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Guatemalan Court Deals Blow To Generics

by LADB Staff

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Recent decisions in Guatemala and the region will do much to ensure that the poor and the sick will stay that way if the intervening variable is access to medicines. The most recent of these decisions was a legal one: the Corte de Constitucionalidad (CC) of Guatemala ruled in August that Decree 9-2003, reforming the Ley de Propiedad Industrial, is unconstitutional.

The decree would have changed the law to remove a prohibition against the sale of generic medicines in the country. Opponents argued that a law against selling these drugs violated constitutional guarantees of protection of the person, of life, and of the obligation of the state regarding public health and social assistance. Supporters of striking down the prohibition, who included President Oscar Berger and the attorney general, argued the law discriminates against the poor because the difference between prices of generic and branded drugs is often around 80%.

The CC ruled, "Those who make extensive and costly investments in research and development of new medications have the right to rely on the legal measures that permit them to recover those unavoidable costs incurred and to stop third parties, without their authorization, from benefiting directly or indirectly from the results of those efforts." The clamor regarding drug affordability pits not only consumers against the industry but also, within the industry, those who make the branded drugs versus those who make the cheaper versions. In this, the issue is competition rather than public health.

A twenty-year period of patent protection established by the World Trade Organization (WTO) was not at issue in the battle nor was it in the CC decision. The problem was that Guatemala gives the patent owners an additional five years of exclusive rights beyond the internationally recognized twenty. Just a matter of high expectations Rodolfo Lambour, executive director of the Federacion Centroamericana de Laboratorios Farmaceuticos (Fedefarma), said the decree would do little more than create false expectations regarding the benefits to be obtained from it.

The law as it stands does not, he insisted, prohibit access to generics at low prices because, of the 13,000 drugs on the market in the country, only 16 are currently protected. "They say that decree blocks access to generics, but that hasn't been proven. It's not enough that someone says something to make it true, it has to be demonstrated," Lambour said, adding that he does not oppose the sale of generics, he just wants to avoid violation of the property rights of his members.

Health Minister Julio Valdez said the government's decree never sought to abridge those rights but rather to scale them back to the 20 years the rest of the world lives with. In this, he is supported by the Asociacion de Industriales Farmaceuticos Guatemaltecos (Asinfargua), whose representative Luis Velasquez said, "We are businesspeople who believe in free competition, that's why we think that with the reform there will be cheaper drugs, because the competition will be expanded." He

said the contention that there are only 16 products involved is a false one, because, "there are 16 products, but it is progressive, and that is prejudicial, because there will come a time when the list is much longer."

At stake for the manufacturers, according to Asinfargua's figures, is annual wholesale sales of US \$353 million, of which 50% to 60% is generic and the rest branded, protected drugs. There are 91 factories in Guatemala producing US\$162.3 million worth of generics, of which US\$40 million are exported. The industry employs about 9,000 workers directly and as many as 150,000 indirectly. President only appears to care But while Berger and his administration appear to support clipping the five-year bonus to manufacturers, others doubt that their hearts are really in it.

In the legislature, Victor Hugo Toledo, president of the Comision de Prevision y Seguridad Social, acknowledged that pressure from the transnational manufacturers was slowing the progress of Decree 9-2003 reform through the legislative process. "I don't know how, but at the moment [August 20, before the CC decision] the [governing party] Gran Alianza Nacional (GANAN) seems not to be interested in this initiative. The only way would be for the rest of the parties represented in the Congreso to agree to pass it," he told reporters.

In February, Doctors Without Borders (DWB) cautioned that the Central America Free Trade Agreement (CAFTA) negotiations ended in a deal that would restrict access to cheaper drugs by the addition of compensatory periods to the standard 20-year protection. Rachel Cohen, US director of DWB's Campaign for Access to Essential Medicines, said, "The negotiators of CAFTA have backed down against US pressure and have failed their citizens agreeing to measures that put trade benefits above human lives." Her most chilling example was the AIDS and HIV epidemic ravaging the region, where the high price of anti-retrovirals (ARV) prevents treatment and guarantees proliferation of the diseases (see NotiCen, 2003-05-01), but with CAFTA as yet inoperative, it is not clear how, or if, compulsory licensing exceptions would work to the benefit of anyone actually sick.

Compulsory licensing allows the importation of a generic medicine without the consent of the patent holder. The patent holder is, however, compensated. Compulsory licenses can be issued, under certain critical conditions, by public authorities. They are permitted under the TRIPS agreement. The TRIPS agreement's full name is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights. It took effect in 1995. The details DWB says that 67,000 people in Guatemala, 4,800 of whom are children, have either HIV or AIDS. Branded ARVs are available at a cost of from US\$320 to US\$800 a month. The average income is US\$160 a month.

Doctors Without Borders treats about 400 patients in the country using generic ARVs. Their costs are from 75% to 99% less than the Guatemalan government pays, because the government uses the branded versions, whose prices would be even higher had they not been reduced because of generic competition. Luis Villa, DWB head of mission in Guatemala, said that only about 1,500 infected people in the country are being treated, and, if trade agreements or other complications prevent the continued use of generics in the country, "virtually no patients will receive treatment." Failed reform of Decree 9-2003 could serve to keep drug prices high in still another way.

In the fierce competition among manufacturers, the generic makers have adopted a strategy of introducing cheap versions even while fighting patent claims in court. On the other side, holders of patents seek to extend their patents by adding some feature, often frivolous, to a drug due to lose its 20-year protection. These extensions keep consumers paying more. The launch-at-risk strategy is based on the idea that liability for damages costs less than losing out on being first to market with the generic of a hugely successful drug.

Industry analyst Albert Rauch said, "This is very positive for consumers because it allows cheaper drugs to get to market sooner." Generics can gain 70% of the market of a branded drug. In the international market, six months after Prozac lost its patent protection in 2001, generics drove prices down 80%. Ecuador has recently attempted to break the hold of a drug manufacturer trying to extend its patent.

The Instituto Ecuatoriano de Propiedad Intelectual (IEPI) annulled the patent of Merck's Rofecoxif. In this case, the company tried to extend exclusivity by patenting a new procedure for administering the drug. Juana Ramos, director of the Asociacion Latinoamericana de Laboratorios Farmaceuticos (Alafar), said of the manipulation, "This is a clear example of what it means to patent methods of treatment. They can prolong the length of the patents; they can protect by irregular means products that already could have a generic. It is incredible the number of products on which they don't let the patents expire. Now they don't patent inventions, they invent patents." Merck said they will appeal.

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