

# Question of regulatory authority may lead to constitutional fight

## Patented drugs price review could impact innovation

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For Law Times

The federal government has charged the Patented Medicine Prices Review Board with finding a way to lower brand-name drug costs.

Lawyers say this will impact the intellectual property concerns of drug companies and could have major impacts on innovation in Canada.

The PMPRB has recently proposed changes that could have a negative impact on the pharmaceutical industry in Canada, say intellectual property lawyers.

One proposal is to change the group — or “basket” — of countries with which they compare drug prices. The proposal recommends expanding this group to 12 from seven countries and, in the process, excluding the United States and Switzerland, which would drop the prices of being compared with countries.

Daphne Lainson, partner with Smart & Biggar in Ottawa, says lawyers should be concerned that patents are being used for political tools in order to deal with a larger issue as opposed to being the benefit that they were intended to provide to companies.

“It really is quite concerning because the changes are very significant and, at this point, it’s very difficult to advise [clients] because there’s still a lot of grey,” says Lainson.

“As a patent lawyer, my biggest concern is that this is undermining the patent estate, the patent right and intention that these patents are to be used in order to promote innovation.”

John Norman, partner and leader of the life sciences group at Gowling WLG (Canada) LLP in Ottawa, says the PMPRB estimates that its proposed new framework will save Canadians \$12 billion over 10 years in drug prices, citing figures found in an impact assessment statement

posted by the federal government in the *Canada Gazette*.

“PMPRB is pretty upfront about this,” says Norman.

“They feel that, right now, the price of drugs in Canada on the brand side is too high, and they feel that by changing this basket and by looking at socio-economic factors, they can take \$8.6 billion out of the innovation profits over the next 10 years.”

Andrew Skodyn, partner with Lenczner Slaght Royce Smith Griffin LLP in Toronto, says the PMPRB’s decision to look at cost effectiveness and affordability as part of its assessment hasn’t been its role and there are other mechanisms in the Canadian health-care system to address those things.

“That’s a really activist and subjective role that the PMPRB has historically not taken, and there’s a real question on the part of the innovator community as to why the PMPRB would be doing this, what the legislative authority for that is and [questions around] what is wrong with the current system,” says Skodyn. “In many corners, the answer is nothing.”

Skodyn says the proposed changes may be setting up a conflict between the federal government’s right to regulate patents, granted under the Constitution, and starts to fall into the regulation of property and civil rights, which is provincial jurisdiction.

“There is a question about where the regulatory authority for the PMPRB controlling prices of goods that are being sold in provinces comes from,” says Skodyn. “There is a tipping point at which we ask if the patent issue is just a pretext for national price controls.”

Skodyn says this could become a constitutional question, where the PMPRB’s authority under the Patent Act treads on the provincial governments’ authority in negotiating drug prices with suppliers.

“Are they drifting into the provinces’ lane?” asks Skodyn.



Daphne Lainson says that a price limit on patented drugs could stifle innovation in the industry.

Steven Mason, partner with McCarthy Tétrault LLP in Toronto, agrees that the PMPRB is wading into territory that is not part of its mandate.

“They don’t have the jurisdiction to do that,” says Mason, adding that it could become a constitutional fight.

While the PMPRB says these changes won’t affect small or medium enterprises, Norman says this assertion has been challenged because Canada has an industry ecosystem where these smaller companies partner with the larger multinational companies.

“If you take that \$8 billion off of their ledger, there’s less money to go around,” says Norman.

Because some of these deals are not publicly disclosed, the PMPRB or the federal government may not be aware of them as part of their calculations. He says this affects lawyers who do mergers and acquisition work because those funds would be used to purchase the smaller companies with up-and-coming products, and it means they can’t engage in licensing deals and it could drive those deals outside of Canada.

Norman says the PMPRB is also proposing to take “orphan” drugs and look at them as a basket based on the size of the mar-

ket rather than on the rarity of the disease they treat or the costs of development.

“What’s going to happen to patent lawyers like myself is, because a lot of these companies basically only have this one orphan drug, and if PMPRB says your price is excessive, we’re going to have to go to court more often to fight that,” says Norman. “This is bet-the-farm litigation in some cases.”

Norman says the PMPRB is still consulting on the potential impact on the industry of the proposed changes, and he credits them for moving more slowly than they initially planned to after hearing from those companies about some of the adverse effects that could come from the proposals.

“The more active the PMPRB gets, the more clients start to feel like they’re treated unfairly,” says Norman. “The more that happens, the more often litigation is pursued. Perhaps if there was a more open dialogue, that wouldn’t happen.”

Mason says there has been a lot of negative feedback from the research-based pharmaceutical industry on the proposed changes and he wouldn’t be surprised if an action resulted in order to do something about it.

In *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, the Supreme Court of Canada found that The Promise Doctrine is not the correct method of determining whether the utility requirement under s. 2 of the Patent Act is met.

Mason says his clients’ patents are constantly under attack in Canada and that they lived through some difficult decisions by the Federal Court that resulted in a lot of patents being invalidated as a result of the promise of patent doctrine.

“Finally, after a long period of time, the Supreme Court of Canada weighed in to the debate and declared that the promise doctrine was bad law, but in the

interim, many good patents had been invalidated with the result that the market for those products had gone generic,” says Mason.

“Having just gone through 20 years of that, the government has come along to say that we’re going to look at [the PMPRB mandate] to recoup your investment in Canada,” says Mason. “It’s pretty unfair.”

Lainson says the regime that was in place was recognized and understood, and companies had a lot of confidence as to what to expect in the Canadian marketplace.

The lack of clarity around the proposed changes has created concerns that it will have a “crushing effect” to an innovation economy.

“I find it perplexing that the government on the one hand can espouse a commitment to an innovation economy and on the other hand focus on penalizing innovators for having patents on their technology,” says Lainson. “I don’t think those things can go hand in hand.”

She says a price limit on patented drugs could stifle innovation in the industry.

Lainson says she is disappointed that after the engagement with Europe under the Comprehensive Economic and Trade Agreement and bringing in a supplementary protection system for drugs, which could give an extension to patent terms because of the time lost between filing the patent and getting a drug approved, the PMPRB is proposing these changes.

“I find it troubling that very shortly after we enter into that agreement, we’re in a position where we’re revisiting how we price drugs, making it very difficult for people to enter the market early,” says Lainson.

“These proposals to pricing will make it hard to look at Canada as being a jurisdiction that is going to be in the top jurisdictions where people pursue their new drugs.”

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