Based on a novel legal theory used nowhere else in the world, Canadian courts have revoked 24 patents granted by the Canadian Patent Office for innovative medicines, 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 is typically shown much later through clinical trials.

After a string of misguided Canadian court judgments, biopharmaceutical innovators no longer know how to secure patents in Canada. They are even less able to maintain those limited rights. Lost patents and uncertainty are harming patients in Canada and beyond by undermining incentives to invest in new medicines, limiting treatment options and reducing access to experimental medicines in development. Timely action is needed to restore those incentives and prevent further damage.

HARMING PATIENTS

To attract, sustain and eventually recover the substantial resources needed over many years to develop new medicines, innovative biopharmaceutical firms must be able to secure and maintain patents. Even where patents are protected, just two in every ten marketed medicines return revenues that match or exceed average research and development costs.1 But where patent protection is uncertain or unavailable, there are far 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 harming patients everywhere. Canadian patients are already seeing the problem first hand through more limited access to improved treatment options and clinical trials.

Limiting Access to Innovative Treatments

- Lost patents mean fewer incentives for innovators to develop and bring new improvements to existing medicines to market.

- Improvements might include new dosage combinations that reduce the number of medicines or the number of times a day a medicine must be taken. They might include new delivery mechanisms that make it easier for patients to use a particular therapy.

- Such improvements strengthen health outcomes and help lower treatment costs by increasing patient adherence to medicines and enabling them to better manage diseases and conditions. They give healthcare providers multiple treatment options.2


But recent research conducted by Charles River Associates found that although improvements had been made to almost half 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.

While patients in the United States, the United Kingdom and other countries that maintained patents on these products benefitted from improvements like new dosage combinations and delivery mechanisms, Canadian patients did not. For example, for Lyrica, which treats nerve and muscle pain caused by diabetes, shingles, fibromyalgia or a spinal cord injury, Canadian patients are only able to access an oral solid, whereas in other countries there is an oral liquid to help patients who aren’t able to swallow pills.

Reducing Access to Experimental Medicines

By volunteering to participate in local clinical trials, patients can get early access to innovative new treatments in development that are not yet widely available.

By enabling local healthcare providers to become more familiar with an innovative new treatment in development, clinical trials can also promote faster uptake and wider use of new medicines once they enter a market.

With an advanced healthcare infrastructure, Canada traditionally has been a leading location for clinical trials. But since Canadian courts started applying the “promise doctrine” in 2005, Canada’s global share of clinical trials has dropped 21 percent annually.

4. Data from clinicaltrials.gov.