

Eli Lilly sues Canada on drug patents

By ADAM BEHSUDI | 9/12/13

U.S. pharmaceutical giant Eli Lilly has filed a \$500 million international lawsuit against the Canadian government, saying it unfairly shortened the life of patents for its best-selling drugs.

The case, filed Thursday under the rules of the North American Free Trade Agreement, threatens to shed a negative light on a dispute resolution mechanism also being proposed by the U.S. as part of the Pacific trade deal.

Eli Lilly has been arguing with Canada for almost a year over the patents for its best-selling drugs Straterra, used to treat Attention Deficit Hyperactivity Disorder, and Zyprexa, used to treat schizophrenia. The pharmaceutical company says Canadian courts unfairly threw out these patents when challenged by generic drug manufacturers, using a legal doctrine that requires a company to provide an unreasonable amount of scientific data in order to secure the patent.

Eli Lilly argues that the Canadian courts are creating too high of a standard for companies to prove the “usefulness” of their products when their patents are challenged by other firms seeking to produce their own versions of drugs. Usefulness is a common benchmark for establishing or maintaining a patent.

The legal fight is moving to the next stage after the two sides failed to settle their differences during a 90-day consultation process, which ends Friday.

Doug Norman, Eli Lilly’s chief patent counsel, told POLITICO in an interview this week that the court decisions are “so misaligned” with Canada’s obligations under NAFTA, Ottawa should be held accountable for stopping any future judgments that threaten the company’s presence in the Canadian market.

“The Parliament could have stepped in and fixed Canada’s patent statutes,” said Norman. “To date they have looked the other way.”

But critics argue that the case is another example where trade agreements have enabled private companies to run roughshod over government decisions made in the public interest.

“It’s an eye opener that a domestic court decision can be second-guessed by a foreign tribunal,” said Lori Wallach, director of Public Citizen’s Global Trade Watch, an advocacy group that traditionally opposes trade deals.

She said the Eli Lilly’s use of NAFTA’s dispute resolution mechanism is particularly “invasive” because it subjects Canada’s entire patent system to the whims of a single company.

Public interest groups are trying to battle a similar “investor-state” dispute mechanism being advocated by the Obama administration as part of the proposed 12-country Trans-Pacific Partnership agreement. Australia, which is also involved in the talks, has vehemently opposed an investor-state dispute mechanism and other countries remain skeptical about its inclusion.

At the March round of Pacific trade deal negotiations in Singapore, Wallach said she packed the house with more than 60 TPP negotiators when she gave a briefing on the negative impacts of the Eli Lilly case.

Wallach said the case may also give the administration heartburn in Congress, where some members may use it as ammo in the debate over trade promotion authority – legislation that would allow President Obama to “fast track” final trade deals by allowing only an up or down vote.

Outside observers also view the case as unique because Eli Lilly is not directly challenging Canadian patent law, which by most accounts is very similar to U.S. law, but rather how Canadian judges have interpreted the law.

The drug company is entering relatively untested legal waters because NAFTA cases have normally been geared toward the administrative or legislative actions of government, not the decisions of courts, said Lawrence Herman, a Toronto-based attorney and former senior Canadian trade official.

“I would call it an aggressive claim because it goes pretty far in its reach,” Herman said, adding that his initial reaction to the case was that “you can’t attack judicial procedure because the NAFTA is geared towards measures of government.”

However, Wallach argued that an earlier NAFTA dispute between a Canadian firm and the U.S. government established that the functions of domestic courts can be the subject of disputes.

But Herman believes Eli Lilly isn’t just trying to secure just one victory in this latest dispute. He said the company’s ultimate goal is not compensation. It most likely wants to see any outcome result in Canada’s Parliament tweaking the patent law in a way that would prevent judges from being able to make similar interpretations in the future.

But Simon Lester, a trade policy analyst at the Cato Institute, said for Eli Lilly to secure a favorable ruling, it would require Canada to change its own laws. It’s unlikely that the government of Canada can order its courts to cease their approach toward testing pharmaceutical patents because the courts, as they are in the U.S., are independent in Canada.

“It’s not easy to tell courts what to do,” Lester said.