# Patent Register ruling bad news for drug makers

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

The Ministry of Health has a duty to remove patents improperly listed on the Patent Register under the Patented Medicine (Notice of Compliance) Regulations, (the "Regulations") according to Justice Marc Nadon of the Federal Court, Trial Division.

The decision is a blow for innovator drug companies, which have an interest in listing as many patents as possible.

The controversial Regulations came into force in 1993. They essentially set up a complex new procedure for pharmaceutical patent litigation, applying only to the drug industry. Briefly, if a patent is "listed" on the Registry maintained by the Ministry of Health as relating to a particular medicine, the patentee then has certain court remedies above and beyond its normal right to enforce its patent. In particular, any submission for regulatory approval for a generic version of that medicine is subject to various injunctions and delays imposed by the Regulations if the patentee brings a judicial review application. If the innovator company does so, the generic is automatically kept off the market for 30 months. There has been a huge volume of litigation under the Regulations, about 120 court cases so far.

Listing a patent therefore confers a major benefit because it potentially gives patentees the ability to delay automatically the entry of generic competition, even if the generic company maintains its formulation is not infringing the patent. This has a huge economic impact. In the prescription drug business, keeping a generic version of a particular drug out of the market for a few months may make a difference in revenues in the tens of millions of dollars.

However, not all patents can be listed. In 1995, the Federal Court of Appeal, in a case called Deprenyl, ruled that the Regulations did not apply to process patents, that is, patents claiming a method of manufacturing a drug as opposed to the drug itself.

The Ministry of Health therefore ordered an "audit" of the Register, which found that about a quarter of the seven hundred or so patents on the Register were process patents,

and therefore listed improperly. The audit, done in mid-1995 by patent examiner Michael Howarth, also found that some of the patents on the Register did not relate to medicines at all. There were patents listed for, among others things, a bicycle brake, a lens for a cathode ray tube, and a mobile crane.

The Ministry decided in late 1995 to remove all of the approximately 160 process patents on the Register The issue that led to the recent litigation was whether it had the jurisdiction to do so.

Two innovator drug companies, Merck Frosst and Glaxo Wellcome, brought judicial review proceedings, alleging that the Minister did not have jurisdiction to remove patents from the Register, but had to list any patent submitted. An initial attempt by Merck to obtain an interim injunction against the Minister failed in February, 1996. The matter was then set down for a hearing in early April, 1997.

In late 1996, two large generic drug companies, Apotex and Novopharm, became aware of Merck and Glaxo's judicial review proceeding against the Minister (they had not been served or informed). In February, 1997, both moved successfully to get intervenor status, including the ability to file evidence, and to appeal. Merck and Glaxo appealed the intervenor order to the Federal Court of Appeal on an expedited basis, but lost.

The judicial review application itself, with the generics present as intervenors, was heard by Justice Nadon at the beginning of April. In a 33 page judgment released June 13, Mr. Justice Nadon found that the Minister had not only the jurisdiction, but the duty, to remove the process patents from the Register. Justice Nadon noted that identifying a process patent was straightforward, and also found that "at least some of the major innovators would be willing to insist of a full judicial review application despite the fact that the issues for the court to determine would be moot."

**Merck and Glaxo have appealed.**

An issue which arises out of the case is, what will should happen with respect to intermediate patents, i.e. patents claiming chemicals used in manufacturing; the Federal Court of Appeal has said in yet another case that intermediate patents should not be on the Register (although many are, for the moment, listed). As well, the federal government has promised to reconsider the very existence of the Regulations as a whole "on a priority basis" this fall.

Lest it be thought I am an entirely omniscient and impartial commentator, I should disclose I represented the intervenors, Apotex and Novopharm, although I have tried to present both sides fairly.