

"Evergreening" drug patents become big issue

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Now that the baby boomers are becoming middle aged, and prone to high blood pressure, ulcers, erectile dysfunction, and so on, things look great for the drug industry. Invest in it for the long term!

The prescription drug market in Canada is now worth \$9.2 billion per annum at the wholesale level, which is going up steeply every year.

But there's a snag for big pharma: patents are key to success in the world's most profitable industry, but unfortunately, patents, like youth, are fleeting; a patent expires twenty years after the filing of the application.

Some major drugs are due to go off-patent both in the US and in Canada in the next few months or years. That's why some generic drug stocks in the US have doubled in the past year.

The revenue of big pharma drug companies often comes mainly from only one or two blockbuster products, like Astra's LOSEC or SmithKline's PAXIL, both of which have world-wide sales in the billions. Keeping the franchise going as long as possible is all-important.

Like aging actresses getting cosmetic surgery, the drug companies want to hold off the ravages of time as long as possible. Rather than getting a nip and tuck, they get new patents on old products that expire long after the original patent. Such patents may be for uses, a pill coating, a manufacturing method, or a metabolite - a slightly different form of the active molecule. The idea is to keep patent protection alive as long as possible ie. to "evergreen", as such strategies are sometimes called.

In the US, evergreening patents are suddenly a major, high-stakes intellectual property issue. Both Republicans and Democrats support curbing them. A bill before the US Senate, co-sponsored by John McCain, George W's rival for the Republican presidential nomination, and Democrat Charles Schumer (NY), would limit the patents that can be used to block generic competition through listing in the Orange Book.

Some background is needed, to explain.

Both Canada and the US link the health and safety approval of generic drugs to the patent status of the equivalent brand drug. Other countries do not do this; in most, health and safety approval of generic drugs is confined to health issues.

Under the 1984 Waxman-Hatch amendments in the US, a generic manufacturer, before it can get its drug approved for sale, must not only satisfy the Food and Drug Administration (FDA) its drug is safe and effective, it must also "certify" to any patents listed by the brand for its equivalent product in the so-called Orange Book, an FDA publication.

If the generic "certifies" its product would not infringe a patent in the Orange Book, the brand can start patent litigation. If brand does so (and here's the point), the statute automatically prevents approval of the generic drug for 30 months, or until the litigation is resolved.

In short, listing a patent in the Orange Book gets you an automatic injunction, regardless of the merits, in an industry where keeping the generic out of the market may be worth millions in revenues per day.

The problem is there is no real limit on what patents that can be listed in the Orange Book.

If you were counsel for the brand, what would you advise? Put as many patents as possible in the Orange Book, relevant or not, and litigate like crazy! And, of course, that is exactly what happens.

There have now been succession of drugs where evergreening patents were listed in the Orange Book, triggering the stay, and complex litigation between the brand and generic followed, about whether the patent should have been listed.

The latest drug to become involved in a controversy of this kind is buspirone, a sedative, sold by Bristol-Myers Squibb (BMS) under the brand BuSpar. A metabolite patent was listed by BMS in the Orange Book just before Christmas, just as generic versions were on the verge of approval. Two generic companies, Watson and Mylan, sued the FDA, claiming the patent is improperly listed.

Last fall, Ivax, another US generic company, defeated an Orange Book strategy aimed at preventing FDA approval of the cancer drug paclitaxel. The US anti-trust cops are investigating whether listing the patent in question in the Orange Book was anti-competitive.

Similar issues are also becoming urgent in Canada. Before any significant new generic drug can be approved, there will be years of complex litigation under the Patented Medicines (Notice of Compliance) Regulations, Canada's equivalent of the Orange Book regime, passed in 1993.

As in the US, the litigation triggers an automatic injunction. New patents can be added to the patent register, as we call our Orange Book, to repeatedly re-start the injunction. In response to lobbying, Health Canada has gradually become somewhat more pro-active than the FDA in policing what patents are listed on the register, but there are still only vague, easily circumvented limits.

The system is great for lawyers like me, because it's complicated, and breeds litigation. But it's lousy for anyone who pays for drugs. Low-cost drugs are kept off the market for years due to litigation over irrelevant evergreening patents.

The health regulator should deal with health issues, not patents. Drug patent disputes should be resolved through ordinary patent litigation, as in other industries.

At some point, rising drugs costs will make these issues critical, as is already happening in Washington DC.

Full disclosure: I represent generic manufacturers in discussion with the federal government on these regulations. So I'm paid not to like them.

But I don't think I'd like them anyway!