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Canada: A penalty box for pharma innovation

A series of court decisions suggests the country's intellectual property laws aren't as strong as you'd expect for a developed nation.

By David J. Kappos
Corporate Partner
Cravath, Swaine & Moore LLP

Consumers often hear complaints about the lack of patent protection for branded drugs in lesser-developed countries, where counterfeits are common and patents are frequently not respected. Surprisingly, however, the most aggressive nation on the planet when it comes to restricting patent coverage for innovative new medicines may be Canada.

The problem can be found in a narrow part of the country's law called 'the promise' doctrine, which imposes a unique and rigid requirement for patent protection.

It demands that innovators in the pharmaceutical industry prove their new drugs will pass regulatory requirements necessary to gain government approval before a patent can be granted. This is reasonable in theory, but a 'Catch-22' in practice. Regulatory testing takes many years to complete, and in that time, the opportunity to obtain patent protection is likely lost due to other laws requiring prompt submission of patent applications and industry reporting requirements that would, paradoxically, render the invention unpatenable.

Given Canada's status as a highly developed country, it is worth asking how its approach compares with those of other advanced countries. The answer: not well. In the United States, a pharma invention is presumed patent eligible, without need for direct evidence, so long as the purpose of the drug is specific (the patent identifies a real-world use) and credible (the invention is congruent with generally accepted scientific principles). This approach is echoed by European practice, as well as international treaties. Indeed, there is a growing list of drug patents that have been approved not just in the U.S., but in Europe and Japan as well — and in many cases in Korea and even China—but rejected in Canada. So adherence to the "promise" doctrine unquestionably positions Canada as an outlier.

The ramifications of Canada's "promise" doctrine are not confined to its pharmaceutical industry. Last year, the Federal Court of Appeal upheld a ruling that a patent for helicopter landing gear was invalid. So while the "promise" doctrine has thus far had a disproportionate impact on the pharmaceutical industry, it holds the potential to chill innovation across any number of industries.

Canada's Supreme Court set the stage for the "promise" doctrine in 2002 with the seminal decision, Apotex v. Wellcome, where the court established stricter requirements for pharmaceutical companies when it dismissed an appeal challenging patentability of the AIDS treatment and prevention drug, AZT.

Justifications of the "promise" doctrine rely on the premise that requiring additional disclosure ensures patentees will uphold their end of the patent bargain. But the doctrine actually incentivizes less disclosure. The savvy applicant will simply make a less explicit disclosure, leaving less room for the patent's "promise" to be misconstrued, and thus making it less likely that the invention will be found lacking.

The "promise" doctrine ultimately forces Canadian judges in some cases to perform feats of logical acrobatics in order to reach the right conclusion. In a recent decision upholding Pfizer's

Canadian patent for the drug Celebrex, the Federal Court rightly avoided a finding of invalidity for a drug with clear benefits. But it had to resort to curious reasoning in order to accommodate the muddled "promise" doctrine. The Court noted that the patent refers to the treatment of a "subject"— not "humans." The patent described testing in rats, and thus demonstrated itself in rats. Since that was all that was promised, that was all that needed to be delivered.

A confluence of events played out through a series of court decisions has put Canada into an awkward position: a modern, innovation-based economy with a patent doctrine transparently hostile toward an important class of innovation. But why? Has Canada cleverly crafted a national health policy that outsources its share of the R&D burden necessary for creating new medicines, effectively free-riding its health care system on foreign innovation investment? Or has Canada given up on its own pharma sector, concluding that its interests are more in line with lesser-developed countries versus similarly sized advanced economies in the western world? Or is there a benign explanation—bad facts making bad law through spiraling court decisions, putting Canada's patent system in the proverbial penalty box for a major foul of indefinite duration?

Whatever the explanation, the "promise" doctrine certainly is not sending positive messages to the pharma industry. Unsurprisingly, the branded pharma industry that conducts the vast majority of global R&D is not sitting by quietly. Their collective response started with normal diplomatic inquiries along the lines of 'this must be a mistake'— and in time moved to the more emphatic 'you've got to be kidding!' As a sense of extremis has set in, one U.S. company, Eli Lilly, has taken the highly unusual step of filing a NAFTA action against the Canadian government for violating its treaty obligations. That a company is taking a country to its continent's trade tribunal underscores the gravity of Canada's perceived defection.

The stage is set for Canada to put this odd chapter behind it by clarifying its patent law through Parliamentary action overruling the "promise" doctrine. This simple step would return Canada to the norm among developed and developing countries. Resituating Canada amongst its peer economies would encourage investment in pharma R&D and send a message to all considering doing business in Canada that it welcomes the value added to its economy via investment in innovation.

David J. Kappos is a partner at New York City-based law firm, Cravath, Swaine & Moore, where he supports the firm's clients with a wide range of intellectual property issues. From August 2009 to January 2013, Kappos served as director of the U.S. Patent and Trademark Office, advising the president, secretary of commerce and the administration on intellectual property policy matters.