



Broken promises

Has Canada really gone off its meds with 'promise of the patent?'

BY JENNIFER BROWN

You might say it's a battle that's been brewing for more than a decade — one that pits international mega pharmaceutical forces against Canada's scrappy patent law that some say holds "utility" in a different light than the rest of the world.

In January, the Supreme Court of Canada granted leave to appeal a decision of the Federal Court of Appeal in *Sanofi-Aventis v Apotex Inc.*, noted for its analysis of two of the most heavily litigated aspects of patent law: the "obvious to try" test and the "promise of the patent." The hearing of the appeal at the SCC is slated for November 2014 and will bring forward a long history of litigation surrounding the Sanofi-Aventis blood thinner Plavix (clopidogrel bisulfate). This appeal is of interest to the Canadian pharmaceutical mar-

ket, in particular, mainly in the hope that it will bring clarity to the law of promised utility — the so-called "promise doctrine."

"I think the courts are getting off into the woods and trying to figure out technicalities like what is the promise and is there a promise or statement of advantages that may work?" says Noel Courage, a partner with Bereskin & Parr LLP in Toronto. "What has people upset internationally is the utility standard here has gone higher than other countries."

Generics will say that's a good thing — we should be holding people to what they say — but the brand companies' point of view is they are filing at an early stage and need to cast a broad net. But ultimately, Courage says the big companies like Eli Lilly are spending the money, developing the drugs, prov-

ing they treat patients, and bringing the drugs to market and need the patent to make back the hundreds of millions of dollars they've spent in development. It's putting the big brands in a situation of uncertainty as to whether their patent is going to stand up. "You're getting some patents upheld and some invalidated. We're getting a lot of inconsistent decisions," says Courage. "The courts wander off and look at: are they promising it may treat the disease or just promising it may one day treat the disease so the whole thing is creating unpredictability — is there a promise in there — if you say it's less toxic is that a promise or an advantage?"

However some say there's just been a "cherry-picking" of a few cases where brand-name pharmaceutical companies were unsuccessful, largely for factual reasons. "There's history here," says

MATTHEW DALEY

Ildiko Mehes, vice president and general counsel with generic drug company Teva North America. “This is a wonderful branding campaign by companies who have been unhappy with some of the results in their patent cases. They’ve branded this the ‘promise of the patent’ and the argument that there’s this area of the law that is out of step with international norms. The truth of the matter is there’s nothing different that’s happened in the law over the last 10 years and it’s an attempt to get some traction and make some major changes in well-established Canadian law.”

The promise doctrine is a principle of Canadian patent law and has been the basis for the recent invalidation of several pharmaceutical patents and for having sparked a challenge by Eli Lilly against Canada under the North American Free Trade Agreement. “It’s a very big issue for us. We think the Canadian judiciary has gotten far out of bounds on their heightened scrutiny being set forth against the utility question,” says Doug Norman, general patent counsel at Eli Lilly in the U.S. “In a harmonized global patent arena what is needed to seek a patent is you must have a molecule that is new, non-obvious, and must show utility. That’s the way it used to be in Canada.”

But Norman argues since 2005, decisions from the Canadian judiciary began around the utility question that started raising the bar according to the promise doctrine, which is “singularly peculiar to Canada and Canada alone,” says Norman. “There have been about 18 to 20 pharmaceutical patents held invalid for lack of utility arising from this promise doctrine. If you look around the world those same patents are not being stricken anywhere else in the world, arising from the utility question.”

Eli Lilly and others argue Canada’s system is opposite to the rest of the world. Last fall, Lilly filed a notice of arbitration under NAFTA against Canada over its patent dispute with the Canadian government for allowing its courts to invalidate patents for two of its drugs — Strattera (atomoxetine), used for attention deficit-hyperactivity disorder, and Zyprexa (olanzapine), an anti-psychotic drug. Zyprexa is said to be the company’s biggest product. Eli Lilly is seeking damages of \$500 million.

The Zyprexa patent was challenged in dozens of countries around the world and upheld everywhere except Canada. That decision was so off base Lilly says it had no choice but to seek the arbitration under NAFTA. “It would be great if the Canadian legislature would step in and pass a new utility law statute that puts things back the way they were but that would not satisfy our NAFTA claim because what we’re seeking is remuneration for the damage that has been caused arising from having lost our patents significantly more early than we otherwise should have,” says Norman.

Mehes says a comparison of how courts in Europe, the U.S., and Canada treat patents show they differ on a number of grounds. As well, Canada was the only jurisdiction where a detailed, extensive trial took place over olanzapine, dealing with more evidence than anywhere else in the world. The

court decided the patent was invalid based on the facts, she says. “There is no substantive harmonization of patent law with which Canada is out of step because there is no international norm,” she says. “There are different standards for obviousness, double patenting — a multitude of aspects of patent law. You can’t cherry-pick this utility requirement we have in Canada and say we’re out of step because the question is: Out of step with what?”

But it’s perhaps not as clear cut as either side presents it, says Andrew Skodyn, a partner with Lenczner Slaght Royce Smith Griffin LLP. “In both the Eli Lilly cases, the decisions in other countries were largely, if not exclusively, in Eli Lilly’s favour and so it’s a bit of a shock to lose both of them here when everywhere else in the world you’re winning,” he says.

Skodyn says he understands where Eli Lilly and others are coming from, but notes, as the old maxim goes, “hard cases make bad law.” It comes down to the fact the systems in each country are very different. “For them the facts are compelling, for the broader jurisprudence the results have been more mixed,” he says. “That’s why you don’t see other companies making as much noise about it because it’s been more even — you win some you lose some. You need to look at the whole picture and say yes, ‘promise’ is an argument you may not find in other countries but it’s balanced by other opportunities in other countries for invalidating patents you don’t have here in Canada.”

Not surprisingly, no universal standard of patentability has arisen internationally and patent litigation routinely results in different outcomes for patentees in different jurisdictions, says John Lucas, an associate with Deeth Williams Wall LLP in Toronto. “To the extent an innovator pharmaceutical company wants to include promises of what a drug can do in a Canadian patent application, greater upfront research costs may be incurred in order to adequately support those promises at the time of filing,” he says.

McGill University Faculty of Law professor Richard Gold has filed an application to intervene as an *amicus* at the SCC hearing in November on two points: is Canada out of line with the rest of the world, and on “non-obviousness.” He believes the non-obviousness test needs to be holistic in order to maintain the internal balance of the Canadian Patent Act. “We can’t take any one rule and isolate it from the rest — it really is about balancing out these various factors,” he says.

In the U.S., the term is referred to as “assertion of the utility” but in Canada it’s the “promise of the patent,” but they mean the same thing. Gold admits “sometimes judges get things wrong” and it’s possible they got it wrong in the Eli Lilly cases but the notion that we identify what the asserted utility is dates back 200 years. Australia and New Zealand have the same principle.

Gold takes great issue with Eli Lilly’s position. In fact, he says its claim has “zero merit” and questions its statistics. “We went back and looked at the 53 cases they listed from 2005 [to] spring 2013 (a period in which there were at least 300 cases) when they filed leave to appeal at the Supreme Court

and they claim 18 were invalidated due to utility but in fact what you find is out of those 18, utility was the deciding factor in eight of them,” he says. “There were multiple grounds.”

Because most cases so far have been from the pharmaceutical industry, it has felt the impact most strongly, but it is an issue for anyone with a patent portfolio of significant value. For example, oil and gas is starting to catch up to pharma in terms of the number of cases. Skodyn says companies and their patent agents need to be aware of the promise issue when drafting patents now and be

precise about what you’ve invented and what you think it will do. “I would say to those patentees, ‘you need to look at your portfolio from that perspective,’” says Skodyn. “For Canadian sectors in the post-Research in Motion world, oil and gas is our domestic patent area. A significant part of value now is in a company’s patent portfolio.”

Skodyn says Supreme Court Justice Marshall Rothstein, who is close to retirement, has been the driving force on patent law at the top court. He speculates he might try to “unify the law” or clarify the issues. At the end of the

day, when the SCC looks at the issue, Mehes is hopeful it will look at the facts and see there is no international standard and the Canadian law of utility is entrenched and hasn’t changed significantly in the last decade. “The cases are fundamentally factual cases,” she says.

From his perspective, Norman says the SCC could “fix this” or Parliament could step in. “Lilly has a future in Canada and would like to get the patent ship back on course but it would not obviate the need for us to carry on with our NAFTA claim because we’re seeking damages from past conduct,” he says. ■