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Pharma in brief - Canada

Federal Court strikes biologic PM(NOC) application on account of non-infringement of use claims

Case: *Janssen Inc. v Celltrion Healthcare Co, Ltd.,* 2016 FC 525; 2016 FC 651
Nature of case: Motion to dismiss under s. 6(5)(b) of the *PM(NOC) Regulations*
Successful party: Celltrion Healthcare Co. Ltd.
Date of decision: May 26, 2016 and June 9, 2016

Summary

The Federal Court granted a motion to dismiss an application under s. 6(5)(b) of the *PM(NOC) Regulations* on the basis that the second person would not infringe the patent. The Court affirmed that a dismissal of an application is an extraordinary remedy, but that such relief was warranted due to the unique facts of the case.

Background

Janssen's product and the patent at issue

Janssen Inc. (**Janssen**) markets the drug infliximab under the brand name REMICADE® for use in the treatment of various rheumatoid arthritis indications (the **RA Indications**). Janssen listed a patent claiming the RA Indications (the **630 Patent**) against REMICADE® on December 6, 2012.

Celltrion's NDS – the RA Indications

Celltrion Healthcare Co., Ltd. (**Celltrion**) also markets the drug infliximab for use in the treatment of RA Indications, under the name INFLECTRA. Celltrion was not required to address the 630 Patent when it filed its New Drug Submission (**NDS**) in respect of the RA Indications (November 14, 2012), as the 630 Patent was not yet listed on the patent register.

Celltrion's SNDS – the IBD Indications

In 2015, Celltrion filed a Supplementary New Drug Submission (**SNDS**) seeking approval for the use of INFLECTRA in the treatment of various inflammatory bowel diseases (the **IBD Indications**). Celltrion served Janssen with a Notice of Allegation (**NOA**) alleging that none of the intended uses would infringe the 630 Patent. In response, Janssen commenced a prohibition application for Celltrion's SNDS with respect to the IBD Indications.

Celltrion brought a motion to strike Janssen's application under s. 6(5)(b) of the *PM(NOC) Regulations*. Prothonotary Aalto granted the motion and dismissed Janssen's application, but stayed his order for 30 days. Justice Hughes upheld the Prothonotary's Order regarding dismissal, but dismissed the stay.

A s. 6(5)(b) motion will succeed if there is no chance of infringement

Prothonotary Aalto affirmed that dismissal of an application under s. 6(5)(b) of the *PM(NOC) Regulations* is an extraordinary remedy only to be granted when the application has no chance of succeeding at a hearing. Recognizing that the underlying premise of the *PM(NOC) Regulations* is to prevent infringement, Prothonotary Aalto held that an application has no chance of succeeding if the granting of an NOC will not result in infringement.

Janssen argued that expert evidence was required to construe the claims. Prothonotary Aalto disagreed and stated that it was "sufficient to read the claims of the 630 Patent which, given a plain and ordinary construction on their face, relate only to the RA Indications [and] do not in any way discuss nor allude to the IBD Indications."

Justice Hughes upheld the Prothonotary's finding on both points.

Comparing "drugs" versus comparing "uses of drugs"

Janssen also raised the statutory interpretation of the *PM(NOC) Regulations*, arguing that under s. 5(2), the relevant comparison is between the generic and innovator drugs and not the uses of the drugs. Prothonotary Aalto rejected Janssen's argument, and noted that "if a submission refers to uses of a drug that do not infringe and on the plain and ordinary meaning of the claims of the patent those uses do not infringe it should be the end of the matter." On appeal, Hughes J. agreed that, where a patent claims a particular use, that use must be compared with the generic's indicated use.

The Court also noted that Celltrion already had an NOC for the use of its drug for the RA Indications, and that the RA Indications were at issue in a separate infringement action which was not relevant to the current proceeding.

An order dismissing an application cannot be stayed

Prothonotary Aalto stayed his order for 30 days to allow Janssen to take "whatever steps it deemed appropriate." On appeal, Hughes J. dismissed the stay, noting that it was not raised by the Prothonotary or any of the parties. He held that a stay in such circumstances is not available, as there is nothing to stay, and stated that, even if available, he would not grant one that would maintain Janssen's statutory injunction without ever addressing the merits of the case.

Janssen has appealed to the Federal Court of Appeal.

Link to decisions:

Prothonotary Decision: *Janssen Inc. v Celltrion Healthcare Co, Ltd*, 2016 FC 525

Federal Court Decision: *Janssen Inc. v Celltrion Healthcare Co, Ltd,* 2016 FC 651: Order. Reasons.

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