Canada wins legal battle to set patent rules

■ Cite as: CMAJ 2017 April 18;189:E578. doi: 10.1503/cmaj.109-5168

anadian federal lawyers repelled a \$500-million arbitration claim filed in 2012 by United States drugmaker Eli Lilly to recover profits it claimed it lost due to the alleged wrongful termination of two of its Canadian drug patents.

The March 16 decision came from a tribunal of three arbitrators appointed by The International Centre for the Settlement of Investment Disputes in Washington, DC. It refuted Lilly's claim that its profits were unfairly curbed after 2010 when Canadian federal judges ruled against patents on two Eli Lilly drugs: Strattera (atomoxetine) for attention-deficit hyperactivity disorder and Zyprexa (olanzapine), an antipsychotic.

The Canadian federal court rulings enabled generic companies to market lower-cost copies of the drugs.

Eli Lilly lost its patent protections in 2010 and 2011 under the "promise utility doctrine," which stipulates that patent owners can be compelled to prove in court that their patents are legitimately based on useful new inventions. Lawyers for Lilly argued this doctrine emerged in Canadian patent law in the 2000s and amounted to a "radical change" in Canadian patent law that occurred after these patents were issued, and consequently unfairly infringed on its profit-making rights.

Eli Lilly claimed for international arbitration on the grounds that the promise doctrine contravenes Canada's obligations under the North American Free Trade Agreement.

The tribunal concluded, however, that Lilly "has not demonstrated a fundamental or dramatic change in Canadian patent law." can phrase their patent laws in a way that suits their national needs."

It will likely "give comfort" he added, to countries with especially acute needs for generic drugs, such as Brazil, India and South Africa.

In a March 21 statement, Eli Lilly said it was "particularly disappointed and sur-

A tribunal refuted Lilly's claim that its profits were unfairly curbed after a 2010 Canadian ruling.

And, "under any plausible standard, the challenged decisions of the Canadian courts are neither arbitrary nor discriminatory."

Richard Gold, a law professor at McGill University's Centre for Intellectual Property Policy in Montreal, says that if Lilly had won the case, "it might possibly have led to a change in the availability of generic drugs in Canada."

The decision, Gold says, can be interpreted as "sending a signal that countries

prised the Tribunal found that Canada's current promise utility doctrine was somehow part of Canadian law when Lilly's patents were granted."

A description of the tribunal decision posted on Global Affairs Canada's website on March 22 says both "Eli Lilly and Canada agree that Eli Lilly was not denied justice by the Canadian courts."

Paul Webster, Toronto, Ontario