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Pharma in brief - Canada

FCA again confirms that inventor should not be held to elevated standard of utility absent a clear and unambiguous promise

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Case:	*Teva Canada Limited v Novartis Pharmaceuticals Canada Inc*, 2016 FCA 230 (Court File No. A-404-15), aff'g 2015 FC 770
Drug:	EXJADE® (deferasirox)
Nature of case:	Appeal from a prohibition proceeding under Section 6 of the *Patented Medicines (Notice of Compliance) Regulations* in which the prohibition order was granted
Successful party:	Novartis Pharmaceuticals Canada Inc.
Date of decision:	September 15, 2016

Summary

The Federal Court of Appeal dismissed Teva's appeal of a decision of the Federal Court granting a prohibition order against Teva in respect of its generic version of EXJADE® (deferasirox). Utility was the only issue on appeal. Teva did not dispute the legal principles applied by Justice O'Reilly (**Trial Judge**), and the FCA held that he had not misapplied these principles to the facts.

Background

Norvartis's patent covers two classes of compounds: formula I and formula II. Formula II is a subset of formula I. The patent differentiates between the two classes, as formula I includes some previously known compounds whereas the compounds of formula II are all said to be new.

As we reported, Novartis obtained a prohibition order against Teva at the Federal Court. On appeal, Teva argued the Trial Judge erred in finding different promises for formula I and formula II compounds. Teva also asserted that the Trial Judge erred by applying the doctrine of claim differentiation to construe the promise and by relying on the patent's abstract in construing the promise.

Promises must be made in a clear and unambiguous way

The FCA reiterated that the "promise" doctrine will hold an invention to an elevated standard of utility "only where a clear and unambiguous promise has been made" and that where validity is challenged on the basis of an unfulfilled promise, the patent will be construed in favour of the patentee if it can reasonably be read by the skilled person as excluding the promise.

This is the second recent confirmation from the FCA on this point (see our report on *Nova Chemicals Corporation v The Dow Chemical Company*, 2016 FCA 216 here).

The "promise" doctrine has been the subject of much recent litigation, and as we reported, the Supreme Court of Canada will hear the appeal from *AstraZeneca Canada Inc v Apotex Inc*, 2015 FCA 158 on November 8, 2016. In that

case, the FCA dealt extensively with the standard of utility including the "promise" doctrine, and the appeal should provide guidance on a much-debated issue.

Different claims can have different utilities

The FCA confirmed that different claims can have different utilities for the same compound and held that the Trial Judge's construction of the promise of the patent was consistent with the differentiation between the formula I compounds and the formula II compounds in the disclosure and the claims.

The abstract should not be considered when construing the promise of the patent

The FCA agreed that the Trial Judge ought not to have considered the abstract when construing the promise of the patent. However, his error was not material as he supported his construction with appropriate references to the patent.

Links:

FCA decision: *Teva Canada Limited v Novartis Pharmaceuticals Canada Inc*, 2016 FCA 230
FC decision: *Novartis Pharmaceuticals Canada Inc v Teva Canada Limited*, 2015 FC 770

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