

Patent Wars: Apotex Scores Upset in Hypertense Litigation over Drug used to treat hypertension

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Generic drug company Apotex has scored a major victory in the latest round of its patent infringement slugfest with Merck Frosst over enalapril, Canada's best-selling prescription drug, marketed by Merck under the brand name VASOTEC.

Enalapril is used to treat hypertension (i.e. high blood pressure). Most of the people involved in the long and bitter court battle are probably good candidates for hypertension medication themselves by now. But it's not over yet; Merck plans to seek leave to go before the Supreme of Canada.

The case has been closely watched by the health care and pharmacy industries, anxious to know whether the generic product, Apo-Enalapril, can be listed on government drug benefit plans, and sold by pharmacists.

The big development is that Federal Court of Appeal in mid-April overturned the trial level decision of Mr. Justice MacKay in part. The Court of Appeal, in a decision written by Mr. Justice MacGuigan, agreed with the trial judge that Merck's patent was valid and infringed (infringement was in fact not disputed), but found that Apotex had a good defence in respect of most (but not all) of the infringing material, overturning MacKay on this key issue. The defence, in a nutshell, was that Apotex had purchased the infringing material prior to the issuance of the patent.

The amounts of money at stake are enormous. VASOTEC had sales in 1993 topping \$150 million. Merck says that since Apo-Enalapril came on the market in September, 1993, Merck has lost \$100 million in sales. Under the Patent Act, an infringer can be required to pay either its own profits or compensation for the patentee's lost profits. The whole thing turns on a particularly murky section of the Patent Act, section 56.

Section 56 is one of those dense blocks of print found in many statutes which, when read, cause a dull ache in the frontal sinus. The drift of it is that, if you buy or make something which infringes a patent, but you buy or make it before the patent issues, then you can go ahead and use or sell that “specific article”, even after the patent issues. (The key date is actually the “laying open” of the patent application, that is, when the patent application becomes public, but since this just a newspaper column, let’s skip getting into all that.)

“Specific article” is in italics earlier in this paragraph because the issue in the case comes down to what those words in section 56 mean.

Bear with me while I briefly digress on the theoretical background here. Patent law is in many ways fundamentally different from trade mark or copyright law. You can enforce rights in a trade mark without having a trade mark registration. You can enforce copyright without a copyright registration. But you can only enforce a patent if the patent has been examined and issued by the Patent Office. A patent is a deal between the inventor and the state. The inventor gets 20 years of exclusivity in return for disclosing the invention publicly so that everyone can use it (at least after the 20 years are up).

The idea behind section 56 is that if someone else makes or acquires something that is in the patent, before the invention in the patent application becomes public, he should still be able to go ahead and sell or use it after the patent issues, because he didn’t learn about the invention from the disclosure in the patent application. (Of course, he might have learned about it from an equivalent patent in another country, since patents issue in different countries at different times, but, again, let’s skip all that, and keep moving along here).

The wrinkle in the enalapril case was that Apotex bought large quantities of the raw material enalapril maleate prior to the issuance of the patent (which took place in 1990), but had to do some processing after the issuance of the patent to turn the raw material into tablets. Were the tablets therefore the “specific article” Apotex had bought? This is the Big Question.

The trial judge said that the tablets were not the “specific article” Apotex had bought before the patent issued. He reasoned that the raw material had been changed into something different by the act of adding other ingredients and creating tablets. The Federal Court of Appeal disagreed, holding that “‘specific article’ refers to anything coming within the scope of the patent.” As long as what Apotex bought prior to the key date was covered by the patent, Apotex could do with that material what it chose, said the Court, and still be protected by section 56.

Apotex had learned about enalapril, not then on the market, sometime in the mid 1980s. Under the regime which existed in Canada prior to Bill C-91, Apotex would have been able to get a compulsory license to manufacture the drug. However it was clear by then that by the time Merck got its Canadian patent on enalapril, compulsory licensing would probably be a thing of the past.

Apotex therefore bought large quantities of the raw material, enalapril maleate, and stockpiled it, before Merck's patent issued. The problem was, it couldn't turn all the bulk raw material into tablets before the patent issued because of shelf-life problems. The raw material can be stored in bulk almost indefinitely it seems, whereas enalapril in tablet form has a relatively short shelf life - about two years.

Apotex also of course applied for regulatory approval to sell Apo-enalapril, which it received in September, 1993 (also after litigation with Merck which went up to the Supreme Court of Canada, but that's another story).

Some shipments of the raw material still required "repurification" as of the date in 1990 when Merck's patent issued. The Federal Court of Appeal held that these shipments did not fall within the words "specific article" in that they had not yet been processed to a stage where they embodied the invention in the patent, as of the crucial date. Therefore, those shipments were not protected by section 56. So Apotex, decided the Court, infringed the patent at least in respect of those shipments. But these seem to have been a relatively minor portion of the whole.

Apotex had also counterclaimed seeking a declaration that certain composition and use claims of the Merck patent were invalid, but the Federal Court of Appeal declined to interfere with the decision of the trial judge that the claims were valid and the counterclaim should fail.

Apotex, as of the time of writing, had not decided whether it would also seek leave to appeal those portions of the Court of Appeal's decision where it was unsuccessful, according to Harry Radomsky, counsel for Apotex. I forgot to ask him how his blood pressure was doing.