NOC Regulations: What patents can be listed?

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I was recently sitting in court with an intellectual lawyer I know. We were both waiting to be heard on different cases. As is usual in such situations, we chatted briefly about what kind of case we were there on.

When I said I was there on a case to do with the Patented Medicines (Notice of Compliance) Regulations a.k.a. the NOC Regulations, my friend shook his head and said, "there are two areas of IP that I know absolutely nothing about: Industrial Design, and the NOC Regulations."

We both laughed. When it comes to the Industrial Design Act, Canada's most obscure intellectual property statute, I'm the same: I don't know a thing. No doubt there must be cases under it. But I've never read one. There must be lawyers who know all about it. But I don't know who they are.

In some ways, the NOC Regulations are like that too: they can be seen as an arcane speciality within a specialty, with their own terminology ("patent lists," "the patent register," "serve an allegation") unfamiliar even to most IP lawyers, let alone the man on the Clapham omnibus.

But the NOC Regulations raise vital public policy issues that affect all of us, because they directly affect the cost of prescription drugs, which we all pay for one way or other. It is worth understanding how, and it's not really that complicated.

In short, the Regulations are a patent enforcement scheme only for pharmaceutical patents. They allow a brand name drug company to get an automatic injunction against generic competition, through a convoluted scheme linking health approval of the generic with patent issues.

Big drug companies can file a "patent list" with Health Canada, a form setting out the name of a drug, and the patent they claim is relevant to it.

Health Canada then puts that information on the "patent register" (basically, a government website with a list of drugs in alphabetical order, with the listed patents).

If a generic drug company wants Health Canada approval for a generic version of drug for which a patent is listed, it has to respond to the patents on the register. It can do this either by (a) agreeing it will not get its approval (Notice of Compliance or NOC) until any listed patent expires, or (b) sending a document called an "allegation" to the brand-name drug company in which it asserts that the patent would not be infringed by its product, or is invalid.

When it receives an allegation, the brand name drug company can then start a judicial review application, a kind of mini-patent action, for an order that the generic not get approval until the patent expires.

Here's the important part: when the brand drug company starts the court case, Health Canada is automatically prevented from granting the NOC for 24 months to the generic drug. In other words, the brand immediately gets what amounts to an automatic interloctory injunction against competition.

Complex strategies can be used to turn this into a more or less perpetual monopoly. Commonly, there will often be several patents listed at various times for a given drug. Every time the brand lists a new patent, it can in effect re-start the 24 month stay against generic competition. Every week it can keep a generic off the market may be worth millions of dollars in additional revenue, so there's lots of incentive to be ingenious.

Even if the generic wins the court case, it often still can't get on the market because the 24 month stay has started up again on some other patent. Since this makes it very hard for low-cost generics to get on the market, the cost of provincial and private drug plans are going through the roof.

Over the last year or two, the big issue that has emerged is which patents can be listed on the register. There are some rules set out in the NOC Regulations as to timing, and relevance to the product, but they are not as clear as they might be. For years, Health Canada essentially listed any patent submitted. Lately, Health Canada has been attempting to enforce at least some rules, but issues of interpretation come up all the time. If in doubt Health Canada generally lists the patents, as the path of least resistance. Every time Health Canada says it will not list a patent, there is inevitably a judicial review application against the Minister of Health brought by the brand name drug company.

The US has a somewhat similar scheme, but Europe and other G7 countries do not. In the US, the automatic stay is for 30 months. There is a lot of concern about the anti-competitive effect of the automatic stay. The state Attorney Generals recently brought action against Bristol-Myers for alleged anti-competitive listing of a patent in connection of its Bu-Spar anxiety medication. In late April, the Federal Trade Commission (FTC), the US anti-trust cops, for the first time, prohibited a drug company, Canada's own Biovail, from listing a patent or triggering the 30 month stay, for Biovail's drug TIAZAC.

The FTC is now doing an industry wide-investigation on the effect on the possible anti-competitive effect of the 30 month automatic stay, due out this summer. Various proposals to amend the scheme are before the US Senate.

In Canada, the Chretien government zealously supports the Regulations, which it sees as pro-Quebec, because so many of the multi-national drug companies are big employers in the Montreal area. Canada's Competition Bureau, unlike its US counterpart, has been inactive so far.

You can live a long and fruitful life without ever hearing much about the Industrial Design Act. But the NOC Regulations are likely to come up more and more.