

Federal Court Clarifies Good Faith Requirement in Patent Prosecution

On November 23, 2009, Madam Justice Mactavish of the Federal Court of Canada released a decision in the case of *Lundbeck Canada Inc. V. Ratiopharm Inc.* regarding an Alzheimer's drug available and marketed in Canada under the brand name EBIXA.

Ratiopharm initially served a Notice of Allegation ("the NOA") under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 on Lundbeck, for the purpose of obtaining a Notice of Compliance ("NOC") from the Minister of Health for a generic version of EBIXA. There were two patents at issue, CA 2,014,453 ("the '453 patent") and CA 2,426,492 ("the '492 patent"). In the NOA, Ratiopharm alleged anticipation, obviousness and lack of utility of the both patents as well as lack of good faith prosecution for the '492 patent. Ratiopharm also alleged that neither patent would be infringed if it were allowed to market its generic version of EBIXA.

THE '453 PATENT

The '453 patent claimed the use of memantine for the treatment of dementia, a category of diseases that includes Alzheimer's. Madam Justice Mactavish found it to be both anticipated by the prior art and obvious in light of it. The prior art disclosed the use of memantine as claimed, or failing that, suggested its use strongly enough to render treatment with memantine obvious to try. Disclosure of the previously unknown mechanism of action of the drug was deemed insufficient to prevent a finding of invalidity. Although Ratiopharm had conceded infringement of the '453 patent, the finding of invalidity made consideration of this issue unnecessary.

THE '492 PATENT

The court's findings with respect to the '492 patent were more interesting. The patent claimed that the use of memantine in combination with an acetylcholinesterase inhibitor would achieve a synergistic effect. Both drugs were previously known to be beneficial individually. The court found that the prior art did not disclose any synergistic effects which could render the '492 patent either anticipated or obvious.

However, the '492 patent was found invalid for lack of utility. The parties conceded that the patent's disclosure could not meet the test for sound prediction and Madam Justice Mactavish held that the synergistic effect had not been demonstrated. The study relied upon by Lundbeck demonstrated a beneficial effect from combination therapy but this effect could have been interpreted either as synergistic or as additive.

The '492 patent was also held to have been abandoned for lack of good faith during prosecution, a requirement imposed by paragraph 73(1)(a) of the *Patent Act*. The court accepted an analogy drawn between patent prosecution and ex parte court proceedings as articulated by Justice Hughes in *G.D. Searle & Co. v. Novopharm Ltd.*, 2007 FC 81 (reversed on other grounds in 2007 FCA 173), and held that the Patent Act imposes a duty of candour on the applicant to ensure that the patent examiner has all relevant information.

In this case, the examiner had expressed some doubts regarding the obviousness of the combination therapy since both memantine and acetylcholinesterase inhibitors were both known treatments. The patent agent responded with four studies showing that four particular acetylcholinesterase inhibitors lose their effectiveness in the presence of memantine and argued that it would not have been obvious to a person skilled in the art at

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the time to try a combination therapy. However, the agent failed to mention an article by Wenk, which demonstrated that not all acetylcholinesterase inhibitors behaved in this way. In fact, Wenk discussed some of the very compounds claimed in the '492 patent while the contradictory studies were applicable only to unclaimed compounds.

The court also found Ratiopharm's allegation of non-infringement of the '492 patent to be justified. Ratiopharm had applied for an NOC to produce memantine, not a combination therapy. A finding of inducement of infringement would have required more than Ratiopharm's supply of memantine and the near certainty that the product would be used to infringe the '492 patent. It would have required some act on the part of Ratiopharm that induced the infringement. The court found no evidence of such an act and was not prepared to speculate on what Ratiopharm might do in the future to induce infringement.

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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