April 2018

Global Patent Prosecution Newsletter

Sterne Kessler Goldstein Fox
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A U.S. Perspective on Global Strategy

Patents and a New Patent Linkage System in Taiwan

Patent protection in Taiwan is becoming of ever-increasing importance as the country's economic influence grows worldwide. The April 2018 issue of Sterne Kessler's Global Patent Prosecution Newsletter includes information on patents and patentability in Taiwan, as well as a proposed patent linkage system for pharmaceutical products.

Sterne Kessler's Global Patent Prosecution Newsletter is designed to help meet the needs of biotech/pharmaceutical companies regarding global patent prosecution strategies. For more information, please contact Paul Calvo or John Covert. If you wish to unsubscribe from this and other newsletters, please click on the unsubscribe link below.

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In this issue

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Patents and Patentability in Taiwan

By: Paul A. Calvo, Ph.D. and Miklos Gaszner, Ph.D.

Patent protection in Taiwan has increased in importance as the economic relationship between the US, Europe, and Taiwan has grown. According to the United States Trade Representative, Taiwan is currently our 10th largest goods trading partner with $65.3 billion in total (two way) goods traded during 2016. Goods exports totaled $26.0 billion, while goods imports totaled $39.3 billion. As for Europe, Taiwan is the European Union's (EU) seventh largest trading partner and EU exports to Taiwan totaled € 16.5 billion while EU imports from Taiwan totaled € 22.1 billion.

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Hatch-Waxman goes to Taiwan

By: Miklos Gaszner, Ph.D. and Paul A. Calvo, Ph.D.

In December 2017, the Taiwan Pharmaceutical Affairs Act has been amended to harmonize generic approval process with prevailing international norms. The amended Act is expected to come into effect in late 2018 or early 2019. As discussed below, the amendment (1) introduces data exclusivity periods for new chemical entities and new/ changed indications of previously approved drugs, and (2) establishes linkage between the approval of generic drug applications and the patent status of the originator product. The new Taiwanese system is very similar to the Hatch-Waxman Act governing U.S. generic approvals.

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It is important to remember that Taiwan is not a member of the World Intellectual Property Organization (WIPO) and has not signed on to most WIPO-administered agreements, but Taiwan has bilateral intellectual property related agreements and memorandums of understanding with a number of countries, including the U.S. and EU. Even though Taiwan is not a contracting state to the European Patent Convention (EPC), or the Patent Cooperation Treaty (PCT), a foreign applicant can still claim priority to a first-filed EPC or PCT application in a later-filed Taiwanese application. Taiwan is not a PCT member, the 30-month timeframe for national phase entry is not applicable with regards to Taiwan. Instead, a Taiwanese national application must be filed within 12 months from the earliest filing date to appropriately claim priority. Taiwanese patent applications can be filed in a language other than Chinese. However, a Chinese translation printed in traditional Chinese characters must be submitted within a specified period. According to the Implementation Regulations Governing Foreign-language Patent Applications, the languages currently accepted are Arabic, English, French, German, Japanese, Korean, Portuguese, Russian and Spanish.

There are three types of patents in Taiwan: Invention, Utility Model, and Design. Invention patents are what most practitioners have come to recognize as traditional patents and are granted to the creation of new and useful products and technologies. As with other patents worldwide, an Invention patent provides 20 years of protection (subject to payment of annual maintenance fees) from the date of filing. As for patentable subject matter, animals, plants, and essential biological processes for the production of animals or plants, except for processes for producing microorganisms, are NOT patentable in Taiwan. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals are also NOT Patentable in Taiwan. An article that is detrimental to public order, morality, or public health is also NOT patentable. In general, the application process takes between 24 to 36 months for prosecution of an Invention patent.

A Utility Model patent protects inventions, such as innovations relating to shape or structure, that are considered to have a lower degree of inventiveness than is required for Invention patents. Utility Model patents provide only 10 years of protection from the date of filing. Since Utility Model patents

are not examined as rigorously as Invention patents, Utility Model patents are generally granted more quickly than Invention patents.

A Design Patent is an article created, wholly or in part, for visual appeal through the use of shape, pattern, color, or any combination thereof. This includes computer-generated icons and graphical user interfaces. Design patents last 12 years from the date of filing.

The opposition system in Taiwan was abolished in 2004, although third-party observations stating why the patent should not be grated can be presented during the examination procedure. Thus, the only way to a challenge a granted Taiwanese patent is through the invalidation procedure. The Intellectual Property Court (IP Court) deals exclusively with matters relating to IP rights. Judges on the IP Court have expertise in hearing IP cases with some also having a technical background. Technical examination officers act as technical assistants to the judges. The examination officers are mostly senior examiners of the Taiwan Intellectual Property Office (TIPO) with technical backgrounds and experience in patent examination. And similarly to the U.S. system, infringement and validity issues are adjudicated simultaneously.

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Data exclusivity periods

New chemical entities are given 5 years of regulatory data exclusivity, the first of 3 years of which are absolute regulatory exclusivity. Thus, during the first three years following the approval of marketing authorization for a new chemical entity, the Taiwanese Food and Drug Agency (FDA) is barred even from accepting a generic drug application citing data submitted by the reference drug's sponsor in support of its request for original registration and marketing authorization. During the last two years of regulatory data exclusivity, the Taiwanese FDA can accept but cannot approve a generic application.

The registration and approval of a new or changed indication for an already marketed drug entitles the marketing approval holder to 3 years of regulatory data exclusivity, the first two years of which are absolute exclusivity barring the Taiwanese FDA from accepting a generic application listing the new or changed indication. To help domestic clinical research, the regulatory data exclusivity based on new indications is extended to 5 years if the reference holder conducts clinical trials on the new or changed indications in Taiwan.

Patent Linkage – Listing of Patents

The amended Act also authorizes the central health authority to establish a database for publishing patent information related to Western pharmaceuticals. Taiwanese law does not distinguish small molecule drugs and biologicals. Thus, unlike in the U.S., the patent linkage system will be the same for both types of molecules.

New drug marketing approval holders will have the option of reporting and listing information on patents related to the new drug or indication if the information is provided to the central health authority within 45 days from receipt of the marketing approval. The patent linkage provisions of the new legislation will not apply if the reporting is completed after the 45-day period. Patents related to compounds, compositions, formulations, and medical or pharmaceutical uses can be reported and

listed. The information that must be provided for the patents varies with the claimed subject matter in that the specific claims directed to an authorized medical or pharmaceutical use must be identified. The approval holder also must identify the patentee, and where applicable, the exclusive licensee.

Third parties will have the right to challenge the listing of a patent in the database. And the marketing approval holder will be required to answer any challenges in writing. Both the challenge and the response will be published in the database.

Patent Linkage – Generic Approval

The amended Act also establishes a framework for resolving disputes related to the listed patents between the generic applicant and original marketing approval holder. Similar to under Hatch-Waxman in the U.S., a generic applicant is required to make one of four possible certifications regarding the listed patents:

1. No patent information has been listed for the approved drug;
2. The patent has expired;
3. Generic approval shall be issued after the expiration of the patent; or
4. The patent is invalid or is not infringed by the generic drug.

The generic applicant is required to notify both the marketing approval holder and the central health authority of the certification. If a certification under 4 is made, the notice also must provide evidence showing that the listed patent is invalid or is not infringed by the generic drug. Upon receipt of the notice, the marketing approval holder has 45 days to initiate patent infringement action on the listed patent. The receipt of the notice by the marketing approval holder also triggers a 12-month suspension of the approval of the generic drug application.

The central health authority may approve the generic application during the 12-month suspension period under certain circumstances. These include the failure by the marketing approval holder to initiate patent infringement action based on the listed patents within the 45-day period, failure by the marketing approval holder to initiate patent infringement action based on patents that have been listed prior to the filing date of the generic application, a final determination that the asserted patents are invalid or are not infringed by the generic drug, and a settlement by the marketing approval holder and the generic applicant.

To encourage generic challenges, the amended Act grants a 12-month exclusive marketing term to the first generic applicant to have filed a complete application with a certification that the listed patent(s) is invalid or is not infringed by the generic drug. Where there are two or more generic applicants to have filed a complete application, they will be jointly granted the 12-month exclusive marketing term.

The amended Act also allows generic applicants to carve out indications that are protected by a listing patent. The approval of a generic application that carves out indications to avoid infringement of a listed patent(s) will not be suspended by the central health authority. And the generic applicant that carves out protected indications will not be eligible for the 12-month exclusive marketing term.