The Battle Over Notice of Compliance Regulations

IP column published in *The Lawyers Weekly* September 9, 1994

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

Since most of us prefer being healthy to being sick, pharmaceutical drugs generate lots of money - around $200 billion dollars (U.S.) annually around the world. Merck Frosst's Vasotec for high blood pressure, probably Canada's largest selling pharmaceutical, generates around $150 million annually in sales in Canada.

Nevertheless, life is tough and may get tougher for pharmaceutical companies for various reasons. The costs of developing new drugs are rising, due to the increasingly complex technology involved in research. Governments around the world are seeking to limit medical and drug costs for their aging populations in various ways, cutting into profits. And, most important of all in Canada, aggressive generic drug companies sell low-price equivalents whenever possible.

What the generics can or can't sell of course depends on the pharmaceutical companies' patent protection. The rules dealing with patented medicines and generic equivalents have changed a number of times over recent years. As a result of confusion over these changes, the battle for market share in Canada's pharmaceutical business is now fought on the courtroom floor to a greater degree than in any other industry.

The latest battleground between the "innovator" or patent-holder companies and the generics are the new Notice of Compliance (NOC) regulations under the Patent Act. The regulations came into force in March, 1993. There are now, at last count, fifty-five lawsuits arising out of these regulations, all involving complex issues. The deluge has put a burden on the facilities of the Federal Court. The generics will go to court early this fall to argue that the regulations themselves are improper and should be struck down.

In order to explain what the acrimony is about, it is necessary to go into a bit of background. Generic drugs companies used to be able to get compulsory licenses on patented medicines. This was good for Canadian drug users since it kept prices down, but angered the pharmaceutical companies. After intense lobbying, the law was changed, first to shorten the time compulsory licenses were available, and then, in 1993, to get rid of compulsory licenses in most circumstances altogether (although grandfathered licenses were allowed to continue).

As a sop to the generics, certain exemptions were added to the Act at the same time, supposedly to make it easier and quicker for the generics to get products on the market after pharmaceutical patents expire. Under one exemption they are allowed to manufacture and stockpile drugs so as to be ready to go on the market once the relevant patent expires; under another they can go through the lengthy regulatory process to get their generic equivalent approved (i.e. to get an NOC). These activities were deemed not to be infringements of any patent.

However, to keep the generics on a tight leash, the government was permitted to "make ... regulations ... necessary for preventing the infringement of a patent" by the generics when making, using or selling anything under the two exemptions. Somehow, it was thought, the sneaky generics would do things under cover of the exemptions, which would in fact infringe patents, even though they were deemed not to be infringing patents when they did them. Or something like that.

Anyway, the result was the NOC regulations. What they do, in effect, is allow the innovators to claim patents rights in a particular drug, and thus prevent or at least slow down a generic company from getting an NOC for its generic equivalent. This is in addition to the normal right of any patent-owner to sue anyone infringing a patent.

The scheme, very basically, works like this: The innovator files a document called a Patent List for every drug for which it has an NOC, listing all product patents it claims are relevant to that product.

If the generic company wants to market an equivalent before the patent expires, it must send the government and the innovator a "Notice of Allegation" and a "detailed statement" of the basis of the allegations. These documents say why the generic company thinks its equivalent will not infringe the innovator's patent rights. Usually, the generic company says the patent is invalid or irrelevant, or both. There have been many motions as to how much detail these documents must contain, and who has the onus to establish what.

After receiving the Notice of Allegation, the innovator can apply to the Federal Court for an order that the Health Protection Branch not issue an NOC for the generic equivalent. This is how all the lawsuits got started. Eventually, months or years later, a court decides whether a NOC should be issued for the equivalent or not.

There have been two cases (involving sulindac and deprenyl) in which the courts have said that the NOC *should* be granted to the generic because the innovators' Patent Lists listed only process patents (i.e. patents on ways of making the stuff), rather than product patents. The regulations seem to apply only to product patents. Both those cases have been appealed. But most of the cases under the regulations are still far from being resolved.

The generic companies claim that most of the patents listed by the innovators are invalid or irrelevant, and that the innovators are using the process to slow them down. The Federal Court of Appeal has remarked that a curiosity of the scheme is that, while the innovators commence the litigation and have carriage of it, they also have an interest in moving it forward as slowly as possible.

From the point of view of the innovator companies, the beauty of the whole scheme is that they can keep generic equivalent off the market for a long time (30 months is the usual estimate), and possibly until the patent expires. As the Federal Court of Appeal has also remarked, the scheme seems to allow the innovators to get what amounts to an interlocutory injunction, without having to prove irreparable harm.

The Tory government had plans to amend the regulations prior to last fall's election. The Chretien government, lying low in this as in so many other matters, seems to have no immediate plans to change the scheme unless it is forced to do so by the courts.

This may well happen. It seems likely that the harassed Federal Court judges would like to get rid of the scheme, and force the government to come up with something else.