Dominican Republic: December 2009 meeting between PhRMA and US Embassy to discuss CAFTA+ demands on patent protection

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Among other things, the cable illustrates the degree to which USAID is asked to advise developing countries on ways to enhance patent protection in ways that benefit foreign pharmaceutical companies, at the expense of local consumers and generic drug manufacturers.

The **Dominican Republic** has a population of 10.1 million, a 2010 per capita income of $4,570, and is located on the island of La Hispaniola, where it shares a border with Haiti.

In 2004, the United States signed the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR) with five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua) and the Dominican Republic. According to USTR "the CAFTA-DR is the first free trade agreement between the United States and a group of smaller developing economies."

Lampert often reports the Dominican Republic government "is observing the letter, but not the spirit, of DR-CAFTA." That is to say, the Dominican Republic is expected by PhRMA and the US government to do more than what the agreement actually says, sort of an instant CAFTA+, in favor of the foreign drug companies. *(Note: In a July 30, 2004 cable, the US Embassy wrote: "In March 2003, the GODR made regulatory changes to the patent law that appears to bring the law into compliance with TRIPS.")*

Domestic generic manufacturers are described as the "domestic drug-pirating industry," even though they are described as operating withing the DR law.

The local industry association is represented both by local drug company managers and lobbyists, and by Mary Fernández Rodríguez, of the firm Headrick Rizik Alvarez & Fernández. Novartis, the giant Swiss pharmaceutical company, took a lead role in the meeting.

Much of the discussion beetween the Embassy and big drug companies centers around the processes for obtaining patent protection in the DR, and the linkage between patent status and drug registration. On the one hand Novartis and other companies complain about the failure of the DR to grant drug patents, while at the same time, they assert that patents are not being enforced aggressively enough.

Here are a few highlights from the cable:

- On December 2, the ChargC), PolEcon Counselor, and EconChief met PhRMA (the Pharmaceutical Research and Manufacturers of America), Fedefarma (La Federación Centroamericana de Laboratorios Farmacéuticos), Novartis, and Merck as well as Mary Fernández Rodríguez, the group's local counsel.
- The meeting began with the Novartis representative observing that the DR was a critical market for the pharmaceutical industry, not necessarily in proportion to its market share but due to its important role as a Free Trade Agreement (FTA) partner of the United States. The industry would like to use successful cooperation with the DR as an example to encourage other countries throughout Latin America to follow its lead (and not the lead of the "Venezuelas and Bolivias").
- The group informed us that the average wait time for a patent request in the U.S. is three years; in Guatemala - one of the countries lauded by the group for its efforts - it takes three to four years, while in Argentina it takes seven to eight years.
- Of the 700-plus patent requests lodged to date by the pharmaceutical industry, only ten to 15 have been approved in the last decade and none has been approved this year. The process is complicated by both a Dominican Supreme Court ruling and a law passed in 2000 that ban "confirmation patents." These patents would allow ONAPI (Oficina Nacional de la Propriedad Industrial), the country's patent issuing authority, to use patents issued by other countries as the basis for its decision. Without authority to recognize confirmation patents, ONAPI must fully assess each request it receives rather than using work done by external authorities with greater expertise.
- The industry representatives lamented their difficulties in contending with the powerful influence of the "copying" industry, which opposes any efforts to close the gaps in the law and regulations that it currently exploits.
- The group expressed the common sentiment that ONAPI was committed to improving the patent-issuing process, but significant amounts of technical assistance would be needed to get its staff to the required level of competence. ONAPI is hamstrung by a more general lack of resources. According to USAID's DR-CAFTA implementation team, ONAPI currently has only six patent examiners, and only one of them focuses on pharmaceuticals. It is hoping to hire six more, two of whom would focus on pharmaceuticals.
- The group was unequivocal in pointing the finger of blame for the paralysis in patent-issuing process at Yahaira Sosa Machado, the head of the Industry & Commerce Ministry's Directorate of External Commerce and Trade Agreement Administration (La Federación Centroamericana de Laboratorios Farmacéuticos), or DICOEX.

- According to Rodríguez, Sosa - who, as head of DICOEX, has primary responsibility for DR-CAFTA implementation - told the group that she will implement the letter, and no more, of that Agreement and implementing laws and regulations.
- As proof of Sosa's obstructionist role, Rodríguez highlighted comments made by the head of SESPAS that DICOEX was blocking many of its attempts to work with the industry. The PhRMA representative noted that it was pursuing projects with SESPAS that did not require the expenditure of Dominican Government resources in order to get around DICOEX.
- In response to these comments, PolEcon Counselor and EconChief met with members of USAID's DR-CAFTA implementation team to get its assessment of the situation. Although the team agreed that DICOEX was not going to go beyond the letter of the law, it observed that the DR was technically in compliance with its DR-CAFTA requirements. The problems came not from the failure of DICOEX to implement the law, but from gaps in the laws and regulations that weakened cooperation between ONAPI and SESPAS.
- In theory, a pharmaceutical company would lodge its patent application with ONAPI and, if issued, ONAPI would notify SESPAS, which would in turn enforce the patent by ensuring that no new pharmaceutical products entered the sanitary registry if they violated an existing patent. However, the team explained that not only is ONAPI not issuing patents, but a patent registry does not, at this point, exist. Moreover, even if a patent registry did exist, SESPAS is not legally required to check it before registering a new product. Instead, under current law, a company need only file a notarized letter ("declaración jurada") stating that its product does not violate any patents, and SESPAS uses this statement as sufficient evidence to register the product.

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