect to a post-grant opposition.

Also, under the amendments, a post-grant opposition can be filed in addition to the pre-grant opposition. Before, an opposition could only be filed at the pre-grant stage. The Commission's extended authority should be welcomed by patent holders, as it provides another alternative to invalidation of a granted patent without having to engage in litigation.

Patent Annuity Fees

One of the most challenging issues related to patent protection in Indonesia over the past few years has been the collection by the Directorate General of Intellectual Property (DGIP) of outstanding patent annuities or "debt" for abandoned patents.

Before the new Patent Law, back annuities were due within one year from the issue date. A 2.5 percent penalty fee was applied to late payment for each month from the due date. The fee for late payment could be paid up to three years from the due date. If the annuity payment was not made within three consecutive years, the patent would be deemed null and void.

In addition, if the patent had been abandoned passively or by way of non-payment of the annuity, a patent holder would still have an obligation to pay the outstanding patent annuity fees. This is because the three years of annuity fees which had not been paid were considered as debt owed to the DGIP. To avoid having to pay the remaining annuity fees, the patent holder had to file a petition to abandon the patent before the annuity due date.

The amendments have improved these issues. A patent holder is no longer obligated to pay the outstanding annuity fees. Additionally, the back annuity fee payment must now be made within six months from the issue date, and failure to pay will result in the patent being deemed null and void. However, a dispensation will be given to a patent holder who has requested a grace period for the annuity payment to the DGIP within 12 months from the time limit of the back annuity fee payment. This request must be filed in writing within seven days before the deadline of the payment of the back annuity. There is a 100 percent penalty fee of the total amount of back annuity fees.

Statement of Ownership

There is now a requirement to submit a Statement of Ownership of an invention, signed by the applicant, when filing a patent application. This requirement was already in place for trademarks and industrial designs, and so this amendment brings patent registration procedures in line with standard practice.

Genetic Resources and Traditional Knowledge

The amendments require inventions related to and/or derived from genetic resources or traditional knowledge to clearly stipulate the origin of the genetic resources or traditional knowledge in the description. This provision is designed to support Access Benefit Sharing, which refers to how genetic resources are accessed and benefited from.

Patents as Fiduciary Objects

The new Patent Law allows patents to be used as fiduciary objects, such as a guarantee between a debtor and a creditor. Under the previous law, patents could not be used for this type of securitization.

Online Filing

Under the amendments, an online filing system will be introduced to allow applicants to file patent applications on the Internet. At present, an applicant can only file a patent application manually at the DGIP's office. An online system will simplify the administrative procedures involved in filing a patent application, which should encourage applicants to file a greater number of applications.

Summary

Based on the above, many of the changes under the new Patent Law provide much-needed procedural improvements in Indonesia. For example, the expanded authority of the Appeal Commission provides the opportunity for post-grant oppositions, which is an alternative route to costly and time-consuming invalidations in court. The government has also done well to address the problematic issue of what had previously been deemed "debts" arising from abandoned patents.

While most patent owners will be pleased with these changes, pharmaceutical innovator companies may have concerns about some of the new provisions and their implications. The newly introduced exemptions from infringement, the prohibition on second use medical claims, and the possibility of expanded compulsory licenses could all present challenges for pharmaceutical patent holders.

Given that these amendments are coming into effect on August 28, patent holders will need to ensure that they fully understand the new requirements, review their portfolios, and consider the impact of these changes on any upcoming patent applications.