Prime Minister drags IP into the political arena

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In December, something unusual happened. Jean Chrétien involved himself in an intellectual property question. Usually, such issues are only of interest only to highly-specialized patent litigation nerds.

The issue was what to do about the Patented Medicine (Notice of Compliance) Regulations. These are regulations under the Patent Act, sometimes known as the Linkage Regulations or NOC Regulations. Of course, the eyes of any normal reader will glaze over at the mention of regulations under the Patent Act, and rightfully so. But these are no ordinary regulations. That, of course, is why the PM's involved.

Why would the highest level of government wade into this?

Oddly enough, the Regulations essentially deal with civil procedure, normally one of the world's most boring topics. What they do, in brief, is change what happens if there is a dispute about whether a valid patent is infringed. But they apply only to one industry: prescription drugs.

The mechanism under the Regulations is convoluted. The wording is, to be charitable, unclear. The gist is that a drug patentee that wants a stay before trial in a patent dispute doesn't have to establish the normal criteria for an interlocutory injunction we all remember from law school: an arguable case, irreparable harm, the balance of convenience, etc. Instead, under the Regulations, the drug company sues the generic, and by filing the court papers is automatically entitled to a stay. It can then get an injunction at a special hearing where the test is much easier than in normal litigation.

Since a stay is triggered by merely starting litigation, the voume of litigation has of course been huge since the Regulations came into force in 1993. Easily three quarters of all the intellectual property cases coming out of the courts these days arise from these Regulations.

All this begs many questions. Why are pharmaceutical patentees entitled to automatic remedies, but not, say, mechanical or electrical patentees, or for that matter, your Uncle

Charlie? If generic drugs are kept off the market, through regulatory stays imposed by Regulations, but do not in fact infringe a patent, isn't the patentee getting a windfall, at the expense of Canada's consumers and health care system?

Lobbying has been fast and furious (full disclosure: I appeared before the parliamentary committee considering the regulations last spring, on behalf of the generic industry, and have represented generics in court). Generic manufacturers are outraged, and say the Regulations deny them rights in court all other litigants have.

The reason Chrétien got involved is he had to settle a public squabble between two cabinet ministers over what to do.

In the fall, Allan Rock, Minister of Health, who, as it happens, was a civil procedure expert before becoming a politician, said that the Regulations should be repealed. However, Industry Minister John Manley disagreed, and said the Regulations should be kept, but modified in some unspecified but presumably minor way.

Chrétien overruled Rock, reported the Globe and Mail on December 23, and said Manley should make some minor changes, but otherwise keep the Regulations.

There seems to be a notion in Ottawa that questions of civil procedure in patent disputes in the pharmaceutical industry have a bearing, in some way not clear to this writer, on Quebec's relationship with the Rest of Canada. Many brand name drug companies have offices located around Montreal. This may be why Rock was overruled. We need a special civil procedure for patent disputes about drugs, decreed the PM, make it so.

Manley's ministry came out with proposed draft changes to the Regulations in the Canada Gazette on January 24. Although billed as making the regulations fairer, they are in fact window-dressing. In their present form they are likely to increase the amount of and length of the litigation. The proposed changes are in draft only, and have touched off another furious round of lobbying, over what boil down to civil procedure questions.

Cabinet ministers, and possibly the PM himself, are likely to be dragged into these debates again, because of the muddle. After all, the government is trying to re-invent the wheel, for political reasons.

If for some reason, it is politically unacceptable to let the courts deal with interlocutory issues as they see fit, as they do in any other disputes, the problem then is, how do you come up with a procedure which is unique to pharmaceuticals and therefore politically acceptable, but also even-handed? If automatic remedies must be imposed, how stringent must they be? To what extent should procedural safeguards available to other defendants in other industries be thrown out, in this one industry?

There is an old saying that there are two things you never want to see being made: sausages and laws. I've never seen sausages being made, but it can't be worse.