All drug consumers affected by NOC Regulations

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Everybody buys prescription drugs at some time or other. Many of us pay indirectly through a drug plan. Through our tax dollars, we also pick up the tab for all prescription drugs used by senior citizens (even though seniors are richer on average than the rest of us).

All of us therefore have a stake in drug prices, and therefore in some arcane pharmaceutical intellectual property cases going on in the Federal Court arising out of the *Patent Medicine (Notice of Compliance) Regulations* (the NOC regulations) under the *Patent Act*, enacted in 1993.

The NOC Regulations call to mind that line in Tennyson's *Charge of the Light Brigade:* "someone had blundered."

Before we get into why that is, it is important to understand why everyone is affected by the regulations. The provincial drug plans only cover the cheapest version of a drug - so once a cheaper, generic drug is approved for sale, its price then becomes the price that governments will pay for that drug - and it may be 25 - 40% cheaper than the brand name drug. This obviously affects the cost of the provincial drug benefit programs and thus taxes, since so many drugs in Canada are paid for with taxpayers money.

Briefly, the system works like this: the NOC regulations create a new remedy against patent infringement, in addition to the old-fashioned, time-honoured one, which is to sue and claim damages or an accounting of profits, or perhaps seek an interlocutory injunction. But this new remedy is only available to pharmaceutical patentees, not to patentees in other industries.

Under the regulations, the originator companies can prevent generics from getting regulatory approval from Ottawa (in the form of a "Notice of Compliance" or NOC) to enter the market until after the originator's patent rights expire. Thus the originators can get what is, in effect, an interlocutory injunction.

Under the Regulations, the originator is entitled to file a "Patent List" with the Health Protection Branch in Ottawa (the drug mandarins) for any drug it has on the market, listing any patents it says are relevant to the product. The generic company can then file a "notice of allegation" in which it alleges that its generic drug should get an NOC because it doesn't infringe the listed patents, or that the listed patent are invalid. If the originator disagrees, it can bring an application in the Federal Court seeking an order that the NOC not issue.

Merely by starting the court application, the originator gets what is in effect an automatic "injunction". The moment the application is commenced the NOC then cannot issue for 30 months, or until a judge hears the case or until the patent expires. The 30 months can be extended by order of the court, and has been in some cases. This "injunction" keeps the generic off the market until the case is eventually heard by a federal court judge at a judicial review hearing, months or more likely years later.

The judge's job at the hearing is to determine if the generic's "allegation" is "justified". No one seems to know exactly what this means, but the Federal Court of Appeal has made it clear that infringement and validity can not be determined at such a hearing because the evidence is limited and there are no live witnesses on these crucial questions.

Therefore, whether the judge decides at the hearing that the "allegation" is "justified" or not, the actual issue - does the generic drug infringe a valid patent - is left unresolved.

Since 1993, there have been 67 such cases commenced, although some have settled. There seem to be just under forty new generic products which are the subject of disputed applications right now. In most, the generic company says the generic product does not infringe the listed patent(s), and the originator says it does. In short, there is a patent dispute.

The cases take a long time to get in front of a judge, so final (as opposed to interlocutory) decisions are just now beginning to appear. So far, by my count at the time of writing, there have been eleven final decisions at the trial level, with the generics winning five and the originators six. All have been appealed, and only one of the appeals has been heard (although interlocutory and procedural issues have gone before the Federal Court of Appeal a number of times, due to ambiguities arising from the vague wording of the Regulations). In short, virtually all the disputes cases are still dragging on at the trial or appellate level.

The odd thing about all this that even if the generic company wins the NOC proceedings and the generic product gets its NOC and goes on the market, the originator is still in the same position as any other patentee. It can sue for patent infringement, and move for an interlocutory injunction. Conversely, it would seem that if the generic company loses the NOC proceeding, and does not get its NOC, it could commence a full scale action for a declaration that its product does not infringe the originator's patent.

Which raises the question, what is the purpose of the NOC proceedings? The substantial issue between the parties (usually, is the originator's patent infringed or not?) is left unresolved, despite all the vast amounts of time and money spent on the NOC proceedings by the court, the lawyers, and the companies. The generic product is kept off the market possibly for years while this is going on, which may be fair if the patent is infringed, but is surely not fair if the patent is ultimately found not to be infringed (the patentee might be liable to the generic company damages in such a case, but the regulations are silent on this point). Either way, the consumer pays higher drug prices.

The original intention may have been that all such court cases would be concluded during the period in which the generic would have been in the regulatory approval process anyway. But it is now becoming clear that the Federal Court is taking much longer than expected to hear the cases. At least six drugs would have been granted their NOC and gone on the market already, but for unresolved NOC proceedings. Many others will be due for regulatory approval in 1996, but are likely to be delayed from going on the market because it is taking so long to resolve the court cases.

There is certainly nothing wrong with a patent owner suing an infringer and seeking its remedies before the court. Consumers pay monopoly prices to a patentee, but those higher costs are a legitimate cost of the patent system, which is intended to reward invention. But the skirmishing under the NOC regulations keeps generic products off the market which may *or may not* infringe a valid patent - without providing a mechanism to determine that crucial issue. This means consumers could pay higher drug prices for years because products are kept off the market that ultimately might be found not to infringe a patent. The drug companies gain, but the public loses.

The Regulations confer what is mush like an interlocutory injunction, but without the safeguards available at common law. There is no undertaking as to damages if the injunction is wrongly granted. There is no need for the brand-name company to show that damages would not be an adequate remedies (i.e. that it would suffer irreparable harm). There is no need to demonstrate an arguable case.

Most of all, if a non-infringing drug is kept of the market by the Regulations, then consumers and taxpayers pay more for drugs - even though the premium in drug prices is not based on legitimate patent rights.

Someone has blundered, all right, and it is costing us all money.

To be fair, I should disclose that I do some work for the generic drug industry (I have also done work for originator companies). If readers disagree with what I have said, please feel free to write in and say so.