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How Much Disclosure Is Required to Support Utility of a Patented Drug In Canada?

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In a rather lengthy 271 page judgment, the Federal Court of Canada held that Sanofi-Aventis' ("Sanofi") patent 1,336,777 ('777) for clopidogrel bisulfate (Plavix®) is infringed by Apotex, but is invalid on the basis of lack of utility[1]. Noticeably, the same patent had previously been the subject of a complex litigation under the *Patented Medicines (Notice of Compliance) Regulations* and had then been found both infringed and valid in a landmark decision by the Supreme Court of Canada[2]. After its loss in the Supreme Court, Apotex brought an impeachment action against Sanofi, after which Sanofi filed an infringement action. The decision rendered by the Federal Court on December 6, 2011 relates to both actions. The key issue in the determination of invalidity of the '777 patent in the present case was the lack of demonstrated, or soundly predicted, utility, an issue which was not addressed in the NOC proceedings.

By way of context, the '777 patent discloses and claims clopidogrel, its bisulfate salt and processes for its manufacture. The compound is the single enantiomer of a previously disclosed racemate used as an anticoagulant drug in humans. The '777 patent describes various tests on clopidogrel, which demonstrated the compound had a better therapeutic index than the racemic mixture and a better tolerability, including *ex vivo* measurements of inhibition of platelet aggregation and *in vivo* measurements of toxicity and tolerability conducted in rats. Although not mentioned in the patent, human clinical trials were ongoing at the time the patent application was filed.

In its analysis, the Court ascertained the promise of the patent and opined that the '777 patent makes an explicit promise for use of the compound in humans. Because the Court was not persuaded that the utility in humans had been demonstrated, the Court analyzed whether the promise for use in humans was soundly predicted.

After considering the science and contextual history of the development and testing of the patented compound, the Federal Court acknowledged that Sanofi had a factual basis and sound line of reasoning for predicting that clopidogrel bisulfate could be used in humans. However, the Court concluded that the underlying factual basis and line of reasoning that grounded the inventor's alleged prediction were not disclosed and, as a result, the patent failed the third branch of the sound prediction test.

This decision is one of a series of at least four fairly recent decisions in which patents for drugs were found invalid for lack of utility[3] [4] [5]. This calls into question the validity of many pharmaceutical patents given the very high thresholds for utility in Canada compared to other jurisdictions. Indeed, the recent decisions from the Federal Court and the Court of Appeal seem to suggest that clinical trial data may be required for new drugs directed to humans. The Supreme Court of Canada may address this high threshold in *Teva v. Pfizer*, which will be heard in the spring of 2012.

These recent decisions highlight the importance for Applicants to include in their patent application any supporting data they may have on hand to ensure that the utility requirement is met. The language used in the application should also be considered carefully to ensure the patent is not bound to a higher promised utility that what may be supported.

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[1] *Sanofi-Synthelabo Canada Inc.* v. *Apotex Inc.* 2011 FC 1486, appeal pending.

[2] *Apotex.* v. *Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61.

[3] *Eli Lilly Canada et al*. v. *Novapharm Ltd*, 2011, FC 1288, relating to the drug Olanzapine (Ziprexa®)

[4] *Sanofi-Aventis Canada Inc.* v. *Apotex Inc.*, 2011 FCA 300, relating to the drug ramipril (Altace®)

[5] *Apotex Inc.* v. *Pfizer Canada Inc.*, 2011 FCA 236, relating to the drug latanoprost (Xalatan®)