

This newsletter does not constitute legal advice

NEWS FLASH - Paclitaxel Generic Victorious

In a split decision, the Supreme Court of Canada (SCC) last month ruled against Bristol-Myers Squibb (BMS) in its attempt to prevent Biolyse Pharma from obtaining a Notice of Compliance (NOC) from the Minister of Health, permitting the sale by Biolyse of a low-price version of the anticarcinogenic drug paclitaxel, sold by BMS as Taxol™. Paclitaxel is in the public domain, but BMS obtained several Canadian patents covering new formulations and methods of administration of the drug.

BMS argued that as the Biolyse drug is the bioequivalent of Taxol™, Biolyse should have been required to prove non-infringement or invalidity of BMS's patents before an NOC would issue. But the Biolyse product is obtained from a natural source; Taxol™ is made synthetically, so the SCC ruled that the Biolyse product is not a mere copy-cat generic version of Taxol™, and accordingly could not be considered *a priori* to be a copy-cat drug.

While BMS lost this round, the war is not necessarily over. BMS may, if so advised, bring an action for patent infringement against Biolyse.

The SCC took the opportunity to review the policy underlying §55.2 of the *Patent Act* and the related *Patented Medicine (NOC) Regulations*.

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Patent Act Amended

The *Patent Act* has been amended for certain housekeeping purposes, the most important of which is an attempt to overcome the consequences of the ruling by the Federal Court of Appeal in the *Dutch Industries* case that after the expiry of the grace period provided in the *Patent Rules*, the Commissioner lacks jurisdiction to entertain late payment of make-up fees when a given fee, e.g. a maintenance fee, had been paid incorrectly at the small-entity scale. For this purpose, added to the *Act* is new §78.6 whose operative subsection reads as follows:

If, before the day on which this section comes into force, a person has paid a prescribed fee applicable to a small entity, within the meaning of the *Patent Rules* as they read at the time

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The amended *Patent Act* overturns the *Dutch Industries* case ruling that a patent is invalid if an official fee had been incorrectly paid on the “small entity” scale and the late-payment grace period has expired.

Before *Effigy*, the trademark applicant having the earliest date of use in Canada could sometimes prevail over a conflicting applicant.

After *Effigy*, the applicant with the earliest effective filing date prevails.

of payment, but should have paid the prescribed fee applicable to an entity other than a small entity and a payment equivalent to the difference between the two amounts is submitted to the Commissioner in accordance with subsection (2) either before or no later than twelve months after that day, the payment is deemed to have been paid on the day on which the prescribed fee was paid, regardless of whether an action or other proceeding relating to the patent or patent application in respect of which the fee was payable has been commenced or decided.

§78.6 will take effect only upon proclamation following completion of the drafting of new Rules to implement the new section. We'll try to let you know when the amendment takes effect.

Of the other housekeeping amendments, the one officially incorporating the Schedules of §21.02 and 21.03 into the *Act* is perhaps the most noteworthy. This step is expected to facilitate measures to supply crucial patented medicines to developing and least-developed countries at low prices.

Trademarks Practice: Conflicting Applications

The 10 May 2005 decision of the Federal Court of Appeal in *Attorney-General v. Effigy* is more alarming at first sight than upon reflection. Nevertheless, it deserves careful consideration by all trademark practitioners.

Prior to *Effigy*, whenever they recognized a conflict between two or more pending applications, Trademarks Examiners would cite the application with the earliest critical date against the others. If one or more of the trademarks were allegedly used in Canada before the filing dates of the other conflicting applications, then the application entitled to precedence, according to the prevailing pre-*Effigy* practice, was the one whose alleged date of first use was the earliest. Absent any fatal objections by the Examiner, that application would proceed to publication in the *Trade-marks Journal*, and then, absent an opposition, to allowance and eventual registration.

The *Effigy* decision requires Examiners to cite the application with the earliest effective filing date, taking into account Convention priority dates if applicable, against the other conflicting application(s). Subject to answering any other objections by the Examiner, that earliest-filed application is entitled to proceed to publication, and thereafter to allowance and registration, absent a successful opposition against it.

Let us suppose that you represent a prospective applicant who has used its trademark in Canada, so that the application will be based at least in part on the date of first use in Canada. (The date of first use in any other country is irrelevant unless your client files or defends an opposition or becomes involved in litigation.) What guidelines should you observe? We suggest the following:

1. File your client's application in Canada as soon as possible, and within the Convention priority period if applicable. Don't delay filing until a date of first Canadian use is ascertained. The date of first Canadian use can be specified as being “at least as early as” some date about which you and your client are tolerably comfortable, and if it later turns out that the date specified in the originally filed application cannot be substantiated, a later date may be entered by amendment, or the use-in-Canada basis for the application can be cancelled.
2. Within a few months after filing the application, conduct a state-of-the-Register

search for conflicting applications. It is best to wait a few months after filing so that (i) the Trade-marks Office index is reasonably up to date, and (ii) any conflicting applications claiming Convention priority with a possible effective date earlier than your client's filing date will be located in the search. Depending upon the results, a supplementary directory or internet search, or other supplementary searching, may be indicated.

3. If it appears that a conflict exists, and that some other applicant is likely to have precedence, consider whether there is any way around the conflict that may help your client. For example, your client may have filed to protect a word mark, but your client's design mark containing a potentially conflicting word may have sufficient distinctive graphic matter that non-confusion between your client's mark and the conflicting mark could be argued. (Of course, any time you argue non-confusion, you run the risk of inferentially reducing the ambit of protection to be given any registration that you may ultimately obtain for your client, so that risk should be weighed.) Or it may be possible to cancel some of your client's wares and services listed in its application and to re-identify others to avoid a finding of confusion. Et cetera. Note that if you are able to obtain registration for one mark of a family of similar marks used by your client, you will have established a foothold that may be available as a foundation to support later registration of one or more other members of the family. It should be readily possible under Canadian practice to advance the prosecution of the application for the most promising of the marks and to delay prosecution for other members of the family.

4. If the conflict appears to be unavoidable and the other party is likely to prevail, begin preparing for a possible opposition against the conflicting party's application. If your client has fairly extensive use in its home country and some spill-over reputation in Canada, your client may be able to prove non-distinctiveness of the conflicting applicant's mark even without proof of prior use in Canada. Further, there are decided cases suggesting that distinctiveness is to be tested as of the date of commencement of opposition proceedings. So you may wish to advise your client to use and advertise its trademark extensively in Canada before the opposition is commenced. While this step presents your client with the risk of over-investing in a mark that eventually may have to be abandoned in Canada if your client loses, the investment may be worthwhile both for negotiating leverage in possible settlement discussions and as partial proof of your client's case in the eventual opposition. Or your client may be able to modify its mark for Canadian purposes in some way that eliminates or greatly reduces the potential for confusion with the conflicting mark, and to file an application to register the modified mark.

5. Note that it should be possible to keep your client's application pending in Canada notwithstanding the adverse citation of the conflicting application, and notwithstanding any opposition proceedings. The Trade-marks Office may be expected to grant time extensions lasting in total several years in order to permit your client to fight to conclusion an opposition against the cited application.

Each case is unique; our advice would of course be tailored to fit the circumstances. The main point is that *Effigy* is not necessarily fatal to your client whose application was filed later than a conflicting application. There may be ways around the citation of a conflicting application that will ultimately avail your client.

The “Gillette Defence” to Patent Infringement in the Age of Purposive Construction

The 1913 House of Lords case *Gillette Safety Razor v. Anglo-American Trading* is authority for the self-evident proposition that a valid patent cannot be infringed if

**Notwithstanding
Effigy, there are steps
that the apparent loser
of a trademark conflict
can take that might
turn its case into a
winning case.**

what the defendant is doing is old or obvious relative to what is claimed in the patent. In other words, if a claim admits of two alternative interpretations, the narrower one of which renders the claim valid but not infringed, while the broader renders the claim invalid, the patentee is on the horns of a dilemma, and the defendant is not obliged to choose between the two interpretations. Such a defence to a claim for infringement is often referred to as a "Gillette defence" from the eponymous case. The Supreme Court of Canada acknowledged the availability of this defence in 1940 in *J.K. Smith & Sons v. McClintock*.

More recently, Canadian courts have adopted as the primary guiding principle of claim construction the doctrine of purposive construction. Under this doctrine, quoting from two recent cases, "the patent must be given a purposive interpretation and not be subjected to a purely literal or technical approach". "The question to be asked is one of construction, but of purposive or realistic construction through the eyes and with the learning of a person skilled in the art, rather than with the meticulous verbal analysis of the lawyer alone." In 2001 in *Whirlpool v. Camco*, the Supreme Court of Canada ruled that

The key to purposive construction is therefore the identification by the court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be the "essential" elements of his invention.

Purposive construction points to an unambiguous meaning of any given claim, not to the ambivalence posited by *Gillette*. How then does the Gillette defence square with purposive construction?

In *Biovail Pharmaceuticals v. Minister of National Health and Welfare* decided this year, the claims as literally read covered any controlled release of a specified drug, yet the description of the allegedly inventive controlled-release process included only a discussion of an osmotic process. Harrington J. held that the "controlled release composition" in the claims had to be restricted, on a purposive construction, to such compositions operating in an osmotic pressure system. On this reading, the claims were not infringed. His Lordship added (aren't you surprised that Canadians still recognize Lords?):

However, if the claims cannot be read in this way, then I am of the view that the patent is invalid for covetous claiming.

So it appears that the Gillette defence is alive and well, albeit applied in a "hedging one's bet" manner, as per Harrington J.'s comment. 0506 AF

We invite questions and comments on this Newsletter and suggestions for topics to be addressed in future newsletters.

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Gillette says that one can't infringe a valid patent by doing something old or obvious relative to what is claimed, and that the defendant need not choose between an invalidity defence and a non-infringement defence. How does that doctrine square with the more modern one of purposive construction of claims?

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