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Pharma in brief - Canada

Federal Court consolidates s. 6 PM(NOC) application with patent impeachment action addressing same patent

Case:	*Apotex Inc v Shire LLC*, 2016 FC 1099 (Court File Nos. T-1056-16 & T-998-16), appeal dismissed on February 6, 2017
Drug:	VYVANSE®
Nature of case:	Motion to partially consolidate action for patent impeachment under the *Patent Act*, RSC 1985, c P-4 (***Patent Act***) and prohibition application pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***).
Successful party:	Shire LLC
Date of decision:	October 3, 2016

Summary

The court granted Shire's motion to partially consolidate an application pursuant to section 6 of the *Regulations* and an impeachment action with respect to the same patent.

Background

Ten days after Shire started a prohibition application against Apotex relating to VYVANSE® and Canadian Patent No. 2,527,646, Apotex brought an action seeking a declaration that the same patent is invalid and not infringed by Apotex's proposed generic version of VYVANSE®.

Shire moved to partially consolidate these two proceedings so they would be heard simultaneously by the same judge, on common *viva voce* evidence, but maintaining the parties' ability to argue the admissibility or relevance of evidence to one or the other proceeding. Apotex asserted that both proceedings should continue in parallel, as the consolidation would be prejudicial to Apotex.

Just, most expeditious and least expensive determination of both proceedings

The court allowed Shire's motion, holding that proceeding in this manner would eliminate duplication and save significant time and expense. The court also noted that a similar procedure had been previously adopted in *Novartis Pharmaceuticals Canada Inc v Apotex Inc*, 2013 FC 142.

Although Apotex's grounds for invalidity and non-infringement were the same in both proceedings, the court acknowledged that the different burdens of proof and procedural rules applicable to each proceeding would result in added complexity if the two proceedings were consolidated. However, the court held that the difficulty and the time required to address the complexity "pales in comparison" with the efficiencies and savings gained from eliminating parallel proceedings.

The court also held that the use of *viva voce* evidence would eliminate the need for the parties to prepare separate affidavits and conduct cross-examinations in the application, as well as require attendance of the inventors only twice,

for discovery and trial. Further, although not a factor in the decision, *viva voce* evidence would likely assist the court in assessing expert evidence.

The court rejected all of Apotex's assertions of prejudice. Further, as Shire acknowledged that it would have no automatic right to an extension of the statutory stay under the *Regulations* if the consolidated proceedings could not be heard within 24 months, the court was satisfied that all of Apotex's rights would be protected.

Link:

Apotex Inc v. Shire LLC, 2016 FC 1099

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