Little New in Canada's Drug Patent Laws

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"Here, you see, it takes all the running you can do, to keep in the same place," explained the Queen of Hearts to Alice, which also sums up nicely the recent "Review" of Canada's drug patent laws; lots of legwork, but no change in position, at least not so far.
The drug patent issue came to the political frontfront in the spring of 1997 as a legacy of the Mulroney government. In 1993, the then-governing Tories included a statutory requirement that Canada's patent laws would be "reviewed" in four years i.e. in 1997, as part of the Bill C-91 amendments passed that year.

Bill C-91 amended the *Patent Act* to abolish compulsory licensing of pharmaceutical patents, among other things. The most controversial part of the 1993 package was the sudden appearance of the *Patented Medicine (Notice of Compliance) Regulations* or "Linkage Regulations" which link the granting of regulatory approval to generic drugs (a Notice of Compliance) to the patent status of the originator drug. These Regulations have generated a phenomenal amount of litigation (120 cases so far), and were at the centre of the recent Review.

The Linkage Regulations essentially create new rules for patent litigation, applying only to drugs. A patentee in any other industry simply sues an alleged infringer for patent infringement, and the dispute is governed by the normal rules of civil procedure. But if the patentee happens to be in the pharmaceutical business, court proceedings under the Regulations can block an allegedly infringing generic from entering the market through various injunctions or "prohibitions", which are easier to obtain than an equivalent injunction would be in normal litigation. An initial 30 month prohibition is in fact completely automatic i.e. is granted without any hearing at all. Oddly enough, this complex and cumbersome process does not allow the court to actually resolve the issue: does the generic in fact infringe a valid patent?

The generics maintain that the Regulations should be repealed, and patent disputes resolved in the courts as in other industries. The brand name companies argue that special rules are needed for the pharmaceutical industry (here, I am obliged to disclose

my partisan involvement: I appeared on behalf of the generic industry on this issue in the recent parliamentary hearings).

Early in 1997, it was announced that the vehicle for the Bill C-91 Review would be hearings before the Standing Committee on Industry, chaired by Liberal MP David Walker. Many weeks of hearings followed, dealing with such issues as, should Canada's current 20 year patent term be extended by a further 5 years to compensate for delays in obtaining regulatory approval for new drugs (the brand name drug industry said yes, the generic industry, no), should compulsory licensing be brought back? (brand names: no, generics: yes), had the brand name industry lived up to the R&D committments made at the time of Bill C-91, in return for a full 20 years of patent protection? (brand names: yes, generics: no), what , if anything, should be done about the Patented Medicine Prices Review Board (PMPRB), the tribunal that monitors drug prices? (numerous conflicting points of view), would a national pharmacare program deal with the problem of rising drug costs? (numerous points of view), and finally, at the heart of the debate, what should be done about the Linkage Regulations?

Minister of Industry Michael Manley made it clear at the beginning of the hearings that it was unlikely that the Liberal government was going to make any substantial changes, with the possible exception of changing or repealing the Linkage Regulations, the subject of much lobbying. The brand name industry also lobbied tirelessly for patent term extensions.

The hearings were rushed to a conclusion because the federal election was about to be called. The Standing Committee released inconclusive recommendations in mid-April that steps be taken to "investigate the feasibility" of a national pharmacare program (a Liberal election plank), and that the Linkage Regulations were "problematic" and should be "revisited". Industry Minister Manley and Health Minister Dingwall then issued a joint communique immediately before the election call, pledging to review the Regulations "on a priority basis" - presumably after the federal election.

No one yet knows whether this means more hearings, or some other process, or possibly, that nothing will happen at all.