

Generics win one on tablet appearance

IP column published in *The Lawyers Weekly*

August 30, 1996

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

Generic drug company Novopharm was successful in a recent court slug-out having to do with the appearance of one of its pills.

The case raises something of a dilemma for me as a columnist since I argued it for Novopharm. Is it perhaps wrong journalistically or ethically to write about ones own case? Is it perhaps bad columnist etiquette?

I have decided to throw these concerns aside, and plunge recklessly ahead. The fact is, not much else has happened over the summer, IP-wise. Besides that, I am about to go on vacation and am too lazy to write about anything that might require research or effort on my part.

To get back to the pill problem, the case involved the size, shape and colour of a tablet, a big issue at present in the pharmaceutical and intellectual property world.

Mr. Justice Wetston of the Federal Court, Trial Division, in *Procter & Gamble Pharmaceuticals Canada v. Novopharm*, released July 5, refused Procter & Gamble's application for an interlocutory injunction, which would have prevented Novopharm from marketing a lookalike generic version of P&G's colitis drug ASACOL.

This case is the latest in a series of interlocutory injunction applications on the question of the size, shape and colour of generic drugs. In these cases, the courts are asked to decide whether generic pills and brand name pills should look alike. The issue got some press attention in March when Eli Lilly won an interlocutory injunction to prevent generic drug companies Apotex and Novopharm from marketing their generic version of Eli Lilly's well-known drug, Prozac. Prozac is the brand name for a drug known as fluoxetine. The Canadian patent ran out in March of this year, which must have cheered up some depressed people because it meant their anti-depression medication got cheaper.

The brand name drug companies say that the size, shape and colour of the pills is proprietary, like McDonalds owns the Golden Arches. The generic drug companies, on the other hand, argue that the appearance of the pills does not belong to anyone, and say

generic equivalent drugs can should be marketed in the same size, shape and colour as the brand name drug for safety reasons.

Many pharmacists and seniors' groups have released position papers in recent months saying that generic drugs should look the same as the originator so as to lessen the chance of medication mix-ups, and to make it easier to identify medications in emergency situations.

Underlying the dispute is a struggle for market share; generic pills that look different from their brand name equivalents are less acceptable to patients and therefore less likely to be purchased by pharmacists. The brand name companies strategy is to (a) stop the independent generics from marketing look-alike generics, and (b) set up subsidiaries or licensee which will sell lookalike generic tablets. Asserting intellectual property rights in the appearance is therefore a way for originator drug companies to their maintain market share and revenues for drugs on which patent protection has run out.

The plaintiff innovator drug companies do not have trade-mark registrations in these cases. The issue is whether brand name company has common law rights under the law of passing off. The test is whether the brand name company has a "reputation" or a "secondary meaning" in the tablet's appearance, and, if so, whether people would confuse the generic drug for the brand name drug.

There has been much litigation on this point over the last thirty-five years. No trial decision in Canada has ever favoured the brand name companies on this issue. Most of the cases are interlocutory decisions. They go both ways.

A 1993 decision of the Supreme Court of Canada, *Ciba Geigy v. Novopharm and Apotex*, favored the brand-name point of view by holding on a reference of an issue that the perception of patients was relevant to the question of whether there was passing off in pharmaceutical size, shape and colour cases. Earlier cases had held that only doctors, nurses, pharmacists and other health care professionals were relevant. This imposed a difficult threshold on the brand name companies because brand-confusion was clearly unlikely among knowledgeable professionals.

In *Ciba Geigy*, Mr. Justice Gonthier of the Supreme Court of Canada, in what was perhaps obiter dicta, also made a general statement that generic drugs should not look like brand name drugs. He also said, however, that every case had to be decided on its own facts. It is still clearly necessary therefore for the brand-name to prove a reputation or, to put it another way, to prove that the appearance of the pill is "distinctive" in a trade mark sense.

In the *Prozac* case, *Eli Lilly v. Novopharm and Apotex*, already mentioned, Mr. Justice Rothstein of the Federal Court of Canada, Trial division granted an injunction preventing Novopharm and Apotex from marketing their generic versions in green and beige capsules like those in which Prozac is sold. Eli Lilly has licensed a generic company to

sell a same-appearance generic version, called an “ultra-generic” or “pseudo-generic”. An expedited trial has also been ordered and is likely to take place late in 1996. The injunction decision is likely to go before the Federal Court of Appeal before then.

The Procter & Gamble case was the first interlocutory injunction case to go before the courts since the Prozac case. The plaintiff has not appealed Mr. Justice Wetston’s decision, but is seeking to push the matter onto trial.

Another interlocutory injunction case is likely to be heard shortly. Monsanto is seeking an interlocutory injunction in *Monsanto v. Novopharm*, which involves verapamil SR, an arthritis medication. In the Monsanto case, an interim injunction was granted, prior to cross-examinations and before the defendant had put in all its evidence. The interim injunction was then struck down by the Federal Court of Appeal in May, 1996, in a brief, emergency ruling. The interlocutory injunction application is likely also to be heard in the fall.