

## Federal Court invalidates patent due to deficiencies in specification

On July 8, 2009 Mr. Justice Hughes of the Federal Court released a decision in the matter of *Ratiopharm Inc. v. Pfizer Limited*. The issue was the validity of Canadian Patent No. 1,321,393 (the '393 patent).

The dispute between Ratiopharm and Pfizer regarding Pfizer's drug Norvasc (amlodipine besylate) has a complex history. It began with Ratiopharm filing a Notice of Allegation (NOA) under the *Patented Medicines (Notice of Compliance)* regulations, which resulted in Pfizer's application to the Federal Court for an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC). In that proceeding, Ratiopharm was successful (2006 FC 220). However, on appeal, Pfizer succeeded in convincing the Federal Court of Appeal that Ratiopharm's allegations were unjustified and a prohibition order was issued (2006 FCA 214). Ratiopharm's attempts to appeal were denied.

That brings us to the present case. Ratiopharm, still believing the '393 patent to be invalid, brought an action in Federal Court seeking a declaration of invalidity. 2009 FC 711 is the judgment in that action. Mr. Justice Hughes found the '393 patent to be invalid for every reason alleged, including obviousness, being an improper selection patent, lack of utility and violations of sub-sections 34(1) and 53(2) of the *Patent Act*. It should be noted that this decision is currently under appeal.

### INVALIDITY

The first ground of invalidity alleged was obviousness. Mr. Justice Hughes applied the test articulated by the Supreme Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* [2008] 3 SCR 265, 2008 SCC 61, and found the '393 patent obvious. The inventors were given a task: try to find a formulation of amlodipine maleate suitable for regulatory approval. They went about it in a routine manner, performing routine tests and when they found a formulation that was adequate, they stopped. According to the court, this is no more than any person skilled in the art would have done under those circumstances.

The second ground of invalidity has to do with the nature of selection patents. A selection patent is a patent that covers an unexpectedly good subset of a known larger set. For example, in the present case, the '393 patent claimed the besylate salt of amlodipine maleate. Amlodipine maleate can form several different salts. Thus, the basis for the claim was unexpectedly superior performance. However, the court found that, as a matter of fact, the besylate salt was not, "unexpectedly" better, "unique" or "outstandingly suitable," as described in the '393 patent. Therefore, the '393 patent was held not to be a valid selection patent.

The third ground of invalidity alleged was lack of utility. Simply put, the court found that the patent did not live up to its promises. The patent promised a "unique" combination of properties that made the besylate salt "outstandingly suitable" for pharmaceutical formulations. On the facts, this was found not to be the case. It was an acceptable choice, but by no means "outstanding."

The fourth ground of invalidity alleged was lack of sufficient disclosure under the old s.34(1) of the *Patent Act* (now s.27(3)). The relevant section of the act reads,

34. (1) *An applicant shall in the specification of his invention*
  - (a) *correctly and fully describe the invention and its operation or use as contemplated by the inventor;*

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The court focused on the last 5 words of the above, “as contemplated by the inventor.” Mr. Justice Hughes acknowledged that, in many cases, one must presume that what the patent says is what the inventor contemplated, simply because the inventor is not available to testify as to what was contemplated. However, in this case the inventors were present in court and gave testimony in regards to what they did, in fact, contemplate at the time. After comparing the evidence given by the inventors to what the patent said, the court concluded that the patent did not describe the invention as contemplated by the inventor.

The final ground of invalidity alleged was a violation of sub-section 53(1) of the *Patent Act* (same in old and new acts). Sub-section 53(1) reads,

*53. (1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.*

Again, using the inventor’s testimony, the court found several misstatements in the text of the ‘393 patent as well as several omissions, all of which served to make the besylate salt seem much more uniquely suitable than it was. The inventor’s original recommendation had been to pursue a patent for the besylate salt and as many as two others, yet the patent was filed claiming only the besylate salt. Thus the statements made and omitted were, in fact, misleading. At trial, Pfizer appeared to be trying to blame the situation on the trainee who was assigned the task of drafting the patent. Mr. Justice Hughes was prepared to infer that Pfizer probably knew that there were problems with the patent as drafted and was further prepared to infer sufficient intent to mislead from the fact that Pfizer did nothing to correct the problems. Therefore, the patent must be held invalid under s.53(1).

**If you wish to discuss these matters, please contact: Stephen Perry at 416.920.8170 x107 (perry@perry-currier.com) or Andrew Currier at 416.920.8170 x109 (currier@perry-currier.com).**

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