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Pharma in brief – Canada

Teva found liable for over $18 million in patent-infringement damages for generic levofloxacin

Case:	*Janssen Inc. v Teva Canada Limited*, 2016 FC 593 (Court Files No. T-2175-04 and T-2056-11)
Drug:	LEVAQUIN® (levofloxacin)
Nature of case:	Determination and quantification of damages further to action for patent infringement/impeachment under the *Patent Act*, RSC 1985, c P-4 (***Patent Act***)
Successful party:	Janssen Inc. and Janssen Pharmaceuticals, Inc.
Date of decision:	May 31, 2016

Summary

Beginning in 1998, Janssen Inc. (**Janssen Canada**) marketed levofloxacin in Canada under the name LEVAQUIN® for use in the treatment of bacterial infection. In 2004, Teva Canada Limited (**Teva**) began selling generic levofloxacin-containing tablets in Canada after successfully challenging Canadian Patent No. 1,304,080 (the **'080 Patent**), which was listed on the patent register against LEVAQUIN®, in a prohibition proceeding under the *Patented Medicines (Notice of Compliance) Regulations*.

Subsequently, the Federal Court held that the '080 Patent was valid and infringed by Teva in an action brought by Janssen Canada under the *Patent Act*. This decision concerns the quantification of Teva's liability to Janssen Canada and Janssen Pharmaceuticals, Inc. (**Janssen US**; collectively, **Janssen**) resulting from that action. The Court held that Teva owed $5,498,270 to Janssen Canada and $13,342,949 to Janssen US, inclusive of pre-judgment interest, plus costs.

Background

The relationship between Janssen Canada, Janssen US, and Daiichi Sankyo Company, Limited (**Daiichi**) was central to the Court's decision in the quantification proceeding.

Daiichi owned the '080 Patent. In the underlying liability proceeding, Janssen Canada and Daiichi were co-plaintiffs. Janssen Canada was a licensee of the '080 Patent; on this basis, it had standing to seek damages as a person claiming under the patentee. Daiichi subsequently settled its damages claim against Teva and did not participate further. After the liability judgment, Janssen US started a second action seeking damages as an upstream member of the chain of LEVAQUIN® sales into Canada. Teva argued that Janssen US lacked standing to seek damages. The two actions were heard and decided together.

Janssen US had standing to claim damages on the basis of transfer sales into Canada

The dispute as to standing turned on whether, by virtue of having sold LEVAQUIN® to Janssen Canada, Janssen US could claim damages as a person "claiming under" the patentee pursuant to subsection 55(1) of the *Patent Act*. Teva argued that because Janssen US never held title to levofloxacin tablets in Canada, it never "used" the invention claimed by the '080 Patent and therefore was not a person "claiming under" the patentee.

In deciding this issue, Hughes J summarized the circumstances under which persons other than the patentee may claim patent-infringement damages. He held that to establish standing as a person claiming under the patentee:

- The person must be one who, as a user, an assignee, a licensee, or a lessee, has a title or a right that can be traced back to the patentee;
- It does not matter whether a licensee is exclusive or non-exclusive;
- The licence must be proved but it need not exist in writing; and
- The claim must be in respect of a use in Canada and not elsewhere in the corporate chain.

Janssen Canada and Janssen US were operating as part of a team whereby licensed levofloxacin tablets ultimately found their way to Canada. Daiichi knew of and acquiesced to the sale of the tablets, which were manufactured by other Janssen companies, through Janssen US to Janssen Canada. The Court was satisfied that Daiichi's acquiescence gave rise to a licence or permission in favour of Janssen US. As a result, Janssen US had standing to claim its lost sales at the transfer price of the tablets, less expenses. Under these circumstances, it was immaterial whether it ever had title to the tablets in Canada.

Quantum of damages, pre-judgment interest, and mitigation

But-for scenarios. In determining the quantum of damages, Hughes J preferred the first of two "but-for" scenarios presented by Janssen over any of the six scenarios presented by Teva, subject to some modification of the underlying assumptions based on the evidence before the Court. These modifications were incorporated into revised damages calculations following the release of draft reasons to the parties.

Pre-judgment interest. In the liability judgment, Janssen Canada was awarded pre-judgment interest, not compounded, at the average established bank rate. The Court held that Janssen US should equally be held to these terms and dismissed its claim for either compound interest or the income it would have earned on profits lost.

Mitigation. Justice Hughes held that a party seeking to recover damages for patent infringement is under a duty to mitigate those damages. However, he also held that it was Teva's burden to show that mitigation was possible and Janssen had not made reasonable efforts to do so. In the absence of any evidence from Teva as to what ought to have been done, the Court refused to conclude that the steps actually taken by Janssen were insufficient to mitigate.

Links:

- **This case:** *Janssen Inc. v Teva Canada Limited*, 2016 FC 593.
- **Validity and liability judgment:** *Janssen-Ortho Inc. v Novopharm Ltd.*, 2006 FC 1234, aff'd 2007 FCA 217, leave to appeal ref'd 2007 CanLII 66767.
- **Prohibition proceeding:** *Janssen-Ortho Inc. v Novopharm Ltd.*, 2004 FC 1631, appeal dismissed for mootness 2005 FCA 6, leave to appeal ref'd 2005 SCC 33.

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