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Pharma in brief - Canada

Heightened sound prediction disclosure requirement remains controversial - Federal Court dismisses *PM(NOC)* application for lack of patent utility

Case:	*Eli Lilly Canada Inc. v. Hospira Healthcare Corporation.* 2016 FC 47
Drug:	ALIMTA® (Pemetrexed disodium)
Nature of case:	Prohibition proceeding under Section 6 of the *Patented Medicines (Notice of Compliance) Regulations* ***(PM(NOC) Regulations)***
Successful party:	Hospira Healthcare Corporation
Date of decision:	January 15, 2016

Summary

Justice Barnes rejected a prohibition order sought by Eli Lilly Canada Inc. (**Eli Lilly**) under section 6 of the *PM(NOC) Regulations* against Hospira Healthcare Corporation (**Hospira**) in respect of its generic version of ALIMTA® (pemetrexed disodium) and Canadian Patent No. 1,340,794 (**'794 Patent**), owned by Takeda Pharmaceutical Company Limited (**Takeda**) and licensed to Eli Lilly for sale of pemetrexed in Canada.

The sole issue considered by the Court as being determinative of the application was Hospira's allegation that certain claims of the '794 Patent were invalid for inutility, more specifically for lack of a sound prediction of utility by the patentee for the untested compounds falling within two claims of the patent. In his assessment of utility, Barnes J. acknowledged that while the issue of what the patentee must disclose to the public where utility is predicted remains controversial, recent case law from both the Federal Court and the Federal Court of Appeal has not displaced the requirement of heightened disclosure in sound prediction cases described by Justice Binnie in *Apotex v. Wellcome Foundation Ltd.* The Court concluded that the test data collected by Takeda was an insufficient basis to predict and articulate a sound line of reasoning for a desired result pertaining to the untested compounds and as such, Hospira's claim of inutility for the '794 Patent's compound claims was deemed justified.

Requirements for sound prediction of utility disclosure in compound claims

Hospira asserted that the test data collected by Takeda before the '794 Patent's filing date was insufficient to support a sound prediction of utility for the thousands of untested compounds encompassed in the two asserted claims of the patent. The Court stated that since it was common ground that the vast majority of the compounds covered by these claims (including pemetrexed) were not specifically disclosed nor were they made or tested by Takeda before the filing date, the utility requirement would only be established if Eli Lilly showed that the promised utility of the untested compounds would have been soundly predicted from the results Takeda obtained from its testing of some of the compounds falling within those claims.

The Court held that expert evidence on the construction of the promise of the patent was largely "unhelpful", with experts either failing to examine the claims on the basis of the entire patent specification, or failing to distinguish between "goal or aspiration" language and promises. The Court ultimately construed the promise of the patent as falling between the positions advanced by the parties and their experts.

While Justice Barnes acknowledged the "controversial" status of the proper level of patent disclosure required when utility is predicted and "expressed some sympathy" for Justice Rennie's and Justice Gauthier's recent questioning of the "general requirement for a heightened level of disclosure in sound prediction cases" in *AstraZeneca v. Apotex,* 2014 FC 638 and *Sanofi-Aventis v. Apotex*, 2013 FCA 186 respectively, he adopted the view that the current state of the law has not displaced the requirement for disclosure from *Apotex v. Wellcome*, as endorsed by the Federal Court of Appeal and in many decisions of the Federal Court.

As such, even if the Court did not give much weight to the absence of an explicit promise of utility in the compound claims of the '794 Patent, it also did not accept evidence of in-house test data or a sound line of reasoning not contained in the patent itself. The Court also reiterated that utility must be proven with respect to the entirety of any particular claim. The Court was of the view that the decisions in *Fournier Pharma* 2012 FC 740 and *Searle v. Novopharm* 2007 FC 81 do not stand for a different proposition.

Ultimately, the Court decided that the person of skill could not draw a *prima facie* reasonable inference that the thousands of untested claimed compounds included in the asserted claims would all be useful as antitumor agents *in vivo* or even *in vitro*.

Nikita Stepin

Link to decision:

Eli Lilly Canada Inc. v. Hospira Healthcare Corporation. 2016 FC 47

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