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Intellectual Property Linkage: Connecting IP Offices with Regulators

Intellectual property (IP) linkage refers to connecting an IP office, through open communication lines and complementary processes, to other government agencies that work on IP. This generally includes agencies tasked with regulating food, drugs, and agricultural products, in order to ensure not only that there is proper communication between the officials of both agencies, but also that each agency's regulations are in line with one another, and the agencies do not promulgate conflicting requirements. IP linkage is also useful in suppressing IP infringement, especially when health regulators work closely with IP offices.

Subcommittee to Suppress IP Infringement

The Suppression of Intellectual Property Infringement Subcommittee was set up earlier this year in Thailand to resolve issues related to preventing IP infringement, reduce problems for IP rights holders, increase IP protection in accordance with international standards, and improve Thailand's image as an IP-friendly country (a particularly important undertaking, as Thailand has been listed on the U.S. Trade Representative's Priority Watch List for the past several years for providing insufficient IP protection).

The agencies that are part of the Subcommittee include the Thai Food and Drug Administration (FDA) and 15 other government agencies. Their inclusion in the Subcommittee is a clear indication that the government has recognized the importance of linkage between intergovernmental agencies that work on IP. The next agency to be added to the Subcommittee should be the Ministry of Agriculture, in order to ensure that agricultural inputs, animal health, and new plant variations are adequately protected.

IP Linkage with Health Regulators

There are many examples of IP linkage around the world. For instance, the National Intellectual Property Rights Coordination Center (IPR Center) in the United States is composed of 23 partner agencies, of which 19 are federal agencies and 4 are foreign agencies (Interpol, Europol, and the Canadian and Mexican governments). The IPR Center is structured as a cohesive task force, in order to allow resources and skills to be pooled and leveraged, and to foster the sharing of information.

There is also a patent linkage system in the United States. When filing a New Drug Application with the U.S. FDA, an applicant must list any patents that cover the drug. The FDA will take these existing patents into consideration when reviewing the application, and if a patent exists, marketing approval will not be granted to a generic applicant unless and until the patent expires or is found invalid.

In the European Union, the EU Agencies Network is comprised of various agencies across EU member states, including the EU Intellectual Property Office. It promotes the sharing of information and expertise among these agen-

cies. While the EU does not have a patent linkage system in place, generic drugs are still not allowed to be placed on the market until an existing patent expires. The EU also provides a period of data exclusivity, during which no other company may use the patent holder's pre-clinical and clinical trials data in their regulatory filings for a generic version of a patented drug substance for a set amount of time. The EU also provides patent holders with a two-year period of market exclusivity, meaning that a generic drug company cannot market an equivalent generic version of an original product, but can instead submit an application for authorization so that they can begin marketing their generic product once the two years have expired.

Thailand has begun to provide linkage between the Department of Intellectual Property and the Thai FDA, but the system is in a very undeveloped stage. Since 2008, the Thai FDA has imposed a requirement on all applicants that are applying for a new drug to fill out a form listing all of their existing patents. While this is a step in the right direction, this type of mandatory disclosure should be enforced on applications for generic drugs, as infringement is most likely to occur with such drugs.

Thailand – Going Forward

Thailand can look to Singapore, its regional neighbor, for guidance on moving forward. After entering into a free trade agreement with the United States, Singapore introduced patent linkage as one of the requirements in an application for marketing approval. This system allows patent owners to monitor for potential infringement before generic drugs are launched by providing a framework that warns a patent owner any time a competitor's application is submitted to market the same drug.

This framework is provided under Singapore's Medicine Act. Under the Act, in order for applicants to obtain a product license, they must declare whether or not a patent is currently in force for the medical product that is the subject of the application. If there is a patent in force, the applicant needs to state that the patent is invalid. However, if the applicant cannot state that the patent is invalid, a notification may be sent to the patent holder to give the holder an opportunity to obtain a court order against the generic company's launch of the drug. This is an example of successful linkage between an IP regime and health regulators—one which allows for better protection of patent holders' rights.

This type of linkage should be implemented in Thailand, particularly in the pharmaceutical industry. Thailand should implement a system of patent linkage in which generic drug applications must include patent information. If any patents that cover the drug exist, marketing approval for a generic drug should not be granted until the patent in question has expired or been found invalid. Such a system will better protect IP rights and reduce the risk of infringement.

Thailand Network Information Center

In Thailand, one instance in which linkage has been successfully implemented involves the Thailand Network Information Center (THNIC), which handles country code top-level domain names. In order to obtain a country code top-level domain name from THNIC, an applicant must confirm one of two things: (1) they are a business registered under that name in Thailand; or (2) they have a registered trademark in Thailand that uses that name.

THNIC is an example of well-implemented IP linkage and providing another means of enforcing IP rights. THNIC is a sign that steps have been taken in the right direction, but there is still more work to be done to link up more agencies and protect IP rights. 🦋