At FTA Commission, U.S. Presses Chile On Brand Name Drug Protections

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The United States this month again pressed Chile to strengthen the system by which patent owners can challenge the approval of allegedly infringing generic pharmaceuticals to be sold in that market, and its protection of test data used to demonstrate the safety and efficacy of drugs against use by generic companies, according to a U.S. trade official.

Both issues came up an Aug. 2 meeting of the U.S.-Chile Free Trade Commission, which reviewed the functioning of the bilateral free trade agreement. But it is unclear to what extent the Chilean government is heeding the U.S. demands, according to sources on both sides of the issue.

"We've been encouraging them to implement the commitments they made under the [free trade agreement] to provide an effective system to address patent issues expeditiously in connection with the applications to market [pharmaceutical] products," the U.S. trade official said in an Aug. 17 interview with Inside U.S. Trade.

The U.S. trade official also said the U.S. pressed Chile to provide "adequate" protection for pharmaceutical data at the Aug. 2 meeting.

The U.S. pharmaceutical industry has also complained that once data used to determine the safety and efficacy of new drugs are disclosed -- either in part by the data owner itself, or by foreign health authorities -- the Chilean government does not guard against other companies using the data to sell generic products.

Under the FTA, Chile is supposed to protect proprietary pharmaceutical test data against unfair commercial use during the five-year "data exclusivity" period from the time a drug is approved, the industry group PhRMA has said.

One business source said that officials from the Office of the U.S. Trade Representative came away from the meeting in Santiago feeling "optimistic" that Chile will make the challenge process more efficient, and told USTR it would seek to boost data exclusivity protection in a package of legislation to be submitted this year.

He noted that the administration of Chilean President Sebastian Pinera seems more open to changes in its intellectual property rights (IPR) regime as part of its effort to be removed from the "priority watch list" established under the Special Section 301 law. This point was echoed by PhRMA in its latest Special Section 301 submission and USTR in its 2011 Special 301 report.

But the business source noted that actually getting the changes the U.S. is seeking through the Chilean Congress would be difficult because the government's party is not in control of the legislature.

Some supporters of the changes sought by brand name drug companies point to the Chilean government's establishment of an inter-ministerial committee on IPR in 2010 as an example of the Pinera government's openness to their demands.

According to PhRMA's submission in the Special Section 301 process, this committee is charged with proposing an amendment to Chile's industrial property law to establish "an effective patent enforcement mechanism."

However, Alberto Cerda Silva, a law professor at the University of Chile based in Washington, said that the inter-ministerial body has a broader scope, and is currently focusing on other issues like how to prevent the circumvention of "digital locks," a separate U.S. complaint.

He also claimed that the Chilean government -- at least officially -- does not care whether it is on the priority watch list, and still does not believe it has to do more to protect pharmaceutical patents in order to fulfill its FTA commitments.

Silva noted that Chile has already established a special tribunal on intellectual property that only handles patent and trademark cases, which has improved the efficiency in resolving such disputes. This tribunal functions just like a court, he noted, and parties who are found to have infringed a patent must generally pay damages.

But a Chilean brand-name drug industry source said this week that the process is still too slow -- taking somewhere between one and three years -- and complained that copycat generic drugs can be sold on the market during that time, hurting a brand-name drug's market presence.

Access to medicines advocates say that barring the marketing of generics until a patent dispute is resolved would lead to abuse of the system and keep drug prices high. One source said that if Chile is considering such a change, it would be especially worrisome in light of its participation in the Trans-Pacific Partnership negotiations.

Some members of Congress have joined access to medicines groups in pushing for USTR to adopt the standards of a May 10, 2007 agreement on IPR in the context of those nine-nation trade negotiations, which would allow developing countries like Chile to opt out of patent linkage and limit patent extensions.

The U.S. pharmaceutical industry has been aggressively lobbying against the May 10 deal being applied to TPP, and USTR is expected to table its IPR chapter in the next round of the negotiations in September (Inside U.S. Trade, Aug. 5).

Since the U.S. and Chile entered into an FTA in 2004, the pharmaceutical IPR provisions have been a major bone of contention. Although the United States has never explicitly charged that Chile is violating the FTA, it has long hinted that the country must do more on IPR in order to live up to its commitments under the deal.

At the root of the tension lies a difference in interpretation of the wording of Article 17.10.2 of the U.S.-Chile FTA. It states that both parties must "make available to the patent owner the identity of any third party requesting

marketing approval effective during the term of the patent," and "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner."

Chile traditionally has claimed it is in compliance with that language because it allows patent owners to challenge allegedly infringing products in court. Chilean officials have also argued that Chile does not grant "marketing approval," but instead simply certifies the safety of drugs by issuing applicants a "sanitary permit" (Inside U.S. Trade, March 11, 2005).

PhRMA, however, has long claimed that the granting of a sanitary permit represents de facto marketing approval. In its Special 301, PhRMA claimed that to comply with Article 17.10.2, Chile must "establish mechanisms to prevent the marketing of patent infringing products" – a system known as patent linkage.

"This is not satisfied by enabling a patent-holder to defend itself, after a third party has requested and received a sanitary registration/marketing approval and marketed an infringing product," PhRMA added.

Access to medicines advocates say that regulators in developing countries that approve drugs for sale do not have the resources to coordinate with their patent offices and determine if an applicant generic drug is infringing on a patent.

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