

**LACK OF GOOD FAITH DURING PATENT PROSECUTION INVALIDATES PATENT [EBIXA (MEMANTINE HYDROCHLORIDE)]**

<b>CASE:</b>	<i>Lundbeck Canada Inc. et al v. Ratiopharm Inc.</i> (Federal Court)
<b>DRUG:</b>	<i>EBIXA (memantine hydrochloride)</i>
<b>NATURE OF CASE:</b>	<i>NOC Regulations: Prohibition proceeding - Section 6</i>
<b>SUCCESSFUL PARTY:</b>	<i>Ratiopharm Inc.</i>
<b>DATE OF DECISION:</b>	<i>October 28, 2009 (public reasons issued November 23, 2009)</i>

**SUMMARY:**

On October 28, 2009, the Federal Court dismissed Lundbeck's application for an order prohibiting the Minister of Health from issuing a notice of compliance to Ratiopharm in respect of a generic version of EBIXA until the expiry of Canadian Patent Nos. 2,014,453 ("453 patent") and 2,426,492 ("492 patent").

Ratiopharm alleged that the '492 patent (which is directed to the use of a synergistic combination of memantine and other agents) had not been prosecuted in good faith, inter alia. During prosecution of the '492 patent, in response to a requisition from the patent examiner to provide prior art cited in corresponding US and EU patent office applications, Lundbeck's patent agents responded that no corresponding applications existed but identified two documents cited in the International Search Report (one of which is the "Wenk article"). A further requisition was sent stating that the claimed invention was obvious. The patent agents responded by citing four documents (none of which was the "Wenk article") and arguing that these documents showed that the "prior art" taught away from the claimed invention.

MacTavish J agreed with Ratiopharm and held that Section 73(1)(a) of the Patent Act (post-1996) imposes a duty of candour and good faith upon those prosecuting patent applications and failure to do so will invalidate an issued patent. The Court found that the failure to cite the "Wenk article" in response to the second requisition was a failure to reply in good faith because it was "relevant" to the claimed invention. The Federal Court held that the duty of good faith imposes an obligation that "prior art be fully and fairly described by applicants and their agents when answering requisitions from the Patent Office." Failure to do so constituted a lack of good faith (notwithstanding that the Court did not conclude that the applicants or their agents acted in bad faith). The Court likened the process of applying for a patent to an ex parte court proceeding where the applicants must inform the Court of any fact or points of fact or law known to it which favours the other side.

MacTavish J also found the '492 patent invalid on the basis that the synergistic effect of the claimed combination was neither demonstrated or soundly predicted at the relevant time. The Court did not find that the '492 patent was anticipated or rendered obvious (including in light of the "Wenk article"). The '453 patent was found invalid on the grounds of anticipation and obviousness.

The finding of lack of good faith raises several potential concerns for patentees. It is difficult for applicants and agents to predict during prosecution those documents that will be deemed "relevant" at some later point by a Court. In addition, the language used in responding to requisitions may be meticulously examined by a Court, as was in this case. Finally the Court used a section of the Patent Act directed at applications to invalidate a patent by retroactively deeming abandonment of the application after the patent had issued.

**LINK TO DECISION:**

This decision has not yet been posted on the Federal Court website. It will have the citation 2009 FC 1102.

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