Canada's Patent Laws Promote Genuine Medical Innovation

By Jim Keon
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In the August 26, 2013 edition of Forbes, Eli Lilly CEO John Lechleiter mischaracterizes Canadian patent law and suggests Canadian courts are invalidating drug patents based on a rogue judge-made law called the "promise of the patent doctrine".

His article reflects the disappointment of an unsuccessful litigant, and is part of a self-interested advocacy campaign by brand-name pharmaceutical companies that seeks to weaken the Canadian patent system to their own financial benefit.

Like everywhere else in the world, Canadian patents must meet three basic criteria – inventions must be new, useful and inventive. Pharmaceutical patents are only granted if the inventor can demonstrate that the patent works for an intended use at the time the patent is filed. To obtain a patent the applicant must "soundly predict" that the drug will work for its intended use by including limited data and a sound line of reasoning why the claimed invention should work.

The utility doctrine is not intended to be onerous, as has been confirmed and clarified by Canadian courts. The utility doctrine is intended to give effect to the words used by the inventor in the patent. It exists to prevent the grant of speculative patents that over-promise and under-deliver – both of which are harmful to society and stagnating to innovation.

As in other jurisdictions, patent cases in Canada are determined on their own merits and all parties are given a fair hearing. Every sophisticated patent system has a way to prevent innovation from being stymied by early speculative patenting. In the United States, the "written description" of the patent is scrutinized, as is its "enablement" of utility. In Europe, the "technical contribution" of the invention is similarly examined to see whether the patentee actually solved a technical problem. Canada's approach to patent utility is consistent with these jurisdictions.

Mr. Lechleiter's "statistic" that 20 drugs have had patents held invalid for lacking utility is deceptive as it is rare that a single patent is filed for a drug. Brand-name drug companies often seek new patents on existing drugs to lengthen their monopoly on the product. Nearly all of those drugs had already benefitted from monopolies granted by previous patents. In addition, many of the patents referenced by Mr. Lechleiter were never asserted outside of Canada because they were never issued by other patent granting authorities or were too weak to stop generic competition.

Eli Lilly has taken the extreme position of filing a notice of intent to arbitrate this issue with Canada under NAFTA if Canada does not get in line with Eli Lilly's corporate objectives. The company is claiming more than $500 million in damages against the Government of Canada because it lost two court decisions on drugs whose patents over-promised and under-delivered.

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Despite the rhetoric, Canada's patent system is consistent with other advanced economies. Brand name drugs are protected by numerous patents over their lifetime, some weak and some strong. Without generic patent challengers many of these drugs would never be subject to the cost-saving competition by generic drug companies that consumers, businesses and governments rely upon.

In fact Canada is home to one of the most onerous and pro-patentee pharmaceutical intellectual property regimes in the world. Canada's patent linkage system provides pharmaceutical patentees with an automatic 24-month court injunction against potential competitors. Despite investing millions of dollars generic drug companies who are successful in litigation are placed in the untenable position of launching new products at risk of being sued for patent infringement. Canada's patent system is the only one in the world where generic companies are required to litigate patent issues in two separate patent proceedings to find out whether they can sell their product. In addition, Canada gives eight-years of data protection that provides brand-name companies eight years of uninterrupted market exclusivity regardless of the patent situation. This exclusivity is unique to the pharmaceutical industry and is among the longest guaranteed exclusivity periods in the world.

But all this is not enough for Mr. Lechelieter. In addition to trying to weaken patent standards in Canada and abroad, Eli Lilly and the brand-name pharmaceutical industry are trying to leverage global trade negotiations to expand international intellectual property protection in an effort to further expand corporate profits.

In the unfortunate event Mr. Lechelieter and the brand-name pharmaceutical lobby are successful in these efforts the result would be longer monopolies for undeserving patents. This is nothing more than a lose-lose proposition for Canadians.

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