

## Drug patent protection: How long is long enough?

A recent Senate committee hearing on Bill S-17, Parliament's effort to comply with international trade rules by extending pharmaceutical patent protection to 20 years, inadvertently opened the door to a broader investigation of the inner workings of the country's pharmaceutical patent legislation. Industry Minister Brian Tobin says the bill must become law by August or Canada "will be in trouble with the World Trade Organization."

Bill S-17 would extend patent protection to 20 years for drug patents issued before 1989, when they lasted only 17 years from time of filing.

Although few debate the need for patent protection, the Senate hearing indicated that there are major disagreements about how long the protection should last. The issue is of major importance not only to Canada's 58 research-based drug companies, which invested \$1 billion in R & D last year, but also to the generic drug industry, which has about a dozen firms in Canada.

These generic companies, represented by the Canadian Drug Manufacturers Association (CDMA), say patents

are often "evergreened" far beyond the 20 years cited in Bill S-17. After receiving the initial patent, it says, brand-name manufacturers can add more patents for changes in coatings or other advances, and each one can add years to the market monopoly. For instance, enalapril will not be off-patent in Canada until 2007 — 28 years after the initial patent was granted.

The CDMA argues that evergreening of patents has become endemic since Patented Medicines (Notice of Compliance) Regulations were introduced in 1993. They allow the research-based companies to block automatically regulatory approval of potential generic competitors for 24 months by launching a court challenge. The CDMA says the 24-month injunction can be repeated for each individual patent on one drug, thereby keeping generic equivalents off the market for years. For example, norfloxacin and nizatidine were blocked for about 4 years. (In the last 8 years, brand-name manufacturers have launched more than 200 court cases. In a 1998 case, the Supreme Court of Canada granted the generic manufacturers' ap-

peal of the patent protection given a drug, calling the regulations a "draconian regime" that are "manifestly unjust" to generic drug manufacturers.

"The regulations have turned into a playbook for complicated, time-consuming and frivolous patent litigation," says Jim Keon, the CDMA's executive director. "This has to stop."

In other manufacturing sectors, patent disputes go before the courts and a judge decides whether to impose an injunction while the case is being heard. The CDMA wants the automatic 24-month injunction that applies to drugs abolished; if that doesn't happen, it wants limits on the number of patents allowed on 1 product. The US Congress is now considering a limit of 2.

However, the association representing the brand-name manufacturers, Canada's Research-Based Pharmaceutical Companies (Rx&D), argues that they need patent protection to recoup their R & D investment, which amounts to about \$750 million per product. "We need absolute assurances that we would get the minimum [20-year protection]," says Rx&D President Murray Elston. He also points out that patent protection lasts no longer here than in the US, Europe and Japan.

"This is a difficult, contentious issue with big financial interests at stake," Tobin told the Senate committee. "The intention [of patent legislation] should be to avoid things that would allow patents to be extended in an unearned way."

Because of price limits set by the Patented Medicines Prices Review Board, brand-name drugs sold in Canada are 40% cheaper here than in the US. In Canada, generic drugs sell for about half the price of their patented counterparts; in the US they sell for 30% of that price. Currently, generic drugs account for about 41% of all prescriptions filled in Canada, but for only 14% of total spending on prescription medicines. — *Barbara Sibbald, CMAJ*

## Urologist's \$1-million gift boosts prostate research on East Coast

A New Brunswick urologist and his wife have donated \$1 million to support research into the disease to which he devoted much of his professional life. The Arthur and Doris Chesley Chair in Prostate Disease, which will be based in Saint John, NB, will be part of the Atlantic Health Sciences Corporation, a teaching hospital affiliated with Dalhousie University in Halifax.

Dr. Arthur Chesley, a 1955 Dalhousie graduate, says his interest in prostate disease began about 20 years ago when he realized that male physicians and their patients both appeared unaware of the threat posed by prostate cancer. He said the \$1-million donation is "not a tremendous amount of money" but interest earned from it should give a urologist based in Saint John the time needed to pursue clinical research.

"Physicians have to put something back into the system if they want it to work," Chesley said. "We just felt that if we had the money, why give it to the government in taxes?" — *Patrick Sullivan, CMAJ*