Pharmaceutical Patent Wars Continue to Rage

IP column published in *The Lawyers Weekly* February 21, 1997

Edward Hore
Hazzard & Hore
141 Adelaide Street West, Suite 1002
Toronto, ON M5H 3L5
(416) 868-1340
edhore@ hazzardandhore.com

At least half the intellectual property court cases in Canada continue to be in the pharmaceutical area.
There are essentially three kinds of cases:

- "Passing off" cases: these have to do with the appearance of generic pharmaceutical tablet or capsules. The issue is whether they can look like the brand name tablets and capsules.

- Section 55.2 cases under the Patent Act: in 1993 regulations were enacted under this section which permit brand name pharmaceutical patentees to use a special procedure to prevent generic drugs from entering the market if patent infringement is alleged;

- Patent trial: one active pharmaceutical patent case is not under the 55.2 procedure because the generic versions got regulatory approval prior to 1993 when the 55.2 Regulations came into force, and therefore the more traditional patent litigation process is being used. It is a high profile case because it involves the well-known AIDS drug AZT.

Passing off cases

The issue in these cases is whether the appearance of the tablet is an indicator of source in a trade-mark sense (i.e. what company made the tablet or capsule) or of type of drug (i.e. what kind of medicine it is). Brand name companies want to prevent generics from marketing lookalike drugs. Generics say selling lookalikes is not "passing off" because consumers do not associate the appearance with any vendor, but rather use it to identify the therapeutic effect of the medication.

In 1996, three such cases were actively pursued by brand name companies involving Monsanto's heart drug Isoptin SR (verapamil), Procter & Gamble Pharmaceutical's colitis drug Asacol (5-ASA), and most famously Eli Lilly's anti-depressant Prozac

(fluoxetine). To make a long story short, interlocutory injunctions were sought but denied in all three cases.

The Prozac case then moved to trial on an accelerated schedule. The trial is still going on as I write. The result in the Prozac case may resolve the issue once and for all, or it may not.

55.2 (Notice of Compliance) cases

Under the 55.2 or "Linkage" regulations, if a brand name drug company commences a judicial review proceeding, there is an automatic injunction imposed which prevents a Notice of Compliance, or regulatory approval, from being granted to a generic equivalent drug for 30 months, pending a judicial review hearing on patent issues. Prior to 1993, when these regs came into force, the question of whether the NOC could be granted to a generic was solely a safety and efficacy matter.

At last count, 115 cases of this sort which had been commenced since 1993. Many of the cases have now gone up to the Federal Court of Appeal. The Regulations are somewhat obscure in their wording, and this has resulted in much interlocutory case law to resolve what the Regulations mean.

The generics vigorously oppose the Regulations and brought an application to have the Regulations struck down, but the application was dismissed by Mr. Justice MacKay of the Federal Court Trial Division late in the fall of 1996. The decision is under appeal. The Regulations will enter the political realm this year because Parliament mandated a "review" of Canada's laws relating to pharmaceutical patents by Parliament in 1997 as part of the controversial Bill C-91 amendments of 1993. The form the review will take is not known at the time of writing. It is likely there will be hearings.

The review will consider the entire issue of patent protection for drugs. It is expected that the brand name companies will seek patent term extensions (that is, extensions of the 20 year term now available). The generics will seek, among other things, a return of compulsory licensing, and repeal of the 55.2 Regulations.

Patent Trial - AZT

Glaxo Wellcome's famous AIDS drug AZT is the subject of what looks likely to be a lengthy patent trial, just beginning as I write. Glaxo claims Apotex and Novopharm, generic drug manufacturers have infringed its patent rights. The generic companies counter that Glaxo's patent protection is invalid.