

Generic pill manufacturers win Prozac fight

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Eli Lilly may be feeling depressed and anxious about its anti-depression and anti-anxiety drug PROZAC. If drug companies have therapists, Eli Lilly's is probably advising it: stay calm, breathe deeply, and try to think positive thoughts.

Eli Lilly's action alleging that three generic drug companies were infringing its rights in the size, shape and colour of PROZAC capsules was dismissed in late April.

PROZAC went off-patent in March, 1996. Three generic companies immediately got regulatory permission to enter the market with lower cost generic versions. The generic capsules have the same green and beige capsules as Eli Lilly's PROZAC. Eli Lilly initially obtained an interlocutory injunction preventing the generics from selling lookalike capsules, but the injunction was overturned last fall. The case then went to trial shortly afterwards.

After a 42 day trial, Madam Justice Barbara Reed of the Federal Court Trial Division, in a lengthy decision released April 25, 1997, rejected virtually all of Eli Lilly's evidence and arguments. Her definitive findings on the facts would seem to make the chances of a successful appeal small.

The decision turned in large part on competing survey evidence about consumer perceptions. The court said Eli Lilly's survey was "a very sloppy piece of work" but found the generics' survey evidence sound.

Reed said the survey evidence showed that consumers are generally "unaware and not greatly concerned about the brand of prescription medicines they consume." As well, consumers "associate the capsule appearance with the character of the medicine and not its trade source."

The Reed decision may cause many people on the brand name side of the pharmaceutical industry to feel depressed and anxious, maybe even in need of some mellowing medication. The ruling affects the entire pharmaceutical sector. There are at least five or

six other cases presently before the Federal Court involving similar passing off claims about the appearance of other pills. Whether those cases will go forward is not yet clear.

Generic tablets and capsules in Canada have generally looked the same as the equivalent brand name products for decades. There has, however, been much litigation about the issue, which intensified after a Supreme Court of Canada case in 1993, *Ciba Geigy*, made some possibly obiter statements seemingly favorable to the brand name point-of-view.

You may ask, who cares what colour and shape little pills are? The answer is, lots of people, because that most mood-enhancing of substances, money, is at stake.

The size, shape and colour issue is key because patients resist taking generic capsules that look different from the brand name product; they assume they will not work as well, or that the capsules must contain an altogether different medication, with obvious implications in terms of market share.

The generic manufacturers also maintain that there are safety reasons why generics tablets and capsules should look the same. Lookalike generics, they say, make it easier to identify the medication in emergency situations, and also prevent dangerous mix-ups. Many health-related trade associations made statements supporting this view. However, Madam Justice Reed found that these statements were merely “recommendations as to what the law should be”, and “not relevant for my purposes.”

In addition to the depressing problems with its survey evidence, Eli Lilly also had what trade-mark lawyers call “distinctiveness” problems. Eli Lilly was selling both the originator product, PROZAC itself and a low cost generic through a licensee, Pharmascience, a small Montreal generic drug company. Both PROZAC and the licensed generic capsules had the same the size, shape and colour. Reed said Eli Lilly should lose for this reason alone.

Reed said Eli Lilly could not argue that PROZAC’s capsule appearance means a particular source (i.e. Eli Lilly itself), while at the same time offering the same product, with the same appearance, through another source, Pharmascience. To use the size, shape and colour of the capsules to designate two sources “destroys distinctiveness”, a conclusion that Reed said, “seems obvious and inescapable.”

I agree. One of the mysteries surrounding the case was always, how could Eli Lilly adopt such a strategy, and still hope to win. Presumably, Eli Lilly did so because the advantages of winning would have been huge: as well as the high-end, full price market, Eli Lilly would also have effectively occupied all or most of the generic market with its licensed product, forever. Most pharmacists would stock only the licensed generic if it was the only one that had the same size, shape and appearance as the brand, thus keeping the independent generics to an insignificant share of the market.

Ah well, that's the way it goes sometimes. We hope Eli Lilly won't get too depressed about Reed's decision. As the song says: "don't worry; be happy!"