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Pharma in brief - Canada

Federal Court of Appeal sets aside section 8 decision over hearsay evidence

Case:	*Pfizer Canada Inc v Teva Canada Limited*, 2016 FCA 161 (A-422-14)
Drug:	EFFEXOR XR® (venlafaxine hydrochloride)
Nature of case:	Appeal from action for damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party:	Pfizer Canada Inc.
Date of decision:	31 May 2016

Summary

Pfizer Canada Inc. (**Pfizer**) markets an extended release formulation of the drug venlafaxine hydrochloride in Canada under the name EFFEXOR XR®. Pfizer (or its predecessors) listed several patents relating to venlafaxine hydrochloride on the Patent Register, including Canadian Patent Nos. 1,248,540 and 2,199,778. Teva Canada Ltd. and its predecessors (**Teva**) have sold venlafaxine hydrochloride in Canada since 2007 after a prohibition application commenced by Pfizer pursuant to section 6 of the *Regulations* was dismissed by the Court. Teva was subsequently awarded damages under section 8 of the *Regulations* (**Trial Decision**).

Pfizer appealed several aspects of the Trial Decision, including that Justice Zinn erred in: (i) relying on hearsay evidence; and (ii) his construction of the hypothetical world used to calculate Teva's lost profits (**Hypothetical World**).

The Federal Court of Appeal (**FCA**) overturned the Trial Decision on the issue of hearsay evidence, remitting it back to the Federal Court for redetermination.

Hearsay evidence regarding third party manufacturing capacity

The hearsay issue arose in the context of Teva's trial evidence that it could have manufactured and sold its generic venlafaxine hydrochloride product in the hypothetical world. Teva purchases the active pharmaceutical ingredient (**API**) used in its product from Alembic Inc. (**Alembic**), a third party manufacturer. Teva did not call a witness from Alembic to testify. Teva relied solely on the testimony of a Teva executive to establish Alembic's capacity and willingness to supply API to Teva during the relevant period.

Despite Pfizer's repeated hearsay objections, the Federal Court admitted this evidence, ruling that Pfizer's objections would go to the weight to be given to the evidence rather than its admissibility.

The FCA held that the evidence constituted hearsay, and as such, could not be admitted unless it met one of the exceptions to the hearsay rule. The FCA found that the impugned evidence was neither necessary nor reliable; in

particular, the FCA noted that a witness from Alembic could have been called to give direct evidence, noting that Alembic "had an incentive to say whatever needed to keep its customer pleased".

The FCA set the Trial Decision aside and remitted the matter back to the Federal Court to be reconsidered in the absence of the hearsay evidence. No new evidence will be permitted.

Constructing the Hypothetical World

The FCA reaffirmed the principles set out in *Apotex Inc v Sanofi-Aventis*, 2014 FCA 68, aff'd 2015 SCC 20 (reported here) regarding construction of the Hypothetical World. The Court held:

- The damages start date is presumptively the date on which a NOC would have issued in the absence of any regulatory impediments imposed by the *Regulations*, however, the Court retains discretion to choose a more appropriate start date.
- In establishing the market entry date of any third party generic competitors, impediments created by the *Regulations* are relevant considerations.
- With respect to the burden of proof, the section 8 claimant must prove its losses, but each party will bear the burden of proof in respect of any issue it puts into play.
- To prove that any party would have taken a certain action in the hypothetical world, it must be demonstrated that it both "could have" and "would have" acted in that manner. That means that both capacity and willingness are necessary, but not independently sufficient conditions.
- Prejudgment interest starts accumulating at the start date of the damages period rather than at the dismissal of the prohibition application.

The redetermination has been set down for hearing on September 1, 2016.

Links:

FCA Decision: *Pfizer Canada Inc v Teva Canada Limited*, 2016 FCA 161

Trial Decision: *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 248, and subsequent reasons *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 634

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