

Federal Court



Cour fédérale

**Date: 20221220**

**Docket: T-124-21**

**Citation: 2022 FC 1746**

**Ottawa, Ontario, December 20, 2022**

**PRESENT: The Honourable Mr. Justice Manson**

**BETWEEN:**

**JANSSEN INC. and  
JANSSEN PHARMACEUTICA N.V.**

**Plaintiffs**

**and**

**APOTEX INC.**

**Defendant**

**PUBLIC JUDGMENT AND REASONS**

**(Confidential Judgment and Reasons issued December 20, 2022)**

**I. Introduction**

[1] This is a motion brought by the Plaintiffs, Janssen Inc. and Janssen Pharmaceutica N.V. [collectively “Janssen”], to vary the Protective and Confidentiality Order issued by this Court on March 22, 2021 [the “Confidentiality Order”] under Rule 151 of the *Federal Courts Rules*,

SOR/98-106 [the *Rules*]. Janssen’s proposed amendments would allow materials that were marked “Confidential” pursuant to the Confidentiality Order to be used in four subsequent actions involving the same parties (Court files T-1121-22, T-1122-22, T-1248-22 and T-1249-22 [collectively the “New Actions”]).

## II. Background

### A. *The Within Action*

[2] The within action is a patent infringement action brought by Janssen pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 in regards to Canadian Patent No. 2,655,335 [the “335 Patent”].

[3] Apotex filed ANDS No. 23382 on June 3, 2020 seeking approval for Apotex’s generic version of INVEGA SUSTENNA, a paliperidone palmitate injection, in strengths of 50, 100, and 150 mg-eq. Apotex alleged that it would not infringe the 335 Patent and did not allege that the 335 Patent was invalid.

[4] On March 22, 2021, the Confidentiality Order was issued on consent of the parties. The Confidentiality Order provides that confidential information produced in the within action is to be used “solely for the purposes of the Proceeding”. “Proceeding” is defined as the within action and any appeals therefrom.

[5] On May 4, 2021, Apotex brought a motion for summary trial raising the issue of whether Apotex would infringe the 335 patent though it was not seeking approval for a 75 mg-eq. strength syringe of the proposed generic product.

[6] In December 2021, the hearing for the summary trial took place *in camera*. Therefore, the trial transcripts remain under seal by the Court.

[7] On January 31, 2022, this Court held that Apotex would infringe the 335 Patent despite not seeking approval for a 75 mg-eq. dose and issued a declaration of infringement and injunction in respect of Apotex's product (see *Jansen Inc v Apotex Inc*, 2022 FC 107).

[8] By Notice of Appeal dated February 10, 2022, Apotex appealed this judgment. This appeal is currently pending (Federal Court of Appeal file A-36-22).

B. *The New Actions*

[9] Apotex delivered Notices of Allegation ["NOA"s] on April 20 and May 5, 2022, alleging that the 335 Patent is invalid on the basis that it is an unpatentable method of medical treatment. In response, Janssen commenced the New Actions.

[10] Janssen intends to file summary judgment motions in the New Actions. Janssen claims it will argue that Apotex's NOAs and associated Form Vs are void and that Apotex's patent-invalidity defence is barred due to *res judicata* and/or abuse of process.

[11] On August 8, 2022, Janssen sought Apotex's consent to vary the Confidentiality Order, for the purpose of allowing Janssen to reference confidential information from the within action in the New Actions. Apotex refused to consent to Janssen's terms.

[12] On October 4, 2022, Janssen brought this motion asking the Court to amend the Confidentiality Order.

### III. Issues

A. *Is Janssen's motion procedurally defective as a result of Janssen's failure to seek relief from its implied undertaking?*

B. *Is Janssen's motion to vary the Confidentiality Order overly broad?*

### IV. Analysis

A. *Is Janssen's motion procedurally defective as a result of Janssen's failure to seek relief from its implied undertaking?*

[13] Under the "implied undertaking rule" information that is compelled during pre-trial discovery can be used by the parties only for the purpose of the litigation in which it was obtained (*Juman v Doucette*, 2008 SCC 8 at para 1). A party seeking to be relieved from the undertaking must demonstrate, on a balance of probabilities, "a public interest of greater weight than the values that the implied undertaking protects: privacy, candor and the efficient conduct of litigation" (*Fibrogen, Inc v Akebia Therapeutics Inc*, 2022 FCA 135 at para 49 [*Akebia*]).

[14] Relying on the Court of Appeal's recent decision in *Akebia*, Apotex argues that Janssen's motion is premature as it has not first sought relief from its implied undertaking (*Akebia* at para 48).

[15] In *Akebia*, the Court of Appeal also held that an implied undertaking is spent only when the documents are tendered in open court at trial (*Akebia* at para 60). In this case, the documents in issue were not tendered in open court, because the portion of the proceedings involving the confidential documents were held *in camera*. As such, I find that most of the documents Janssen requests are still subject to the implied undertaking rule.

[16] Janssen, specifically, claims that it intends to rely on the following documents [collectively the "Specified Documents"]:

- i. Trial Transcripts from Apotex's Motion for Summary Trial;
- ii. Confidential Judgment and Reasons dated January 31, 2022;
- iii. Affidavit of Duane Terrill, including Exhibits A, D, E, G, and I (filed as part of the motion record for summary trial);
- iv. Exhibit 9 from the summary trial;
- v. Apotex Summary Trial Motion Memorandum of Fact and Law; and

vi. Apotex Appeal Factum (from Court of Appeal file A-36-22).

[17] The first two items of the Specified Documents are not documents that, in any event, were compelled from Apotex. The other documents, however, were not tendered in open court and are still subject to an implied undertaking.

[18] At the motion hearing, Janssen advanced a different interpretation of the implied undertaking rule. In Janssen's view, the implied undertaking with respect to evidence is waived as soon as it enters the Court record, and it is irrelevant whether the proceedings are public or confidential.

[19] However, I would observe that, even if this were true, in Janssen's proposed Amended Protective and Confidentiality Order, attached as Schedule A to its Notice of Motion, Janssen proposes amendments which would allow it to use any and all confidential information exchanged between the parties from the within action in the New Actions. This encompasses more than just the Specified Documents, potentially including additional documents to which the implied undertaking still applies and from which Janssen has not been relieved. The request as framed is too broad.

[20] I indicated to counsel that I believe it would be inappropriate to vary the Confidentiality Order until Janssen has sought relief from its implied undertaking. Nevertheless, at the hearing of this motion the parties have agreed to a more limited variance of that Order.

B. *Is Janssen's motion to vary the Confidentiality Order overly broad?*

[21] Even if there was a waiver of the implied undertaking by the filing of evidence in Court generally, the request to vary the Confidentiality Order is too broad.

[22] Under Rule 152(3) of the *Rules*, a confidentiality order “continues in effect until the Court orders otherwise”. Rule 399(2) of the *Rules* provides that the Court may, on motion, vary an order “by reason of a matter that arose or was discovered subsequent to the making of the order”.

[23] The Court of Appeal has confirmed that the test to vary a protective order is whether the facts establish some change in circumstances or compelling reason to vary (*Apotex Inc v AstraZeneca Canada Inc*, 2004 FCA 226 affirming *Astrazeneca Canada Inc v Canada (Minister of Health)*, 2004 FC 378).

[24] While I find that Janssen’s proposed variations are too broad, the parties agreed to a variance of the Confidentiality Order at the hearing that would include certain evidence, outlined below.

[25] Janssen wishes to use documents from the within action in support of its *res judicata* and/or abuse of process claims in the New Actions. Specifically, Janssen wishes to lead evidence from the Specified Documents showing:

- i. Apotex defended the within action only on the basis of non-infringement and that it was not defending the within action on the basis of patent invalidity; and
- ii. [REDACTED]

[26] While the need for evidence to adequately support a *res judicata* or abuse of process claim would establish a compelling reason to vary, neither of the above facts are controversial or contested. With respect to the first, it is not even confidential; the Public Reasons for Judgment explicitly state that Apotex did not allege invalidity (*Janssen Inc v Apotex Inc*, 2022 FC 107 at paras 23 and 105).

[27] With respect to the second fact, Apotex accepts that Janssen ought to be able to advance this argument on a summary judgment motion and consents to a limited variance of the Confidentiality Order to that end. Apotex agrees to allow Janssen to rely on the same evidence Janssen cites in support of this argument in this motion [collectively the “Conceded Evidence”]:

- i. paragraphs 1-5, 21, 23, 26, 53-57, 60-62, 64, 69-70, 76-81 and 83-89 of Apotex’s Summary Trial Memorandum of Fact and Law;
- ii. paragraphs 12-13 and 16-20, and exhibits D and I, of the Affidavit of Duane Terrill affirmed April 30, 2021;



- iii. page 124, lines 4-21, and page 128, line 22 to page 129, line 3, from the transcript of Mr. Terrill's cross-examination;
- iv. page 330, lines 9-15, from the transcript of Apotex's oral closing submissions (as cited at footnote 10 of Janssen's Written Representations);
- v. paragraphs 79, 151, 161, 165 and Judgment paragraph 2, from the Confidential Judgment and Reasons for Judgment; and
- vi. the Notice of Allegation filed by Apotex in this proceeding.

[28] Apotex's concessions will allow Janssen to support its claims in the New Actions fully and fairly. There is no compelling reason for Janssen to require any and all confidential information disclosed over the course of the within action.

[29] It is in the interests of justice to allow the Conceded Evidence and to avoid further unnecessary Court proceedings.

V. Conclusion

[30] The motion with respect to the Conceded Evidence is granted.

[31] Given that counsel agreed during the hearing to a more expanded inclusion of evidence than was initially agreed to by Apotex, I exercise my discretion to award no costs for this motion.

**JUDGMENT in T-124-21**

**THIS COURT'S JUDGMENT is that:**

1. The Protective and Confidentiality Order of March 22, 2021 is hereby varied to allow use of the following evidence in Court actions T-1121-22, T-1122-22, T-1248-22 and T-1249-22:
  - i. paragraphs 1-5, 21, 23, 26, 53-57, 60-62, 64, 69-70, 76-81 and 83-89 of Apotex's Summary Trial Memorandum of Fact and Law;
  - ii. paragraphs 12-13 and 16-20, and exhibits D and I, of the Affidavit of Duane Terrill affirmed April 30, 2021;
  - iii. page 124, lines 4-21, and page 128, line 22 to page 129, line 3, from the transcript of Mr. Terrill's cross-examination;
  - iv. page 330, lines 9-15, from the transcript of Apotex's oral closing submissions (as cited at footnote 10 of Janssen's Written Representations);
  - v. paragraphs 79, 151, 161, 165 and Judgment paragraph 2, from the Confidential Judgment and Reasons for Judgment; and
  - vi. the Notice of Allegation filed by Apotex in this proceeding.
  
2. No costs are awarded.

"Michael D. Manson"

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Judge

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-124-21

**STYLE OF CAUSE:** JANSSEN INC. and JANSSEN PHARMACEUTICA  
N.V. v APOTEX INC.

**PLACE OF HEARING:** TORONTO, ONTARIO

**DATE OF HEARING:** DECEMBER 15, 2022

**PUBLIC JUDGMENT AND REASONS:** MANSON J.

**DATED:** DECEMBER 20, 2022

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