Canada’s Self-Defeating Attack on Innovation

By Philip Stevens & Mark Schultz

Over the last decade, it has become dramatically harder for pharmaceutical companies to protect their intellectual property rights in Canada. Since 2005, Canadian courts have invalidated over 25 patents – most of them for important, beneficial medicines – based on an unusual and uniquely stringent interpretation of patent law.

This controversial rule, often called the “promise utility doctrine,” has recently come under increased fire. The Canadian Supreme Court has agreed to review it in AstraZeneca Canada, Inc. v. Apotex, Inc., a case in which the lower court invalidated the Canadian patent for AstraZeneca’s widely-used gastrointestinal reflux drug Nexium. The doctrine also spurred Eli Lilly to bring a $500 million claim against the Canadian Government under the North American Free Trade Agreement after Canadian courts extinguished its property rights in two popular drugs.

The promise utility doctrine is Canada’s unique take on a standard requirement in patent law that an invention must be “useful” or “capable of industrial application.” The fact that these drugs are widely prescribed and used by people would seem to indicate their usefulness. Indeed, that fact alone would likely go a long way toward demonstrating usefulness or “utility” in most countries.

Not so in Canada, where the courts have turned utility into a test of an inventor’s ability to predict the future. Under the promise utility doctrine, patent owners must be able to demonstrate or “soundly predict” at the time they apply for a patent exactly how their inventions will be useful when fully developed as commercial products. This prediction is treated as the “promise of the

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2 AstraZeneca Canada Inc. v Apotex Inc., 2015 FCA 158.
3 Eli Lilly v Canada, Notice of Arbitration under the North American Free Trade Agreement (1993), 32 ILM 289 and 605
5 Eli Lilly Canada Inc. v. Novopharm Limited, 2010 FCA 197 at 76: The Federal Court of Appeal described the utility requirement in Canadian law as follows: “Where the specification does not promise a specific result, no particular level of utility is required; a ‘mere scintilla’ of utility will suffice. However, where the specification
patent,” and if the patent is later challenged, the owner must show that it had strong evidence at the time of the patent application to back up that promise.

This test puts things backwards. An invention and the patent on it are only the first step on the way to a useful commercial product. Innovators rely on patents to secure the investment they need to fully test and commercially develop their inventions into products. Businesses and investors need a patent before spending money on the testing required to develop an invention into a safe and effective commercial product.

In most countries, the utility requirement is the least demanding of the requirements for getting a patent. Unlike Canada, other countries do not require a patent applicant to provide proof that the invention will actually fulfil its “promise.” They are much more lenient, speaking in terms of mere “plausibility” (Europe) or a utility that is “credible” or “not so vague as to be meaningless” (US). Preliminary testing, such as early stage research conducted on animals, usually suffices to establish credibility.

Canada’s utility doctrine is thus out of step with the rest of the world, and it is placing significant burdens on innovators. The consequences are particularly harsh for the pharmaceutical industry. Canadian courts have voided patents because the inventor did not have proof that widely-prescribed medicines did not perform exactly as predicted in the original patent application. To compound this problem, the Canadian courts perversely forbid patent owners from proving that the patent actually has met its “promise” by submitting data that was developed in clinical trials after the application.

Canada is making impossible demands of pharmaceutical innovators. It’s not fair to ask innovators to know and demonstrate the exact usefulness of a drug when they apply for a patent. Innovators spend many millions of dollars getting that knowledge and proof through extensive clinical and other testing in order to perfect a drug and get government safety approval before marketing it. Innovators cannot make this investment without the security of patents to give them an opportunity to recoup their investment before competitors are allowed to copy their innovation. They thus apply for patents on, and then begin testing, substances that show “credible” or “plausible” uses, as allowed by countries other than Canada.

What the promise utility doctrine asks isn’t just an economic impossibility – it’s also a legal contradiction. Inventions don’t just have to be useful, they must also be new or “novel”. Novelty is a challenging standard to meet, and a patent application can fail easily for lack of novelty. One way to likely lose novelty is to use the invention publicly before filing a patent. And yet, the promise utility doctrine essentially proposes that inventors do just that. The process of clinical trials requires disclosure of the invention to ever-larger numbers of people as a drug progresses through to

sets out an explicit ‘promise’, utility will be measured against that promise. The question is whether the invention does what the patent promises it will do”.


8. Tevi Troy, “The End of Medical Miracles?” The Wall Street Journal (2 June, 2009), online: The Wall Street Journal <http://www.wsj.com/articles/SB124389153780873939>, last accessed 9 June, 2016: It costs about $2.6 billion to develop a new medicine, and only one in every 10,000 new molecules actually makes it to market and only 3 out of 10 of those medicines will recoup their investment.
regulatory approval. Each clinical test presents a risk of disclosure that could compromise the novelty – and thus the patentability – of the invention around the world.

Pharmaceutical innovators in Canada now face a Catch 22. One choice is to file their patent based on initial pre-clinical testing and risk having their patent subsequently revoked for not demonstrating the precise promise specified in the patent application. The other choice is to apply after undergoing lengthy clinical trials to demonstrate the promise, and risk the patent being denied in Canada and other countries for lack of novelty. It's an unfair and galling situation of 'tails I win, heads you lose'.

Another absurdity is the fact that medicines have had their patents revoked on grounds of not demonstrating usefulness even though Health Canada approved the medicines as safe and effective. This has been the case with common, widely used drugs such as the glaucoma drug latanoprost9 and the acid reflux drug Nexium10.

Even beyond clinical trials, the final test of a medicine's usefulness is the open market. If physicians consider the medicine useful, they will prescribe it, or government healthcare systems will procure it. If the medicine lacks utility, then it will fall by the commercial wayside. Invalidating a patent on a drug that has made it through the patent office, experimental development, and regulatory approval thus serves no public purpose.

Canada's stringent utility standard isn't just bad for innovators coming into the Canadian market. It’s also bad for Canadian consumers and innovators. Canada’s courts are placing demands on innovators that no other country makes. When a country makes innovation less secure, it gets less innovation. Canada is thus handicapping its own inventors. It’s also making Canada a less attractive place to sell new products, as innovators are learning that their investment in securing regulatory approval and building a market may go unfulfilled.

The Nexium case presents an opportunity for Canada’s Supreme Court to fix these distortions in its patent system by adopting a utility requirement in line with the rest of the world11. Failing this, Parliament should step in, for the long-term benefit of its own consumers and innovators.

At the very least, Canadian courts should accept evidence of utility generated after the filing of a patent. Such a rule would allow innovators to introduce evidence of usefulness that the Canadian government accepts in other circumstances – clinical trials showing safety and efficacy as well as other regulatory assessments that medicines must undergo before they can be prescribed to patients in Canada.

Accepting such evidence would give innovators some assurance that Canadian courts will rely on truly objective evidence should their patents be challenged. It would also speed up cases regarding patent utility, which often get bogged down in complex legal debates around the nature and breadth of the “promise” and put Canada's IP environment on the same level playing field as other

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international markets. Importantly it would also reduce the number of decisions in which useful medicines have their patents revoked on the grounds they lack sufficient utility.

The bottom line for Canadian consumers is that the legal uncertainty provoked by the promise doctrine means that they are less likely to enjoy innovative products and the benefits and jobs they generate. Canadian judges and policymakers need to restore certainty to Canada's distorted patent system to ensure that innovators from Canada and around the world will continue to provide new medicines and other innovative products to Canadian consumers.

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