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Patent Linkage Case Studies

Patent Linkage is shorthand for the communication that takes place between the Health Ministry and the Patent Office to prevent patent infringement, i.e., to provide marketing approval of generic drugs only upon the expiration of patents covering the drug product or approved use. This paper provides brief summaries of a number of linkage systems employed by WTO Members, in different geographic regions and at varied stages of development.

Common Elements of Patent Linkage

WTO member countries have implemented a variety of approaches to "to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, [or] selling" copies of patented products, as required by WTO TRIPS Article 28.1(a). Because final marketing approval for highly regulated products like pharmaceuticals generally rests with the Ministry of Health of a WTO member state, this necessitates communication between the Patent office and the Ministry of Health to prevent marketing approval of products that infringe existing patents.

Successful linkage systems share a number of common elements:

- WTO Members may provide a publicly available database of patents relating to pharmaceutical products, published by the Industrial Property/Patent Office. This database then serves as a resource for both Ministry of Health officials and applicants seeking marketing approval of new products. The health regulatory authorities also may provide a database of all applications for marketing approval (i.e., new product registration) to provide transparency in the drug registration process.

- In a number of WTO Member linkage regimes, applicants seeking regulatory review and marketing approval for new products must certify that their product does not infringe patents currently in force, and must notify the right-holder if the applicant intends to challenge the validity of an existing patent.

- Health regulatory officials may either bar entirely the submission of new applications for products where there are existing patents in force, or, in the alternative, may accept applications and delay final marketing approval until the expiration of relevant patents.

Patent Linkage In Operation

Following are snapshots of patent linkage regimes implemented by WTO Members in countries at varied stages of economic development (outside the U.S. and Europe) to meet their TRIPS obligations. These summaries are intended to help identify options for policy makers seeking to implement an effective system of patent linkage; they are neither exhaustive nor comprehensive.

- **Australia:** *Health authorities may not provide marketing approval for a generic copy which would infringe an existing patent; the applicant must declare if the product would infringe an existing patent and must notify the right holder.*

  Under Australia's Therapeutic Goods Act 1989, as amended, an applicant seeking registration (or listing) for a medicine ("therapeutic goods") must certify that the application for approval would not involve the marketing of a product in such a way as to infringe an existing patent. In the alternative, the applicant must certify that if there is a valid patent, and if the applicant seeks to market the medicine before the end of the patent term, and that the applicant has provided notice to the patent-holder of the application for registration of the medicine. There also is a serious penalty imposed for false or misleading statements made under this provision by applicants for marketing approval.

  Source: Government of Australia Therapeutic Goods Act, 1989, Section 26B

- **China:** *The State Food and Drug Administration (SFDA) has implemented a database of new product registration files to ensure that it will not issue marketing approval for a product that infringes an existing patent; the applicant must declare if the product would infringe an existing patent and SFDA must notify the right holder.*

  On January 1, 1993, China established a system for administrative protection of patented pharmaceutical products for new chemical entities (NCEs) that has since been replaced by the obligations of the WTO TRIPS Agreement, and a 20-year patent term for drugs and other eligible inventions. Since China's accession to the WTO, the State Food and Drug Administration (SFDA) has had responsibility for maintaining China's patent linkage system, in coordination with the State Intellectual Property Office (SIPO).

  The SFDA maintains two separate tracks by which it provides patent linkage for compound/composition patents:

- The SFDA requires all applicants for marketing approval to check patent status prior to making an application, and to certify that its product does not infringe any existing patents. The applicant also is required to acknowledge liability for damages resulting from any future finding of patent infringement.

- The SFDA also maintains a database of all drug registration applications, as well as a list of all approved registrations. The SFDA lists registration applications by chemical name. The SFDA list is available for frequent inspection by patent holders to check whether there are applications for marketing approval for new products that may infringe an existing patent. The patent-holder then notifies the SFDA in writing of potential infringement. When the SFDA receives written notice from the patent-holder, the SFDA notifies the applicant, and this generally will result in withdrawal of the application. In the alternative, it provides the right-holder with transparency and an opportunity to seek civil remedies.

Sources: China Drug Registration Regulation, May 1, 2005 Effective, US-China Joint Commission on Commerce and Trade, Medical Device and pharmaceutical Subgroup, Pharmaceutical Task force Meeting, Agusut 20, 2005, Beijing, China.

- **Jordan**: *Marketing approval for pharmaceutical products is not provided during the period of exclusivity (data exclusivity or patent protection).*

Since its accession to the WTO in December of 1999, the Government of Jordan has instituted and maintained a system of patent linkage that prevents registration of copies of pharmaceutical products subject to patent protection or data exclusivity without permission of the right-holder. Until implementation of Jordan's new TRIPS-consistent patent law in early 2000, it was not possible to gain effective patent protection for pharmaceutical products in Jordan. In the 1980s and 1990's the Ministry of Health routinely approved marketing applications for infringing products, and Jordan led the region in exports of copy-products. The change in policy in Amman has been profound and consistent. The practical impact of the linkage policy has been to prevent marketing of copy-products during the five-year period of data exclusivity for innovative pharmaceutical products (for which patents were not available in Jordan before 2000).

In October, 2002, the Jordanian Minister of Health clarified the Jordanian policy, pointing out that there would be no acceptance of dossiers for marketing approval during the period of data exclusivity. An application for a new medicine for marketing approval will be accepted by the Ministry of Health for marketing approval only if the new drug produced by a local manufacturer is "similar but not the same as a patented one," ie. not covered by patents or data exclusivity. Jordan's

strong intellectual property regime has been a critical factor in its economic development.

Sources: WTO Working Party Accession Agreement, Letter by H.E. Mohammad Halaiqah, Deputy Prime Minister, Hashemite Kingdom of Jordan, October 24, 2000, also, "Health Ministry reiterates the stringent standards for local pharmaceuticals," Dina Al Wakeel, The Jordan Times, October 23, 2002, p. 3.

- **Mexico:** *Health regulatory authorities will not grant marketing approval to any applicant for a product that would infringe on an existing patent for a substance or active ingredient.*

  Since late 2003, Mexico's industrial property office, known as IMPI, established a practice of publication of patents through a special Gazette listing patents and their chemical, non-proprietary names (INN). The Gazette includes patents on substances or active ingredients.

  In addition to the publication of patents by IMPI, applicants for marketing approval of product registrations relating to "substances or active ingredients" are obligated to indicate to health regulatory authorities whether or not they they are the patent-holder or licensee for any existing patents relevant to the product. If the applicant does not have a patent or a license, they must provide a declaration, under oath, that the application does not infringe the rights of the patent holder.

  Health authorities work with IMPI (over a ten day period) to determine the patent status of the product for which there is a pending marketing application. If the search indicates that there is a valid patent that would be infringed, the Ministry of Health will give the applicant an opportunity to demonstrate that it in fact has the rights to the product. In the alternative, the Ministry of Health will reject the application. International pharmaceutical companies have had a positive experience with the Gazette, and have found that where a patent is listed in the gazette, the Ministry of Health has not provided marketing approval for a new product that would infringe an existing patent.

  Source: Presidential Decree, Diario Official, 19 September 2003, p. 99

- **United Arab Emirates (UAE)**: *Health Regulatory Authorities will not provide marketing approval for pharmaceutical products that remain under patent protection in the country of supply*.

  Under U.A. E. Ministry of Health Decree 404, it is not permissible for an applicant to receive marketing approval for a product that would infringe on an existing patent in the country of supply of the product. In operation, Ministry of Health

officials will either reject such an application, or will hold the application in abeyance until such time as the patent protection in the country of supply (i.e. the country from which the product is imported) has expired. In practice, this system has provided durable protection for proprietary products and prevented patent infringement by unauthorized copy-products. Like Jordan, the UAE has changed from an exporter of infringing products to a country that maintains high standards of protection of industrial property, and has attracted investment and jobs through linkage and other improvements in intellectual property protection.

Source: United Arab Emirates Cabinet Declaration No. 404 issued in 30 April 2000, Abu Dhabi, UAE.