A subsidy parading as a litigation system

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Just as death and taxes are certainties, so is litigation between brand name and generic drug companies about some pill or other, it seems. The last few months have been no exception.

The stories of two drugs in particular are interesting, because, in different ways, both cases illustrate how not only the courts, but also politicians, play an important role in matters to do with drug patents.

The two drugs are naproxen, a non-steroidal anti-inflamatory (NSAID), taken by arthritis suffers among others, and enalapril, a ACE inhibitor, used to lower blood pressure.

The napoxen situation highlights the odd results that flow from Canada's system for dealing with patent disputes in the drug industry. In short, drug patent disputes may be litigated in two parallel litigation processes.

A patent dispute, in any industry other than the drug industry, is dealt with through only one system: a patent action under the Patent Act. Normal civil procedure applies. The infringement or validity issues, as the case may be, are determined at trial.

If there is a dispute about drug patents, however, the generic manufacture is obliged to get involved in complex litigation under the controversial Patented Medicines (Notice of Compliance) Regulations, also known as the Linkage Regulations or NOC Regulations. There may also be litigation under the Patent Act on the same drug, about the same patents

As many people know, there has been an awful lot of litigation under the NOC Regulations. As a result, a kind of alternate body of civil procedure has evolved, unique to NOC litigation, a bit like an alternate universe in a science fiction story where nothing is quite the same.

In effect, the NOC litigation triggers various complex stays or injunctions preventing market approval the grant of a Notice of Compliance (NOC) to the generic. The normal rules governing interlocutory injunctions do not apply.

But here's where it gets weird. A peculiar feature of the NOC litigation system is that the actual patent issue between the parties (is the patent valid and infringed or not) cannot be determined by the Court in NOC litigation because there's no full trial. The only issue in NOC litigation is whether the grant of an NOC should be "prohibited". The form is a judicial review hearing. As a practical matter, the generic has the onus to show in NOC litigation that its product would not infringe a valid patent. But whether it does so or not, there is no res judicata. Either party can still sue the other about the patent issues in parallel litigation under the Patent Act, using normal civil procedure. Your can have years of litigation that does not resolve the issue in dispute.

The Courts have said the actual patent issue can only be determined under a normal patent action under the Patent Act, in which you have a trial, live expert witnesses, and so on.

What happened in the naproxen case is that, for the first time, different results on the same drug were reached in the two different systems. Apotex claimed Hoffmann La Roche's patent on naproxen was invalid and not infringed. Apotex lost in complex multi-year NOC litigation, that is, its NOC for naproxen was prohibited.

Meanwhile, there was parallel litigation under the Patent Act. Apotex won that litigation. In April, 1999, Justice Barbara Reed of the Federal Court Trial Division, found Hoffmann's patent was both invalid and non-infringed.[1]

Apotex by then had had been kept off the market for years by the NOC litigation. Yet at trial it had turned out, when the issues were fully reviewed, that Apotex had been right all along.

All this is the result of political decisions. The NOC Regulations, as this case shows, are a kind of subsidy parading as a litigation system. In effect, Canada's politicians have decided, "whether a given patent is valid or not or infringed or not doesn't matter; consumers should still pay monopoly prices during years of litigation, to reward drug R&D. "

An R&D subsidy to big drug companies may or may not be a good idea. But creating a complex double track litigation is a complex and expensive way of redistributing income to achieve policy goals. Why not just charge consumers a tax and redistribute the proceeds in subsidies or tax breaks to drug companies whom politicians wish to reward?

The present system penalizes desirable behavour. If a generic drug company establishes that a patent is not valid, and therefore monopoly prices are being charged without justification, that is a good thing. Yet NOC Regulations system penalizes the generic manufacturer for doing it.

The other drug that is big news lately is enalapril marketed under the brand name VASOTEC by Merck. In that case, a generic drug company Nu-Pharm got an NOC for

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[1] *Apotex v. Hoffmann La Roche*, F.C.T.D. Court File no. T-2870-96, Reasons, April 23, 1999.

a generic version as a result of a decision of Mr. Justice Cullen of the Federal Court Trial Division.[2] Nu-Pharm claims Merck's patent is invalid.

For complex reasons, the Patented Medicines (Notice of Compliance) Regulations did not apply. Therefore, there was no stay on the grant of the NOC to Nu-Pharm, even though Merck had a patent. That meant Merck did not have the benefit of the two parallel litigation systems usually available to drug patentees. It could only commence normal patent litigation against Nu-Pharm under the Patent Act, not NOC litigation. Merck objected strongly about this to the government.

In response, the Federal government suddenly announced in early August, 1999 that the NOC Regulations would be amended so as to broaden their effect. As you would expect this has been intensely controversial. What form the amendment will finally take is not clear at the time of writing. Although it is too late for the change to effect enalapril, it looks like the amendment may lead to even more litigation under the NOC Regulations in respect of other drugs.

[2] *Nu-Pharm v. A.G. Canada and Minister of Health*, [1999] 1 F.C. 620 (T.D.).