Canada's Tighter Controls on Patents Create Problems Beyond Its Borders

OPINION: A new interpretation of the "utility" requirement is impeding innovation.

Patrick Forrest and Linda Dempsey, The National Law Journal
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Something is happening in Canada — and it should matter to anyone who works in manufacturing or simply anyone who cares about encouraging innovation or protecting intellectual property.

Over the past decade, Canadian courts have revoked 22 patents for lack of utility, including patents on products that are used by millions of people suffering from cancer, osteoporosis, diabetic nerve pain and other serious conditions. From 1980 to 2005, not a single patent was invalidated for that reason, yet beginning in 2005 the Canadian federal courts began applying utility requirements in a new and a troubling way that invalidated already issued patents.

To receive a patent, an invention must be tied to a product or process that offered utility. Historically — and under trade agreements such as the North America Free Trade Agreement — "utility" was a low threshold satisfied by stating, in general terms as understood at the time the patent application was filed, that the patented invention represents an improvement over prior art.

Canadian courts, however, have redefined that utility requirement by creating a "promise utility doctrine" found nowhere else in the world. To sustain the validity of an already issued patent, Canadian courts may require evidence that the "promise of the patent" as stated at the time the patent was filed has been satisfied. If it doesn't meet that "promise," the patent may be revoked.

This creates a Catch-22. To obtain appropriate patent protection, manufacturers must apply for a patent before undertaking the safety and efficacy tests required for regulatory marketing approval. A company that fails to seek patent protection before running clinical trials risks forfeiting its patent rights under other provisions of the patent laws.

But because patents are filed long before evidence of efficacy is available, it is impossible to predict whether a patent granted by the Canadian authorities will be struck down years later under the promise utility doctrine. What's more, utility can evolve throughout the term of the issued patent as new applications for the technology emerge — making it difficult to predict all of the patent's "promise" at the time of filing.
Thus, the promise utility doctrine has undermined in an unpredictable way the current and future patent rights of companies doing business in Canada.

The actions of Canada's courts could affect a range of industries, have harmful consequences to manufacturers in all sectors and spread to other countries, leading to monetary losses and decreased innovation. The National Association of Manufacturers (NAM) has highlighted its concern regarding this approach on several occasions, including in comments to the U.S. trade representative on intellectual property challenges and foreign trade barriers.

**ALREADY IN JEOPARDY**

Pharmaceutical products are already in jeopardy: Zyprexa and Strattera, both owned by major American pharmaceutical company Eli Lilly and Co. In response to Canada's repeated pattern of invalidating patents, Lilly has brought an investment treaty dispute against the Canadian government under the North American Free Trade Agreement. Lilly and Canada are now locked in an international arbitration.

NAM has filed with a NAFTA arbitral tribunal an amicus brief supporting Lilly's challenge to the promise utility doctrine. NAM has been a leader on intellectual property policy issues and is deeply concerned that Canada's creation of promise utility requirements undermines the predictability of intellectual property rights. Out of the many groups that asked to file an amicus brief, the NAM was one of only a handful, and the only U.S. association, to have a brief accepted by the tribunal.

Intellectual property is a manufacturer's "special sauce" in today's knowledge economy. Securing that property is what encourages invention and rewards entrepreneurs. Without it, innovation suffers and so does the economy. Even more troubling, manufacturers' investments in research and innovation depend on expectations of consistent legal and regulatory regimes. These expectations extend to patents.

Canada's unexpected invalidation of intellectual property rights has already imposed real world losses. The Canadian courts' invalidation of Lilly's two patents has cost the company $500 million in lost sales. The future costs are even greater. A lack of predictability means companies are less likely to bring costly and potentially life-saving new inventions to market or to invest in laboratories, factories and distribution channels. Companies may decide that the risk is not warranted if intellectual property protections can be wiped out on new grounds.

Canada is the United States' largest trading partner. Reliable and predictable protection and enforcement of intellectual property rights are critical to ensuring the continued success of that relationship. NAFTA, which came into force more than two decades ago, has helped to drive increased trade and investment, greatly benefitting both countries. The success of U.S.-Canada trade and investment relations is a model for the rest of the world, and no party wants to see that relationship weakened through the disregard of a fundamental right of protection.
Patrick Forrest is vice president and deputy general counsel at the National Association of Manufacturers and the Manufacturers’ Center for Legal Action. Linda Dempsey is vice president of international economic affairs at NAM.