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## **Supreme Court Decision Proves Fed's Gift to Big Pharma Unnecessary**

***"Evergreening" of drug patents should not have been allowed under previous rules***

**Toronto, November 3, 2006** – A decision rendered today by Canada's Supreme Court proves that the federal government's recent changes to drug patent rules amount to little more than a multi-million dollar gift to brand-name drug companies at the expense of taxpayers, provincial governments and consumers, Jim Keon, President of the Canadian Generic Pharmaceutical Association (CGPA) said today.

"In today's decision, the Supreme Court said categorically that evergreening of drug patents should not have been possible under the old rules if the government had properly enforced them," said Keon. "This means that, on whole, the October 5, 2006 changes to the drug patent regime are nothing more than an costly gift to Big Pharma at the expense of everyone else in Canada who pays for prescription medicines, and Canada's domestic generic pharmaceutical industry."

Since their inception in 1993, regulations of Canada's drug patent laws have been systematically abused by brand-name drug companies to unfairly delay generic competition, sometimes for years after the initial 20-year patents expire, by triggering successive 24-month "stays" or legal blocks of Health Canada's approval of lower-cost generic equivalents.

In today's decision [AstraZeneca Canada Inc. v. Canada (Minister of Health), 2006 SCC 49] the Supreme Court stated:

*"Given the evident (and entirely understandable) commercial strategy of the innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original patent for that pioneering product has expired, the decision of the Federal Court of Appeal would reward evergreening even if the generic manufacturer (and thus the public) does not thereby derive any benefit from the subsequently listed patents. In my view, s. 5(1) of the NOC Regulations requires a patent-specific analysis, i.e. the generic manufacturer is only required to address the cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug, in this case the 1989 version of Losec 20."*

The decision went on to state:

*"The only patent-related consequence of the present decision is to deny AstraZeneca the benefit of a 24-month freeze without any proof of patent infringement."*

Along with provisions that merely codify today's and earlier Supreme Court rulings to stop evergreening, the federal government's October 5 changes to Canada's drug patent rules provide brand-name drug companies with an eight and a half year ban on competition from lower-cost generic drugs. Had that eight and a half year ban been in place over the past five years, it would have added an additional \$600-million to prescription drug costs in Canada.

(more)

Other provisions in the government's new rules gutted the damages section of the patent regulations removing any real consequence for brand-name drug companies that unfairly delay competition from lower-cost generic equivalents.

### **About the Canadian Generic Pharmaceutical Association**

The Canadian Generic Pharmaceutical Association (CGPA) represents Canada's generic drug industry – a dynamic group of companies that specialize in the production of high quality, affordable generic drugs and fine chemicals and in conducting the clinical trials required for government approval of generic drugs. The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 44 per cent of all prescriptions but account for less than 18 per cent of the \$17-billion Canadians spend annually on prescription medicines.

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