What is the “promise doctrine” and why is it an issue?

Based on a novel legal theory used nowhere else in the world, Canadian courts have revoked 24 patents on innovative medicines since 2005. Those patents were granted by the Canadian Patent Office for treatments, approved by Health Canada and used by millions of patients suffering from cancer osteoporosis, diabetic nerve pain and other serious conditions. That legal theory, known as the “promise doctrine,” confounds the time-tested way innovators turn basic research into new treatments and cures. It arbitrarily requires information at the time a patent is filed that may only be shown much later through clinical trials.

Furthermore, the “promise doctrine” represents a dramatic and fundamental change in Canadian patent law. From 1980 to 2005, not a single biopharmaceutical patent was invalidated due to lack of utility. But since courts started applying this doctrine in 2005 to determine utility, they have invalidated 24 biopharmaceutical patents.

Is Canada’s “promise doctrine” consistent with its international obligations?

Not at all. The “promise doctrine” did not exist under Canadian law when Canada signed the North American Free Trade Agreement (NAFTA) and is not permitted under NAFTA obligations.

It is also not permitted under the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), of which Canada is a signatory.

Currently, Canada is the only G7 country listed in the U.S. Trade Representative’s annual report highlighting problems with trading partners on patents and other intellectual property issues.

How does the “promise doctrine” affect the R&D process?

The “promise doctrine” places biopharmaceutical companies in a Catch-22. Around the world, when an innovative biopharmaceutical firm is developing a new medicine, it applies for a patent on an active ingredient. If the firm can show the active ingredient is new, useful and involves an inventive step, a patent is granted and the firm then proceeds through clinical trials to show the medicine is safe and effective. This two-step process has been used successfully to bring valuable new therapies to millions of patients who need them across Europe, Japan, the United States and elsewhere around the world. But, by applying the misguided “promise doctrine” legal theory, Canada has upended this practical and proven process.

Is the “promise doctrine” applied evenly?

The “promise doctrine” is unpredictable and inconsistent. Among other issues, different Canadian courts have interpreted the “promise” of a single patent in different ways – a severe lack of consistency.

Due to unpredictable and uneven application of the “promise doctrine,” innovative biopharmaceutical companies face an uncertain business environment in Canada, and are less able to invest in innovation.

Does the “promise doctrine” hurt the economy?

Canada’s competitiveness is declining, falling from a global rank of 16 in 2006 (the “promise doctrine” was introduced in 2005) to 24 in 2014, according to the World Economic Forum’s Global Competitiveness Index.

Additionally, while the U.S. biopharmaceutical sector invested over $51 billion in research and development
in 2013, Canada's biopharmaceutical industry invested barely $1 billion, creating an innovation gap. The biopharmaceutical industry is a global driver of innovation and jobs.

**Does the “promise doctrine” hurt patients?**

When patent protection is uncertain or unavailable, there are fewer incentives to invest in new treatments and cures, including for conditions such as Alzheimer's that do not yet have effective therapies.

Patents and incentives lost to the “promise doctrine” are already harming patients. Canadian patients are seeing this first hand through more limited access to improved treatment options and clinical trials.

Recent research conducted by Charles River Associates found that although improvements had been made to almost half of the medicines that prematurely lost patents in Canada under the promise doctrine between 2005 and 2015, none of those improvements were available to Canadian patients. Compare this to the United States and United Kingdom, where these drugs remained under patent and innovation continued to provide new patient treatment options.

When patients are unable to use all of the potential treatment options to better manage their diseases, the positive health outcomes associated with using these medicines may be negatively impacted. From a health system perspective, a negative impact on a patient’s health outcome implies their disease is less well-managed. This increases the likelihood of longer treatment periods and relapses, both of which can add costs.

Canada has traditionally been a popular location for clinical trials, but it is experiencing a 21 percent decrease in the number of clinical trials conducted in Canada in part due to its unfavorable intellectual property environment. Participation in local clinical trials provides patients with access to potential cures and treatments for some of the world’s most costly and debilitating diseases. It also allows for faster uptake of new medicines once they enter the market because doctors are more familiar with the drugs.

Canada seems like a small market compared to the U.S. and Europe. Why does the biopharmaceutical industry care about this issue?

While it is true that Canada is a smaller market than the United States, it is by no means a small market. In fact, Canada is the world’s eighth-largest market for medicines. Further, improper practices in Canada set a negative precedent for less-developed countries.

Canada could spark economic growth at home and in the U.S. if it enforced intellectual property rights in a manner similar to other developed countries.

Are Canada’s actions consistent with other countries?

Canada’s actions on intellectual property enforcement are out-of-step with international norms. Indeed, since 1989, the United States Trade Representative has identified “serious intellectual property rights deficiencies” in Canada in its annual Special 301 report (placing it on the “priority watch list” from 2009-2012). Canada’s invalidation of biopharmaceutical patents could hurt patients, who may have to wait longer for innovative treatments. Without patent protection, biopharmaceutical companies are unable to go through the lengthy and uncertain process of developing life-saving, critical medicines.

What medicines have been affected by this?

Twenty-four drug patents have been invalidated since 2005 when Canada changed its method of understanding its own patent law.1 These drugs represent treatments to combat a broad range of diseases, from osteoporosis to heart disease.

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