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Pharma in brief - Canada

Ontario Superior Court of Justice dismisses motion for summary judgment in lansoprazole section 8 damages action

Case:	*Abbott Laboratories Ltd v Apotex Inc*, 2017 ONSC 1348 (Court File No. CV-09-391938)
Drug:	PREVACID® (lansoprazole)
Nature of case:	In general: Motion for summary judgment in an action for damages pursuant to Section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party:	Apotex Inc.
Date of decision:	February 27, 2017

Summary

Abbott Laboratories Limited, Takeda Pharmaceuticals Company Limited and Takeda Pharmaceuticals America Inc. (collectively, the **Defendants**) sought summary judgment of Apotex Inc.'s action for damages pursuant to section 8 of the *Regulations*. Apotex's action follows prohibition proceedings in the Federal Court decided in Apotex's favour in respect of its drug Apo-lansoprazole.

The central issue was whether Apotex could, would, and should have received a notice of compliance (**NOC**) in the hypothetical section 8 world, on April 17, 2007, its patent hold date. The Ontario Superior Court of Justice (**ONSC**) dismissed the motion for summary judgment finding that the Defendants had no standing to raise issues relating to Health Canada's generic product approval process. The ONSC further found that an NOC would have properly issued to Apotex on its patent hold date.

Background

The Defendants own patent rights relating to lansoprazole, a proton-pump inhibitor for the treatment of gastro-esophageal reflux disease, ulcers, and related conditions. Apotex Inc. seeks damages pursuant to section 8 of the *Regulations* following prohibition proceedings decided in Apotex's favour in respect of its drug Apo-lansoprazole.

Apotex received a patent hold letter from Health Canada confirming that, in the absence of the *Regulations*, Apotex would have received an NOC on April 17, 2007. However, on December 4, 2007, Health Canada changed its position on the basis that the bioequivalence study Apotex conducted did not conform to requirements set out in Health Canada's guidance documents. In early 2009, Health Canada issued a notice of non-compliance - withdrawal (**NON-W**) on this basis.

Apotex requested reconsideration of Health Canada's decision. After convening a review by an expert panel and conducting a further review on its own, Health Canada reverted to its original position and issued an NOC to Apotex in June 2009.

The Defendants alleged that in light of Apotex's non-compliance with the guidance document, the patent hold letter should never have been issued with the result that Apotex was not entitled to section 8 damages.

Effect of NON-W

The ONSC found that absent the NOC proceedings, an NOC would have issued to Apotex on its patent hold date of April 17, 2007. The review and NON-W by Health Canada occurred subsequent to the patent hold date and would not have prevented the earlier issuance of the NOC.

The ONSC held that Health Canada's guidance documents do not have the force of law and "cannot preclude the Minister from reviewing the contents of each submission received on the basis of its actual scientific merits." Therefore, despite Apotex's non-compliance with the requirements in the guidance document, Apotex's submission was still compliant with the *Food and Drug Regulations* and Health Canada was entitled to issue both the patent hold letter, and, ultimately, the NOC.

The ONSC distinguished a previous decision of the Federal Court of Appeal (2012 FCA 322), as that decision related to an application by Apotex for judicial review of the Minister of Health's treatment of its submission for an NOC. Further, in that case, the approvability status of Apotex had been revoked and never reinstated. In contrast, in this case the ultimate result of Health Canada's subsequent reviews was issuance of an NOC "for exactly the same Apo-lansoprazole pharmaceutical that had initially been approved."

The ONSC also held that patentees lack standing to impugn decisions made under the *Food and Drug Regulations* relating to the generic approval process in a section 8 action, and that "[t]he conduct of Health Canada is irrelevant to the determination of damages."

Impact on trial

The decision in the summary judgment motion establishes that Apotex is entitled to s. 8 damages. The ONSC indicated that it will not hear any additional arguments relating to the conduct of Health Canada or Apotex's conduct in relation to its Apo-lansoprazole submission with Health Canada at trial. However, the ONSC left it open for the Defendants to lead evidence that the subsequent review and NON-W by Health Canada might have somehow interrupted sales in the s.8 period.

Link:

Abbott Laboratories Ltd v Apotex Inc, 2017 ONSC 1348

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