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.

Patent law made in Canadian courts is breaking the innovation chain that transforms promising new molecules into valuable medicines. It is changing the rules in the middle of the game and sowing uncertainty across an industry working to bring thousands of new therapies to patients who need them around the world. The “promise doctrine” just doesn’t make sense. Canada’s government can fix it. Now is the time to act.

**BREAKING THE INNOVATION CHAIN**

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, the patent is granted and the firm then proceeds through a series of clinical trials necessary to show the active ingredient is safe and effective for the treatment of a particular disease or condition.

For decades, 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. It is a sound and sensible course. Granting biopharmaceutical innovators temporary exclusive rights to the medicines they discover enables them to attract, sustain and hopefully recover the substantial resources necessary over many years to develop new treatments and cures.

**CHANGING THE RULES IN THE MIDDLE OF THE GAME**

But now, Canadian courts have upended this practical and proven process and changed the rules in the middle of the game. Applying a misguided legal theory known as the “promise doctrine,” they have revoked 24 patents on 20 innovative medicines since 2005 on the grounds that biopharmaceutical innovators did not “demonstrate” or “soundly predict” those treatments were useful—meaning capable of being put to a practical use in industry—at the time they filed their patents.1

Patent applicants generally face the biggest challenge demonstrating a product is new and involves an inventive step. In contrast, usefulness—or “utility”—generally is a lower bar, interpreted in international rules and national laws as “capable of industrial application.” The “promise doctrine” inappropriately

1. Eli Lilly v. Canada, at para. 43.
imposes an onerous and unjustified new “utility” standard that is inconsistent with those rules and laws and that discriminates against innovative medicines as a field of technology.

Inventors in other fields of technology may have little trouble demonstrating or soundly predicting the utility of a new invention at the time a patent is filed. A new mechanical device either works “as promised” or it doesn’t. But highly regulated medicines are different. Promising new active ingredients developed through basic research must clear a series of clinical trials before biopharmaceutical innovators can establish that they meet health regulatory requirements as safe and effective for a particular disease or condition.

This creates an impossible Catch-22 for biopharmaceutical innovators. They must be able to patent promising active ingredients before clinical trials begin so they can attract and invest the resources needed to conduct those tests over several years. Clinical trials account for roughly 65 percent of the cost of bringing a new therapy to market. If they wait until after clinical trials to patent a new active ingredient in order to satisfy Canada’s “promise doctrine,” they may no longer be able to demonstrate the ingredient is “new” and “non-obvious,” which are separate requirements for a patent.

**SOWING UNCERTAINTY**

The “promise doctrine” confounds the simple reality of medicine development and is sowing uncertainty across an industry that is working to bring some 7,000 new therapies to patients around the world. Biopharmaceutical innovators no longer know what standard must be met to safeguard their patents in Canada. Today, they are less able to obtain new patents and to defend their existing patents through the courts.

---