Widespread Prescription drug wars largely attributable to complex regulatory scheme

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Every month or so a pile of intellectual property decisions lands on my desk. And every month, at least half of them, sometimes three-quarters, are pharmaceutical cases. In other words, intellectual property litigation in Canada in the nineties mostly arises from one sector of the economy, the prescription drug industry.

Most of the court battles are of course between "brand name", "originator" or "innovator" drug companies and Canada's two big "generic" drug companies, Apotex and Novopharm (Apotex and Novopharm also sue each other regularly). Although legislation in 1993 brought an end to compulsory licenses (i.e. government-imposed licenses of patent rights to make pharmaceuticals), the generic-brand name struggle still goes on, probably more vigorously than ever.

Essentially, what underlies the cases is the question is, when should price competition for a particular medicine (or "molecule" in industry parlance) be introduced? Then, once patent protection expires, or is conceded not to be infringed by the generic, what non-patent intellectual property protection (such as unregistered trade-mark rights in the appearance of the pills) can be used in court to minimize the effect of generic competition as much as possible?

Why do other industries not generate the same volume of intellectual property litigation? The answer I think is that the complex regulatory environment governing pharmaceuticals makes it both desirable and achievable to keep generic competitors out of the market for a particular molecule for a long time through litigation. As well, the amount of money at stake per product is simply higher than in many other industries.

There are essentially three broad categories of cases going on: judicial review applications under the Patented Medicine (Notice of Compliance) Regulations (the "NOC Regulations"), passing off cases relating to the appearance of the tablets, and patent infringement actions.

The NOC Regulations: There have been at least ninety cases commenced under certain new regulations under the Patent Act. The regulations came into force in 1993. What is at issue in these cases is whether an "injunction" should be granted in each case preventing a new generic product from entering the market, where patent protection is disputed.

Under the Regulations, a generic company that wants to bring out a generic version of a drug protected by a patent must file a notice with the federal health and safety regulator and the brand name company. If the generic manufacturer admits its drug infringes the patent, it must undertake not to enter the market until patent expiry. The controversial provisions, however, concern what happens if there is a dispute about infringement or validity. In that event, the generic files a "notice of allegation" (known as a Form V) with the regulator and the brand name company claiming that its generic product does not infringe the patent, or that the patent is invalid.

If it gets such a notice, the brand name company has 45 days in which to commence a judicial review application in the Federal Court for an order preventing the generic from being given regulatory approval to enter the market. As soon as the brand name company starts the application, the generic company is immediately and automatically enjoined until the application gets to court, which may be years later. When the hearing at last takes place, the judge decides at a one day or two-day hearing (not a trial) whether the "allegation" is "justified" i.e. whether the generic has conclusively proven by affidavit evidence that its product does not infringe the patent, or the patent is invalid. If he or she thinks the generic company is right, the application is dismissed, and the generic can get regulatory approval, once all health and safety concerns of the regulator are met. If not, the court issues a "notice of prohibition" which in effect continues the statutory injunction already in place.

In other words, the Regulations mean that where there is a patent dispute about infringement or validity, the brand name company has the opportunity to get an injunction stopping the generic from getting on the market before trial. As the issues are often complex and there are no live witnesses, the hearing is no more than a preliminary review of the issues, often turning on the intricate wording of the regulations themselves, rather than on the evidence.

The scheme is obviously analogous to an interlocutory injunction proceeding, in that it may result in an order that the alleged infringer stay off the market prior to trial, or until the patent expires. But there are some key differences, designed to make the procedure more favourable to the brand name company than normal patent litigation would be. Many of the familiar safeguards governing interlocutory injunctions known to all litigators are not present. The applicant brand name company does not have to show that it would suffer irreparable harm. The balance of convenience is irrelevant. No undertaking as to damages must be given by the applicant. There is no need for the moving party to show a "substantial issue to be tried"; rather, it is the generic that must show its "allegation" (of non-infringement or invalidity) is "justified". Another

peculiarity is that there is never a trial to resolve the issues under the procedure in the Regulations. If the generic company wants a trial it must commence a separate proceeding, a full-scale lawsuit alleging non-infringement or invalidity.

The curious thing is that the brand name drug company already of course has all the normal remedies available to any patentee. Like any patentee, it can start a patent infringement action, and seek a permanent injunction and damages. It can move for an interlocutory injunction. The NOC Regulations procedure gives a pharmaceutical patentee an additional, and much more effective, remedy that other patentees in other industries do not have. Essentially, merely by alleging that there is infringement, it can get an interlocutory injunction.

As one would expect, the brand name companies have been quick to use this procedure, resulting in a vast flood of jurisprudence. Not only have the courts had to deal with the prohibition hearings themselves, but there have been innumerable interlocutory issues, arising out of procedural issues. Most trial level decisions, whether final or interlocutory, have been appealed to the Federal Court of Appeal. The actual validity of the regulations themselves was also attacked recently in court, but no decision has yet been released.

Oddly enough, despite this vast flood of litigation, the actual issues between the parties remain unresolved. There is no final determination at the hearing whether in fact the patent in question is infringed or valid, which can only be resolved through an actual patent trial, conducted in the old-fashioned way.

Size, shape and colour: Another type of pharmaceutical IP case now before the courts involves the question of whether the generic tablet can look like the originator tablet, i.e. whether having a similar size, shape and colour is "passing off". The most well-known affected product is fluoxetine, also known by the brand name PROZAC. The patent for Prozac expired in March 1996. The major generic companies both have generic versions ready to go to market. An interlocutory injunction was issued by Mr. Justice Rothstein of the Federal Court Trial division, preventing them from doing so using the same size, shape and colour as Eli Lilly's Prozac tablet in March. The order is under appeal.

Mr. Justice Rothstein also issued a somewhat similar injunction in another case in 1994, involving an arthritis pill, diclofenac. However, the denial of an interlocutory injunction in another case involving a heart pill called verapamil was upheld by the Federal Court of Appeal at approximately the same time. A number of other cases have now been commenced, involving new generic products that have recently entered or are about to enter the market. (It is difficult for me to comment much on these cases since I am involved in one of them as counsel myself).

The brand name strategy in some of these cases is to bring out a "ultra-generic" or "pseudo-generic" product (i.e. a generic which is licensed by the brand name company, or sold through a subsidiary), which has the same size, shape and colour as the brand name product, while at the same time seeking an injunction preventing independent generic

companies from using the same size, shape and colour. The more expensive brand name product can then continue to be sold to that segment of the market that is cost-insensitive (people on deluxe drug plans) at the patent-exclusivity price, while selling the same product at a different price in the generic market (those on government drug plans, or generic-only plans). This will diminish the independent generic market share; pharmacists will tend to order the pseudo or ultra-generic, if it looks the same but the independent generics do not.

The basic factual issue in these cases is, what does the appearance of the tablet actually mean to the patient? Is it an indicator of source or brand or is it an indicator of the type of medicine? Is the patient confused if the generic looks the same?

Patent litigation: There are also some hotly contested patent infringement actions. One involves Canada's best selling prescription drug, enalapril maleate, a hypertension drug. In that case, the Court of Appeal recently found that product acquired by Apotex prior to the issuance of the Merck Frosst patent was subject to the defence in section 65 of the Patent Act. That section, to make a long story short, says that if an infringing substance is acquired prior to the issuance of the patent, then it does not infringe. The Court of Appeal also found that certain batches of Apotex's enalapril maleate did infringe because they had not been entirely processed prior to the issuance of the patent. The Court also dismissed a claim by Apotex that the relevant claims were invalid.

Because some of the enalapril maleate was infringing, and some was not, litigation has been ongoing as to the practicalities of drawing the line.

AZT: There is also litigation between Apotex and Glaxo Wellcome as to the validity of the patent for this famous AIDS drug. Apotex claims that the "invention" in the patent was not really an invention, or that, if it was, that the alleged inventor was not the actual inventor. That case has not yet been heard.

All in all, these cases look likely to keep the Federal Court busy for some considerable time to come.