Canadian IP Law News | September 2009

Poetic License a Big "No No" in Patent Drafting: Changes to Canadian Disclosure Obligations, Utility and Inequitable Conduct

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In the recently released Federal Court decision Ratiopharm Inc. v. Pfizer Limited (2009 FC 711), Justice J. Hughes has developed significant new law regarding disclosure obligations, utility and inequitable conduct that, if affirmed, may have far reaching implications for how patent descriptions and claims are drafted in Canada.

In this decision, Canadian Patent No. 1,321,393 directed to the *Besylate Salt of Amlodipine* was found to be invalid for: (i) obviousness, (ii) being an invalid selection patent, (iii) a lack of utility, (iv) a failure to describe the invention "as contemplated by the inventor," as required by Section 34(1) at the relevant time and (v) for misleading statements and omitting relevant information from the specification in violation of Section 53(2) of the *Patent Act*. This brief summary is limited to a discussion of the last two grounds of invalidity.

Section 34(1) reads:

> *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;*
> *(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it;* [emphasis added]

Previously, the Courts have limited its analysis of "sufficiency" to "whether the patent itself describes sufficient information so as to enable a person skilled in the art to put it into practice" and have not assessed whether the patent specification is an accurate reflection of the invention as contemplated by the inventor. In previous cases, a lack of evidence has required the Courts to "assume that the words in the specification of a patent at issue coincided with what the inventors contemplated". The evidence presented in this case, including the underlying data, various memorandums and witness testimony of the inventors, provided Justice Hughes the unique opportunity to compare the invention as contemplated by the inventors with what the '393 Patent says. Justice Hughes noted that "where we have much evidence from the inventors themselves, their colleagues and contemporaneous documents, the Court cannot assume that the patent specification is *an accurate reflection of the understanding of the inventors*."

In making his findings of invalidity Justice Hughes was heavily influenced by evidence presented detailing discrepancies between the invention as contemplated by the inventor and that contemplated by the patent agent/trainee who drafted the '393 Patent and substantive "errors and omissions" with respect to experimental results. Evidence was presented that Dr. Wells, a named

inventor on the '393 Patent had very limited involvement with the preparation of the patent. Essentially, Dr. Wells' involvement in the patent process was limited to the preparation of a memorandum reflective of a "majority decision" "*with technical details to allow them to convert it into a patent with ease."* This "Patent Memorandum" was "directed to both the besylate salt and the tosylate salt, and also says that the mesylate merits patent protection" and formed the basis of the patent application. Although the initial "Patent Memorandum" described the two salts, the patent "was drafted directed to the besylate salt alone." Justice Hughes noted "many serious errors, omissions, insertions from elsewhere and departures in the '393 Patent in comparison with what the inventors contemplated." Justice Hughes particularly noted that "[w]ords such as "unexpectedly", "unique" and "outstandingly suitable" used in describing the besylate do not come from Dr. Wells or Mr. Davison, the two named inventors or anyone else in the scientific area of Pfizer." Justice Hughes concluded that these words "could only have come from the Pfizer patent department after some person, an executive or a patent agent, had decided to apply for a patent directed to besylate alone."

Although Canada does not have an explicit statutory provision direct to issues of fraud, Justice Hughes notes that Section 53 of the Patent Act "comes close".

Section 53 of the *Patent Act,* corresponding to "New Act" Section 53, says in part:

> *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.*
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> *(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled.*

Justice Hughes noted that the misstatements "served to enhance the alleged uniqueness and outstanding characteristics of the besylate salt, which characteristics were not true. These misstatements and the selection of words such as unique, outstanding and particularly suitable were the work of patent draftsmanship not of the inventors. Referring to his earlier decision of G.D. Searle & Co. Novopharm Ltd., 2007 FC 81, [2008], Justice Hughes further noted "that proper disclosure is essential and that intent to mislead can be inferred".

Although this decision is currently under appeal, this case highlights the importance of inventor involvement in all aspects of the patent process. To ensure that the patent is an accurate reflection of the invention as contemplated by the inventor, the inventors should be actively encouraged to participate in the drafting process by reviewing the specification prior to filing.