Federal Court of Appeal | Cour d'appel fédérale

Date: 20240112

Docket: A-36-22

Citation: 2024 FCA 9

CORAM: **DE MONTIGNY C.J.**
LOCKE J.A.
GOYETTE J.A.

BETWEEN:

APOTEX INC.

Appellant

and

JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

Respondents

Heard at Toronto, Ontario, on December 5-6, 2023.

Judgment delivered at Ottawa, Ontario, on January 12, 2024.

PUBLIC REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: DE MONTIGNY C.J.
GOYETTE J.A.

Federal Court of Appeal  Cour d'appel fédérale

Date: 20240112

Docket: A-36-22

Citation: 2024 FCA 9

CORAM: **DE MONTIGNY C.J.**
LOCKE J.A.
GOYETTE J.A.

BETWEEN:

APOTEX INC.

Appellant

and

JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

Respondents

PUBLIC REASONS FOR JUDGMENT

This is a public version of confidential reasons for judgment issued to the parties. The two are identical, there being no confidential information disclosed in the confidential reasons.

LOCKE J.A.

I. Background

[1] This is an appeal of a decision of the Federal Court (2022 FC 107, *per* Justice Michael D. Manson) in the context of an action brought pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133. In that action, the respondents,

Janssen Inc. and Janssen Pharmaceutica N.V. (collectively, Janssen), sought a declaration that the appellant, Apotex Inc. (Apotex), would infringe Canadian Patent No. 2,655,335 (the 335 Patent) if it were to make, use or sell its generic version of Janssen's patented medicine called INVEGA SUSTENNA.

[2] INVEGA SUSTENNA involves a suspension of paliperidone palmitate for the treatment of schizophrenia and related disorders. The 335 Patent teaches a regimen to achieve an optimum plasma concentration-time profile. It teaches a first loading dose administered in the deltoid muscle on day 1, a second loading dose administered in the deltoid muscle on day 8, and then monthly maintenance doses thereafter administered either in the deltoid or gluteal muscle. For non-renally impaired patients, the first and second loading doses are 150 and 100 mg equivalent (mg-eq.), respectively, and the monthly maintenance doses are 75 mg-eq. each. For renally impaired patients, the first and second loading doses are 100 and 75 mg-eq., respectively, and the monthly maintenance doses are 50 mg-eq. each.

[3] Apotex brought a motion for summary trial seeking dismissal of Janssen's action on the basis that its product would not infringe the 335 Patent since it would not provide the 75 mg-eq. dose, which is an essential element of all of the claims thereof. The Federal Court found that it was an appropriate proceeding for summary trial, but decided the action in favour of Janssen, finding that Apotex would induce infringement of the 335 Patent with its generic version of INVEGA SUSTENNA.

[4] The legal test for a finding of inducing patent infringement was correctly stated by the Federal Court at paragraph 113 of its reasons:

> There is a three "prong" test for inducement: (1) direct infringement by a third party; (2) the inducer influenced the third party to the point that the infringing act would not have occurred without the influence; and (3) the defendant knew that its influence would bring about the infringing act [*Corlac Inc. v. Weatherford Canada Ltd*., 2011 FCA 228 [*Corlac*]].

[5] The Federal Court found that each of the prongs of the test was satisfied. In the present appeal, Apotex takes issue only with the second prong. Specifically, Apotex argues that the Federal Court erred in finding that it would induce infringement of the 335 Patent such that, without its influence, the act of direct infringement would not occur.

[6] For the reasons set out below, I would dismiss this appeal.

II. The Federal Court's Decision

[7] The Federal Court addressed the second prong of the test for inducing infringement at paragraphs 125 to 148 of its reasons.

[8] After correctly defining the legal test, the Federal Court noted Apotex's argument that the facts were similar to those in *Janssen Inc. v. Teva Canada Limited*, 2020 FC 593, 321 A.C.W.S. (3d) 539 (*Teva Paliperidone*), and that the Court should therefore follow its conclusion therein that "any act of direct infringement would be a result of physician skill and judgment applied to specific patient characteristics, rather than any influence exercised by the product monograph for the [Apotex] Product" (paragraph 129 of the Federal Court's reasons). Unfortunately for Apotex,

the argument that the result in this case on inducing infringement should follow that in *Teva Paliperidone* no longer assists it because the Federal Court's conclusion on that issue was reversed on appeal to this Court: *Teva Canada Limited v. Janssen Inc.*, 2023 FCA 68, [2023] F.C.J. No. 467.

[9] The Federal Court went on to address a further argument by Apotex. This is based on the assertions that:

A. "[T]he ultimate dosing decision is based on physician skill and judgment, not the language in the product monograph"; and

B. Because physicians are already familiar with the INVEGA SUSTENNA product, they will not be influenced in their prescribing practices to the extent necessary to meet the second prong of the test in *Corlac* (see paragraph 132 of the Federal Court's reasons).

[10] The Federal Court found that each of the expert witnesses agreed that "patients may receive the claimed dosage regimen as a result of referring to the Apotex product monograph" (see paragraph 138 of the Federal Court's reasons). The Federal Court also found that "Apotex's product monograph includes recommendations to prescribers for use of the claimed dosage regimen" (see paragraph 143 of the Federal Court's reasons).

[11] The Federal Court concluded its discussion of the second prong of the test for inducing infringement as follows:

> [147] Notwithstanding the exercise of skill and judgment by prescribing physicians in selecting the dosing regimen for patients, the evidence before the Court in this case establishes that acts of infringement will be influenced by the acts of the alleged inducer, Apotex, to the point that, without the influence, direct infringement will not take place. Apotex's product monograph will influence prescribers and patients to implement the claimed dosage regimen, thereby directly infringing the 335 Patent.
>
> [148] I am satisfied, on the evidence before the Court that Janssen has proven, on a balance of probabilities, that at least some prescribers of the impugned [Apotex] Product will be sufficiently influenced by the Apotex product monograph to induce infringement by those prescribing physicians.

III. Standard of Review

[12] The parties agree that the standard of review applicable in this case is as set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. Questions of law are reviewed on a standard of correctness, and questions of fact or of mixed fact and law from which no question of law is extricable are reviewed on a standard of palpable and overriding error. A palpable error is one that is obvious. An overriding error is one that goes to the very core of the outcome of the case. When arguing palpable and overriding error, it is not enough to pull at leaves and branches and leave the tree standing. The entire tree must fall: *Canada v. South Yukon Forest Corporation*, 2012 FCA 165, [2012] F.C.J. No. 669 at para. 46 (cited with approval in *Benhaim v. St-Germain*, 2016 SCC 48, [2016] 2 S.C.R. 352 at para. 38).

IV. Analysis

[13] Apotex focuses its argument on the high threshold for influence required by the second prong of the test for inducement: that the infringing act would not have occurred without the influence. This Court has equated this threshold to a *sine qua non* (without which not) test:

MacLennan v. Produits Gilbert Inc., 2008 FCA 35, [2008] F.C.J. No. 128 at para. 38 (*MacLennan*). Apotex urges this Court to treat the threshold as a "but for" test, and it cites jurisprudence that calls this a causation test. I have no objection to Apotex's characterization of the test, but I do not find it to be more helpful that the "would not have occurred without" and "*sine qua non*" characterizations provided in the jurisprudence of this Court. In my view, these are merely different ways of describing the same threshold.

[14] Apotex relies on the fact that its product monograph would essentially be a copy of that for INVEGA SUSTENNA, and the assertion that prescribing practices of physicians would not change if Apotex were allowed to market its generic version of INVEGA SUSTENNA. In light of the foregoing, Apotex argues that any influence that its product monograph could have on any ultimate act of direct infringement could not rise to the level required in *Corlac*.

[15] Apotex supplements its argument by asserting that the Federal Court lacked any meaningful analysis in its consideration of the second prong. It adds that the Federal Court's statement at paragraph 138 of its reasons that "patients may receive the claimed dosage regimen as a result of referring to the Apotex product monograph" (see paragraph 10 above) can be of limited assistance because paragraph 138 contains inaccuracies and appears to have been copied from another decision.

[16] I will address this supplementary argument first. It is helpful to begin by quoting the entirety of paragraph 138 of the Federal Court's reasons:

> As outlined previously, each expert agrees that patients may receive the claimed dosage regimen as a result of referring to the Apotex product monograph. All four

> experts acknowledged on cross-examination that while the product monograph for the [Apotex] Product does not explicitly recommend a 75 mg-eq. monthly maintenance dose, it is a therapeutic option within a recommended range in the Apotex product monograph. Moreover, a 75 mg-eq. loading dose on Day 8 is explicitly recommended for renally impaired patients.

[17] Apotex argues that it was simply wrong to state that the content of the first sentence in that paragraph was "outlined previously". It adds that paragraph 138 is essentially the same as paragraph 131 from *Janssen Inc. v. Pharmascience Inc.*, 2022 FC 62, 190 C.P.R. (4th) 1 (*Pharmascience*), which the same judge (Justice Manson) decided just days prior in another case involving the same Janssen plaintiffs, the same 335 Patent, and the same drug (INVEGA SUSTENNA). Apotex argues that there is a similar problem in relation to the remainder of paragraph 138 – it is essentially the same as paragraph 127 of *Pharmascience*. Apotex asserts that the summary trial that led to the present appeal heard from five experts not four, and that those experts agreed that Apotex's product monograph does explicitly recommend a 75 mg-eq. maintenance dose.

[18] I agree with Apotex that it appears that parts of paragraph 138 of the Federal Court's reasons in the decision under appeal were lifted from *Pharmascience*. It also appears that this paragraph contains some factual inaccuracies. That said, I am not convinced that these inaccuracies rise to the level of overriding errors of such a nature that this Court should intervene.

[19] Firstly, it was entirely reasonable for the Federal Court to state that the content of the first sentence of paragraph 138 was "outlined previously". The Federal Court elaborated on this point in paragraphs 139 and 140 of its reasons. In my view, the following paragraphs from the Federal

Court's reasons addressed the experts' testimony as it related to the issue that "patients may receive the claimed dosage regimen as a result of referring to the Apotex product monograph": for Dr. Oluboka, paragraph 63, for Dr. Zhang, paragraph 71, for Dr. Agid, paragraphs 84 and 85, for Dr. Chue, paragraphs 94 and 95, and for Mr. Jones, paragraph 102.

[20] Further, reading the Federal Court's reasons as a whole, I do not agree that it was actually confused as to the number of experts or that it misunderstood the nature of their testimonies. The Federal Court provided a summary of each expert's testimony at paragraphs 58 to 74 and 80 to 104 of its reasons. The reference in paragraph 138 to "[a]ll four experts" appears to be no more than a slip of the pen.

[21] I also disagree with Apotex's argument that the Federal Court lacked any meaningful analysis in its consideration of the second prong. Paragraph 124 of its reasons, reproduced here, provides some analysis:

> There appears to be several instances in the [Apotex] Product product monograph that will influence a physician to prescribe a 75 mg-eq. maintenance dose as part of the claimed dosing regimen leading to direct infringement of the 335 Patent: (i) in the recommended maintenance dose ranges in which 75 mg-eq. is one of the doses; and (ii) in tables outlining instructions for switching patients from oral paliperidone to an injectable product, like the [Apotex] Product or INVEGA SUSTENNA®. In addition, there is no dispute that 75 mg-eq. is the second loading dose for renally-impaired patients.

[22] Moreover, the Federal Court's discussion of Janssen's arguments at paragraphs 137 and following of its reasons provide an indication of the arguments and evidence upon which it relied. I mention a couple of these at paragraph 10 above. For these reasons, I disagree that the

Federal Court's analysis in its consideration of the second prong was insufficiently based on the facts and law.

[23] I turn now to Apotex's more substantive argument that the Federal Court erred in concluding that the high threshold for the second prong of the test for inducing infringement was met in this case. The main weakness of this argument is that it depends on there being a requirement that prescribing practices of physicians be altered because of Apotex's activities. In fact, this is not necessary. What is required is that the ultimate act of direct infringement occur because of Apotex's activities.

[24] It is important to bear in mind that the ultimate act of direct infringement in the present case could be either by a prescriber (e.g. a physician or a nurse practitioner) or by a patient: *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30, [2020] F.C.J. No. 179 at para. 40, citing *AB Hassle v. Genpharm Inc.*, 2003 FC 1443, 243 F.T.R 6 at para. 127, aff'd 2004 FCA 413, [2004] F.C.J. No. 2079. The Federal Court recognized this at paragraphs 74 and 104 of its reasons. It is also important to understand that inducing patent infringement can occur even where there is no direct contact between the inducer and the direct infringer: *MacLennan* at para. 43, citing *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.*, [1978] F.C.J. No. 812, 39 C.P.R. (2d) 145 at 167. Accordingly, Apotex could be found to induce infringement by a patient even if they have no direct communication.

[25] It follows that, even if the practices of prescribing physicians were to remain unchanged following the introduction to the market of Apotex's generic version of INVEGA SUSTENNA,

the fact would remain that activities by patients (and by prescribers) that had previously been non-infringing (because the drug was sourced from Janssen) would be infringing once the drug was sourced from Apotex, an unlicensed supplier. As indicated at paragraph 11 above, the Federal Court concluded at paragraphs 147 and 148 of its reasons that such infringement would be influenced by Apotex to the point that, without the influence, direct infringement would not take place. It is in this sense that the Federal Court was entitled to conclude that the second prong of the test for inducing patent infringement was met.

[26] Apotex argues that the mere fact that its product monograph would be available for consultation is not enough to meet the test for influence. Apotex also argues that the evidence before the Federal Court did not go beyond merely establishing that Apotex's product monograph would have some influence on the use of its generic version of INVEGA SUSTENNA, and therefore did not meet the high threshold for the second prong (the infringing act would not have occurred without the influence). Apotex notes that none of the experts went so far in their testimony as to state explicitly that any direct infringement using Apotex's product would not occur without Apotex's influence.

[27] In my view, this is a factually suffused issue on which Apotex would have to establish that the Federal Court made a palpable and overriding error. The Federal Court did not err in law. Moreover, I am not convinced that, based on the evidence, the Federal Court could not have concluded that the threshold was met. It was entitled to draw inferences from the evidence before it, and there was evidence to support the conclusion that Apotex's product monograph would give rise to the required influence.

V. Conclusion

[28] It follows from the foregoing that I would dismiss the present appeal. I would award costs to Janssen in the agreed amount of $10,000, all-inclusive.

"George R. Locke"
J.A.

"I agree
Yves de Montigny C.J."

"I agree
Nathalie Goyette J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-36-22
STYLE OF CAUSE:	APOTEX INC. v. JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	DECEMBER 5-6, 2023
PUBLIC REASONS FOR JUDGMENT BY:	LOCKE J.A.
CONCURRED IN BY:	DE MONTIGNY C.J. GOYETTE J.A.
DATED:	JANUARY 12, 2024

APPEARANCES:

Andrew R. Brodkin Daniel Cappe	FOR THE APPELLANT APOTEX INC.
Peter Wilcox Marian Wolanski Megan Pocalyuko Oleyna Strigul	FOR THE RESPONDENTS JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

SOLICITORS OF RECORD:

Goodmans LLP Toronto, Ontario	FOR THE APPELLANT APOTEX INC.
Belmore Neidrauer LLP Ottawa, Ontario	FOR THE RESPONDENTS JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.