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Legal Challenge of Big Pharma Extra Monopoly Rights Heads to Court

Long-awaited hearings on extension of “data exclusivity” to be heard in Federal Court tomorrow

Toronto, December 15, 2008 – Hearings start tomorrow in the generic pharmaceutical industry’s legal challenge of extended market monopolies for brand-name drugs in the Federal Court of Canada in Toronto.

“The generic industry is challenging these extended monopoly rights because they go beyond Canada’s international trade obligations and will add more than \$125-million to Canada’s prescription drug bill each year,” said Jim Keon, President of the Canadian Generic Pharmaceutical Association (CGPA). “These rules will increase brand-name drug companies’ profits at the expense of provincial governments, employers and consumers who will have to pay monopoly drug prices for much longer than they should.”

On October 18, 2006, the federal government published a package of regulatory amendments to Canada’s intellectual property regime for pharmaceuticals. These changes included the creation of a mandatory eight-year ban on generic competition – and an additional six months for paediatric drug products – regardless of whether there are relevant patents covering the brand-name drugs. On November 14, 2006, CGPA initiated its legal challenge to the new regime.

The new rules were the federal government’s response to lobbying from brand-name drug companies and pressure from the United States Trade Representative (USTR) to strengthen Canada’s data exclusivity provisions. But in an interview with the U.S. publication *Inside Trade*, published on October 27, 2006, the Office of the USTR “*acknowledged that the changes Canada made go beyond the five years of data exclusivity the U.S. had demanded.*”

“Canada’s pre-October 5, 2006 data exclusivity regime of five years was in full compliance with our international trade obligations through NAFTA and the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, and should have been left as it was,” said Keon.

Keon also pointed out that Canadians receive very little for the additional costs they incur when the federal government succumbs to pressure from Big Pharma for longer market monopolies.

“Every day generic competition is unnecessarily delayed costs the Canadian health care system tens of thousands of dollars in lost savings,” said Keon. “Twenty years of government concessions to Big Pharma have failed to result in the investments that Canadians were promised when the Mulroney government first increased Big Pharma monopolies in 1987.”

The Patented Medicines Prices Review Board (PMPRB) annual report released on June 18, 2008 shows that for seven consecutive years, brand-name drug companies have broken their promise to spend at least 10 per cent of their Canadian sales on research and development in Canada. The PMPRB report also shows that the brand-name industry spent only two per cent of its Canadian sales on basic research that could lead to the discovery of new medicines.

(more)

The Federal Court hearings are expected to last for three days.

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 50 per cent of all prescriptions but account for only 22 per cent of the \$20-billion Canadians spend annually on prescription medicines.

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