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Patent laws causing drug sector casualties

Roadblocks to generic drugs cost both the economy and the health care system dearly, LEONARD ZEHR writes

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ST. CATHARINES, ONT. -- In 1995, drug giant **Bristol-Myers Squibb Co.** successfully sued a small upstart Canadian drug company to protect the name of its blockbuster Taxol cancer drug, arguing that a similar drug called paclitaxel being developed by **Biolyse Pharma Corp.** was different than Taxol.

Last year, Bristol-Myers sued St. Catharines-based Biolyse again, blocking the sale of paclitaxel and effectively putting the company out of business, claiming the rival drugs are essentially the same.

Welcome to the wacky world of Canada's drug patent regulations.

By keeping lower-priced medicines like Biolyse's paclitaxel off the market, the regulations contributed to drug costs in Canada climbing 14 per cent last year, according to data research firm IMS Health Inc., which was the fastest rate in developed countries.

The House of Commons industry committee has scheduled three days of hearings next week.

The meetings will be held to consider changing a key aspect of the murky regulations highlighted in Roy Romanow's report last November on overhauling the health care system.

Mr. Romanow urged Ottawa to immediately amend the Patent Medicines (Notice of Compliance) Regulations that now compel Health Canada to block approval of a generic drug for up to 24 months if there is any hint of patent infringement against the brand name innovator.

Even though Biolyse's paclitaxel isn't a generic drug, critics contend that big, powerful pharmaceutical companies have used the regulations beyond their

intended purpose by adding extra patents to some drugs, a practice known as evergreening, to keep them free from generic competition for several years beyond the expiry of an existing 20-year patent.

"Our position is that it is becoming increasingly difficult and, in some cases, impossible to bring out a generic because of the regulations and the way brands are able to add patents to the list," said Jim Keon, president of the Canadian Generic Pharmaceutical Association.

"And the courts, which are interpreting the wording of the regulations, are sanctioning the practice," he added.

One of the most glaring examples of evergreening, critics charge, is **AstraZeneca PLC**'s top-selling Losec ulcer drug, which is the second most popular prescription drug in Canada with annual sales of about $428-million.

While the basic patent on Losec expired in mid-1999, Mr. Keon said eight new patents have been filed on the drug covering things like a change to a tablet from a capsule, the internal lining of the tablet, the way the medication dissolves in the stomach and manufacturing methods.

"This is a good drug and it's saved a lot of people from having surgery for ulcers," Mr. Keon said. "But does it deserve four extra years of exclusivity at a cost to the health care system of an additional $500-million?"

Liberal MP Dan McTeague, who is also vice-chairman of the industry committee, offers an unqualified thumbs down.

"Not only doesn't Losec deserve it but the government should immediately contemplate a class-action lawsuit to recover the loss to the Canadian economy," he said.

Last October, generic drug makers in the United States won approval to sell a knockoff version of the AstraZeneca drug and are now taking a significant share of its annual sales of $5.7-billion (U.S.).

Mr. McTeague figures that by doing away with the evergreening ability under the Notice of Compliance regulations, new generic competition against brand name drugs could immediately save the health care system more than $1-million (Canadian) a day.

"This is money that has been siphoned away from consumers and people who are sick and that's disgraceful," he added.

But Jacques Lefebvre, a spokesman for Canada's Research-Based Pharmaceutical Companies, counters that any "measure to diminish patent protection will make it very difficult for our members to convince their international organizations of the positive aspects of investing in research and development in Canada."

Generics are free to copy a product when its patent expires, he said. "But what they want is to come into the market, invest nothing in R&D and copy the latest innovation as soon as possible. This would jeopardize ongoing innovation, and there's value to that."

But in a report earlier this year, the Patented Medicine Prices Review Board found that R&D spending by the pharmaceutical sector in Canada ranks behind other major industrialized countries.

Specifically, the board claims that even though R&D spending in Canada rose 51 per cent between 1995 and 2000, the ratio of R&D to domestic sales is well below Europe and the United States.

Besides Canada, the United States is the only other country in the world with an automatic stay to settle patent disputes in the pharmaceutical industry.

But U.S. lawmakers are planning to introduce a new bill in Congress this year to eliminate the 30-month stay and are turning up the heat to stop anti-competitive behaviour and control prescription drug costs.

Ironically, one of the highest-profile cases in the United States involved a Federal Trade Commission probe of how Bristol-Myers protected nearly $3-billion (U.S.) in annual sales of three monopoly drugs from generic competition, including Taxol.

Earlier this year, the company settled antitrust charges that it stifled generic competition, agreeing to pay $670-million to resolve related lawsuits filed by state governments, generic drug makers and pharmacies.

All of which is unlikely to help Biolyse. "This has been a really discouraging journey," said Biolyse president Bridget Kiecken.

Last month, she laid off 17 of her 20 employees after a Federal Court of Appeal ruling that Health Canada had misinterpreted its own regulations and erred in approving Biolyse's version of paclitaxel, the active ingredient in Taxol, in 2001.

Specifically, the court agreed with Bristol-Myers that under a 1999 addition to the patent regulations, it should have been advised by Biolyse in a "Notice of Allegation" that its paclitaxel drug could infringe on Taxol's two Canadian patents.

Paclitaxel is made from twigs and needles of a coniferous shrub called the yew bush, which are dried and ground in large vats and then purified in a lab. Health Canada initially decided that Biolyse had a new medicine because it was using a different species of yew than Bristol-Myers.

The ruling effectively put Biolyse's drug on the same regulatory footing as a generic rather than a new medicine.

Bristol-Myers declined comment on the case because a 60-day appeal period has not yet expired.

Now Biolyse, which has invested $1-million (Canadian) a year over the past 12 years to develop its drug, has to wait 24 months and prove that it didn't infringe to get back on the market.

But without any sales, "I don't think we can hang on past the end of June," Ms. Kiecken said.

"All we did was follow Health Canada instructions . . . [Health Canada] told us we were a new medicine from a new botanical source that was different than Bristol-Myers and we had to do expensive clinical trials just like a new drug.

"Now the court says Health Canada was wrong. What about Biolyse? Why should Biolyse go under? Why should cancer patients lose access to treatment because agencies have to pay three times as much for this drug? Where's the justice in any of this?"

The British Columbia Cancer Agency yesterday cancelled its contract with

Biolyse even though it previously stated it would save more than $1-million a year using Biolyse's paclitaxel, which offered similar benefits for about a third of the cost of Taxol.

"I've got a lot of sympathy for Biolyse," Mr. Keon said. "But a lot of companies have been caught in these regulations. They're complicated and they're unfair."