



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

SECTION 8 DAMAGES UNDER PHARMACEUTICAL PATENT REGULATIONS

THE ISSUE

An October 2006 change to the *Patented Medicines (Notice of Compliance) Regulations* removes an important penalty for brand-name companies who unfairly delay market entry for a generic product through abuse of the automatic stay provision.

BACKGROUND

Under the *Regulations*, a brand-name drug company can automatically keep a lower-cost generic drug off the market for two years or more by starting a court case asserting that a proposed generic drug infringes its listed patents – even if their patents are not infringed or are simply invalid. This automatic stay has been described as “*draconian*” by the Supreme Court of Canada and is unique to patentees in the pharmaceutical industry.

Past case law shows the generic usually wins when these cases finally reach a court hearing. When that happens, the brand-name company has had a wrongful monopoly during the automatic stay. The generic manufacturer has been unfairly kept off the market by bogus patent issues. Governments, taxpayers, employers and patients have paid more for prescription drugs than they should have during that time.

To discourage abuse, section 8 was included in the Regulations to allow generic companies to collect “damages or profits” from the brand-name company when the generic drug was wrongfully kept off the market by the automatic stay. Cases under the Regulations can cost generic manufacturers millions of dollars to litigate, and the generic company had the option to claim either its own out-of-pocket damages or could elect an accounting of the brand-name company’s profits during the wrongful delay.

In October 2006 the Regulations were amended to remove the words “*or profits*” from section 8. Brand companies no longer can be penalized with the loss of their profits during the period in which a court finds the brand has abused the automatic stay provision.

The brand-name company’s profit from triggering the automatic stay and extending its monopoly will always be far greater than any “*damages*” it might eventually have to pay for the generic company’s lost profit. Brand-name companies have argued in several ongoing section 8 cases that the generic company suffered no significant damages because there would have been several generic manufacturers competing on price, and none would make a profit. If this is correct, the removal of the words

“*or profit*” from section 8 rendered the right of the generic to collect damages virtually meaningless.

The Government of Canada has essentially made it less economic for anyone to make the investment necessary to challenge the brand-name company’s monopoly, and introduce a low-cost generic product to market. The change is a serious setback for generic drug makers, and anyone in Canada who directly or indirectly pays for prescription drugs.

CGPA POSITION

By removing the words “*or profit*,” the 2006 amendments removed a key deterrent for abuse of the system by brand-name companies. Section 8 of the *Regulations* must be fixed as soon as possible to protect Canadian governments, taxpayers and patients from paying monopoly drug prices for longer than they should.