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SUMMARY OF THE STUDY ON PHARMACEUTICAL PATENTS IN CHILE

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1. The Annex to this document contains a summary of the Study on Pharmaceutical Patents in Chile prepared under the Project on Intellectual Property and Socio-Economic Development (CDIP/5/7 Rev.) approved by the Committee on Development and Intellectual Property (CDIP) in its fifth session, held in April 2010.

2. *The CDIP is invited to take note of the information contained in the Annex to this document.*

[Annex follows]

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EXECUTIVE SUMMARY

Historically, pharmaceutical patents are among the most controversially debated issues with regard to intellectual property (IP) protection, especially in developing countries. During the negotiations of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, pharmaceutical product patents represented one of the most divisive issues, being opposed by developing countries because of concerns that stronger patent protection would hinder access to drugs and prevent the development of a domestic pharmaceutical industry. The TRIPS agreement forced developing members of the WTO to grant patents with a statutory lifetime of 20-years from the patent application also to pharmaceutical compounds. Almost two decades after TRIPS, the empirical evidence on its effect on developing countries is at best mixed (see Section 2 below).

Despite the strengthening of IP protection brought about by TRIPS, many developing countries continue to apply a more restrictive approach than developed countries to the granting of pharmaceutical patents. While TRIPS requires the availability of patent protection for processes as well as products in “all fields of technology” (TRIPS Article 27.1), the agreement provides countries with substantial freedom to define the standards of patentability.² Some developing countries, most prominently India, have used this freedom to restrict the granting of so-called secondary pharmaceutical patents.³ As opposed to primary patents which protect directly an active ingredient, secondary patents protect a range of chemicals related to an active ingredient (such as crystalline forms of the original compound), methods of use, formulations, dosages, etc.). Other developing countries, such as Brazil and South Africa, are currently debating new legislation that would emulate India’s approach to restricting the patentability of secondary patents.⁴

The sparse, available evidence on secondary patents, which focuses on the U.S. and the European Union (EU), offers some evidence on the use of secondary patents by originator companies. Empirical and anecdotal evidence suggests that pharmaceutical originator companies use secondary patents extensively in those markets. There is also some evidence that secondary patents can be used to extend patent protection on a given drug in length and breadth and it may create legal uncertainty over the scope of patent protection of a drug. That said, secondary patents can be used to protect genuine follow-on innovation, although distinguishing strategic use of secondary patents from their use to protect follow-on innovation is very difficult.

Despite the widespread use of secondary patents and the current contentious policy debate, there is little evidence on their effect in developing countries. We document the use of primary and secondary patent by multinational originator companies in Chile.

From a data point of view, studying this question is challenging because it requires not only a distinction between primary and secondary patents, but also a mapping of patents to active ingredients and the corresponding pharmaceutical products. Linking patents to active ingredients is an enormous challenge because there is usually no explicit mentioning in the patent claims of the active ingredient contained by a drug.

² TRIPS Article 27.3(a) allows countries to exclude therapeutic and diagnostic methods from patentability, which offers another legal justification for excluding new uses of existing drugs from patentability.

³ Section 3(d) of India’s Amended Patents Act of 2005 excludes from patentability the “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

⁴ In Brazil, Article 3 of Bill No. H.R. 5402/2013 proposes to explicitly exclude new uses and new forms of existing medicines (including salts, esters, ethers, polymorphs, metabolites, isomers etc.) from what is considered an invention. South Africa’s Draft National Policy on Intellectual Property released in 2013 proposes similar provisions.

We address this problem in three ways. First, we rely on the Orange Book of the U.S. Food and Drug Administration (USFDA) to identify U.S. patents on the compounds registered in Chile. We then construct patent families for these U.S. patents and verify whether there are any Chilean equivalents (regardless of whether the Chilean patent has been granted). Similarly, we undertake the same exercise using the Merck Index, which provides information on patents worldwide. Second, we use a dataset compiled by the Chilean Intellectual Property Office (INAPI) that contains the compound-patent mapping for all new compounds registered in Chile between 2005 and 2010. Third, we asked experts in pharmaceutical patents in Chile to match directly the remaining set of all granted Chilean patents to the complete list of drugs registered with the Chilean health authorities.

Because companies can obtain competitive advantage also through brand recognition, we also match the pharmaceutical product-level data with trademark data. The mapping of drugs and trademarks is more straightforward than that of drugs and patents. The trademark database contains trademarks classified by field of use such as pharmaceuticals, health, etc. The pharmaceutical product data provides the names under which drugs are marketed, which we use to search for in our trademark database.

For the matching of patents and trademarks, we rely on a dataset that contains the universe of patent and trademark applications filed with the Chilean Patent Registrar between 1991 and 2008 and with its successor, INAPI, in 2009 and 2010. It includes all patent applications and trademark applications by domestic as well as foreign entities. The pharmaceutical product data comes from the National Public Health institute (ISP). The institute maintains a database that links all registered drugs in Chile to the pharmaceutical compounds that they contain. The database also contains additional information on the drug (e.g. when it was registered), the owner of the drug, whether the drug is produced domestically or abroad. We use the bridge between compounds and drugs contained in ISP's database to link patents and trademarks at the product-level. Patents are linked to active ingredients whereas trademarks are linked to drugs.

Of 12,116 unique products registered at the ISP, 3,709 match to at least one Chilean patent, whereas 9,273 match to at least one Chilean trademark. After cleaning and translation of the active ingredients (including some standardization of names), there are far fewer active ingredients than products, as one might have expected. Of the 2,630 distinct active ingredients (many of which are common chemical compounds, that is, generics – for example vitamins), 322 match to at least one Chilean patent (504 distinct patents) and 2,630 match to at least one Chilean trademark (10,461 distinct trademarks). Overall 82 per cent of the products and 91 per cent of the active ingredients are associated with some form of IP protection, more often trademark than patent.

When we examine the ownership of this IP, we see striking differences in the regional patterns. The data show that almost all the patent filings are by entities based in Europe and the U.S., with the exception of a small increase in Chilean-origin filings during the most recent period. The total share of Chilean-origin filings is less than two per cent of total pharmaceutical patent filings, and none of these filings match to active ingredients in the ISP registration data. In contrast, over half the trademark filings are by Chilean entities, with the other half largely from Europe and the U.S.

A close examination of the ISP registrants makes the reasons behind this phenomenon clear. Chilean firms do almost all of the importing, distributing, quality control, and local packaging of the drugs, whereas foreign firms are the source, licensor, or foreign packagers. Manufacturing can be done in either location. However, it is fairly clear that foreign firms are the source of originator drugs and therefore hold almost all of the patents, whereas marketing and distribution as well as the production of generics is the province of the Chilean registrants, who therefore hold a large number of Chilean trademarks.

Of the 504 Chilean pharmaceutical patents that match to our list of active ingredients, 113 (22%) were identified as primary patents, with the remaining 78% being secondary. This ratio of 1:4 is significantly lower than the ratio of 1:7 found by the pharmaceutical sector inquiry of the European Commission. If we look at all granted patents regardless of whether they have matched to a product registered at the ISP, we find that there are more primary than secondary patents. Of course, this may simply reflect the fact that secondary patents are more often rejected by the patent office precisely because they do not cover a new active ingredient.

The 504 matched patents are associated with 322 of the 2,630 active ingredients. Of these active ingredients, slightly more than one third (185) have at least one primary patent. In about half the cases (89 or 48%), the associated primary patent is the first patent on that ingredient, but in the remaining cases, there is a secondary patent preceding the primary patent.

To investigate the timing between a Chilean patent application and the first associated ISP registration, we computed the lag between the two, which shows that the great majority (86%) of the primary patents are applied for before the first time the associated ingredient is registered at the ISP. In contrast, only 56% of the secondary patents are applied for before the initial ISP registration. The median lag for primary patents is 6 years and for secondary patents it is 2 years. In a number of cases, the lags are over 5 years, which suggests delayed entry into the market.

Our study contributes to the sparse empirical literature on the use of secondary patents, in particular by foreign multinationals. It offers in particular for the first time empirical evidence on the use of secondary patents in Chile.

[End of Annex and of document]