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Pharma in brief - Canada

Federal Court strikes application under s. 6(5)(b) for lack of evidence

Case:	*Valeant Canada LP v Apotex Inc*, 2016 FC 1359 (Court File No. T-953-16)
Drug:	GLUMETZA® (metformin)
Nature of case:	Motion to dismiss prohibition application pursuant to section 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations* (***Regulations***)
Successful party:	Apotex Inc
Date of decision:	December 8, 2016

Summary

Apotex successfully brought a motion to strike Valeant's application under section 6(5)(b) of the *Regulations* on the grounds that the application is an abuse of process or is otherwise scandalous and vexatious. In response, Valeant did not file any evidence and argued that it has no burden to prove anything on the motion as it has a right to a hearing on the merits. The court held that Valeant had no arguable case, and therefore Valeant's application is bereft of any chance of success and must be struck.

Background

Valeant markets metformin tablets under the name GLUMETZA® for the treatment of type 2 diabetes. Apotex sought approval to market its generic 1000 mg metformin tablets and was required to address Valeant's patent. The patent relates to a pharmaceutical composition with a controlled-released coating prepared by a specific process.

In support of its motion to strike, Apotex filed an affidavit from an expert who reviewed Valeant's patent and details of Apotex's formulation as described in its regulatory submission. The expert opined that Apotex's tablets will not infringe Valeant's patent, as the tablets will not contain or be made according to the claims of the patent and will not comprise a coating or a pharmaceutical dosage that operates in the same manner as the dosage forms and coatings of the patent.

Lack of evidence

In what the court described as a "calculated strategic decision," Valeant did not file any evidence in this motion nor in the application. The court also noted that Valeant's notice of application simply alleged that Apotex's allegations of non-infringement were not justified and did not provide the grounds upon which it claims a prohibition order.

As the premise of the *Regulations* is to prevent infringement, Apotex argued that, in the absence of any evidence of infringement, Valeant's application is an abuse of process.

Valeant contended that it has a right to a hearing on the merits, but no burden to prove anything or obligation to respond to Apotex's case on the motion to strike. Valeant also argued Apotex has the burden of demonstrating there is no possible witness anywhere that might support Valeant's case and that by bringing such a motion Apotex will obtain two opportunities to make its case.

Prothonotary Aalto rejected Valeant's arguments and held that it is not sufficient for a party to commence an application without any grounds set out in the application to support its case. Further, the burden on this motion requires Apotex to demonstrate that Valeant's application is bereft of any chance of success, which it has done by demonstrating that its tablets do not infringe the patent. Prothonotary Aalto therefore held that Valeant failed to demonstrate that its application was not bereft of any chance of success.

The right to a hearing is subject to the merits of the application

The court acknowledged Valeant is entitled to a hearing on the merits provided that the application as a whole is not bereft of any chance of success. The right to a hearing is a qualified right that cannot be given when there is no merit to the application. In this case, the court concluded that as there was no arguable case on the merits of Valeant's application, the application is bereft of any chance of success and must be struck.

Link:

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