Date: 20100820

Docket: A-373-08

Citation: 2010 FCA 213

CORAM: **NADON J.A.**
LAYDEN-STEVENSON J.A.
TRUDEL J.A.

BETWEEN:

APOTEX INC.

Appellant

and

JANSSEN-ORTHO INC. and
DAIICHI SANKYO COMPANY, LIMTED

Respondent

and

THE MINISTER OF HEALTH

Respondent

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on August xx, 2010.

REASONS FOR ORDER BY: NADON J.A.

CONCURRED IN BY: LAYDEN-STEVENSON J.A.
TRUDEL J.A.

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REASONS FOR ORDER

NADON J.A.

[1] Before us is a motion by the respondents, Janssen-Ortho Inc. and Daiichi Sankyo Co. Ltd. for an Order varying this Court's Judgment dated June 22, 2009 in the following respects:

1. setting aside the Redetermination Order;

2. dismissing the substantive grounds of appeal; and

3. reversing the Order on Costs at the Federal Court of Appeal and at first instance.

[2] The respondent, Daiichi Sankyo Co. Ltd. ("Daiichi") was the owner of Canadian patent 1,304,080 (the "080 patent") which issued on June 23, 1992, and expired on June 22, 2009. The 080 patent disclosed and claimed levofloxacin, an antibiotic that treats the most severe forms of pneumonia. The respondent Janssen-Ortho Inc. ("Janssen-Ortho") was a licensee of Daiichi and marketed and sold levofloxacin products in Canada.

[3] The appellant Apotex Inc. ("Apotex") sought to obtain regulatory approval for its levofloxacin hemihydrate tablets and, in accordance with section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the "Regulations"), it sent a Notice of Allegation ("NOA") to the respondents, alleging that the 080 patent was invalid and that, if valid, its tablets would not infringe the patent.

[4] On September 2, 2005, the respondents commenced proceedings under the Regulations for an order prohibiting the Minister from issuing a Notice of Compliance ("NOC") to Apotex for levofloxacin hemihydrate tablets until after the expiry of the 080 patent on June 22, 2009.

[5] On June 17, 2008, Shore J. of the Federal Court concluded that the respondents were entitled to an order of prohibition and, thus, prohibited the Minister from issuing a NOC to Apotex until after the expiry of the 080 patent.

[6] On June 22, 2009, this Court, by a majority, allowed the appellant's appeal. The Judgment of the Court reads as follows:

> The appeal is allowed with costs, the decision of Shore J., 2008 FC 744, dated June 17, 2008, is set aside and the matter is remitted back to him for redetermination on the basis that there is no abuse of process on the part of Apotex Inc. in making the allegations found in its Notice of Allegation and in contesting the application for a prohibition order commenced by the respondents. Shore J. is instructed to assess the evidence before him independently of any findings made by Hughes J. in *Janssen-Ortho v. Novopharm Limited*, 2006 FC 1234, 300 F.T.R. 166. With respect to the proceedings below, there shall be no order as to costs.
>
> [Emphasis added]

[7] On June 14, 2010, Shore J. recused himself from sitting on the redetermination. More particularly, at paragraphs 6 and 7 of his Reasons, he wrote as follows:

> [6] In addition, as the judgment of the undersigned has been borne out in subsequent interpretation of the same subject matter outside of Canada through U.K. judgments (*Generics (UK) Limited v. Daiichi Pharmaceutical Co. Ltd. and Daiichi Sankyo Co. Ltd.*, [2008] EWHC 2413 in the High Court of Justice, Chancery Division, Patents Court and also in *Generics (UK) Ltd. v. Daiichi Pharmaceutical Co. Limited and Daiichi Sankyo Co. Ltd.*, [2009] EWCA Civ 646 in the Supreme Court of Judicature Court of Appeal (Civil Division) on Appeal from the High Court of Justice, Chancery Division, Patents Court) and by subsequent expert pronouncements and interpretations thereto, the undersigned is caught in a situation where he would either deviate from deference to the majority in the Federal Court of Appeal judgment, or from the judicial responsibility of independent analysis through the proverbial state of being between a rock and a hard place.
>
> [7] Thus, after time and much reflection, subsequent to receiving the new written pleadings of the parties, the undersigned recognizes he cannot in good conscience, in the integrity of spirit necessary for intellectual honesty, required for the independence of a judge, sit on this matter, yet again, without reaching the same conclusions through the same reasons. As a result, in fairness to the parties, the following decision has been reached in the Order below:
>
> **ORDER**

> **THIS JUDGE ORDERS** that he recuse himself from sitting on this matter, and that he remit to the Chief Justice of this Court this case to be heard by a different judge of this Court.

[8] Relying on Rule 399(2)(a) of the *Federal Court Rules*, which provides that "the Court may set aside or vary an order … by reason of a matter that arose or was discovered subsequent to the making of the order", the respondents say that the three conditions required for the varying of an order are met in the present matter.

[9] First, they say that Shore J.'s recent decision is "a matter" within the meaning of Rule 399; second, that Shore J.'s decision was not discoverable by the exercise of due diligence prior to the making of our Judgment of June 22, 2009; and; third, that Shore J.'s decision would have had a determining influence on our Judgment of June 22, 2009.

[10] I need only deal with the third condition with respect to which the respondents say that this Court would not have remitted the matter back to Shore J. for redetermination had it known that he had made his findings independently of those made by Hughes J. in *Janssen-Ortho Inc. v. Novopharm Ltd.*., [2006] F.C.R. 166. Consequently, they say that this information would have had a determining influence on our Judgment.

[11] In my view, the motion is without merit. A majority of this Court found, contrary to the reasons given by Shore J. in his recent decision, that his findings were not made independently of

those made by Hughes J. in *Novopharm supra*. Our Judgment has not been appealed and is therefore a final decision.

[12] With the greatest of respect, I would add that the Order made by Shore J. on June 14, 2010, and the Reasons which he gives for that Order, are of no relevance in determining whether or not this Court should vary its Judgment of June 22, 2009.

[13] I would therefore dismiss the motion.

"M. Nadon"

J.A.

"I agree.
Carolyn Layden-Stevenson J.A."

"I agree.
Johanne Trudel J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-373-08
STYLE OF CAUSE:	APOTEX INC. v. JANSSEN-ORTHO INC. et al.

MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER BY:	NADON J.A.
CONCURRED IN BY:	LAYDEN-STEVENSON J.A. TRUDEL J.A.
DATED:	August 20, 2010

WRITTEN REPRESENTATIONS BY:

Neil Belmore Lindsay Neidrauer	FOR THE RESPONDENT JANSSEN-ORTHO INC.

SOLICITORS OF RECORD:

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