Federal Court  Cour fédérale

Date: 20170531

Docket: T-944-15

Citation: 2017 FC 434

Montréal, Quebec, May 31, 2017

PRESENT: The Honourable Mr. Justice Locke

BETWEEN:

TEVA CANADA LIMITED

Plaintiff

and

JANSSEN INC. and MILLENNIUM PHARMACEUTICALS, INC.

Defendants

AND BETWEEN:

MILLENNIUM PHARMACEUTICALS, INC., JANSSEN INC., CILAG GMBH INTERNATIONAL, CILAG AG and JANSSEN PHARMACEUTICA NV

Plaintiffs by Counterclaim

and

THE UNITED STATES OF AMERICA REPRESENTED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Patentee Added Pursuant to s. 55(3) of the *Patent Act*

and

TEVA CANADA LIMITED

Defendant by Counterclaim

PUBLIC ORDER AND REASONS
(Identical to the Confidential Order and Reasons issued on May 2, 2017)

I. Background

[1] The plaintiffs by counterclaim, Millennium Pharmaceuticals Inc., Janssen Inc., Cilag GmbH International, Cilag AG and Janssen Pharmaceutica NV, seek leave to amend their defence and counterclaim. The notice of motion was accompanied by a draft Second Amended Statement of Defence and Counterclaim including the proposed amendments. The parties agree on many of the proposed amendments. They disagree only on the proposed addition of new paragraphs 9.1 to 9.12.

[2] The paragraphs in dispute introduce an allegation that the plaintiff, Teva Canada Limited (Teva), is not entitled to the damages it seeks under section 8 of the *Patent Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the *Regulations*] because it is not a "second person" as defined in the *Regulations* (the Second Person Allegation). Section 8 of the *Regulations* provides that a second person (usually a generic drug company) may pursue a first person (generally a

patent rights holder) for any loss suffered during a period that it was kept off the market by the operation of the *Regulations*.

[3] The term "second person" is defined as "the person referred to in subsection 5(1) or (2) who files a submission or supplement referred to in those subsections." Subsections 5(1) and (2) describe the second person's obligation, before obtaining a notice of compliance (NOC) for its generic drug, to address any patent on the patent list associated with first person's reference drug. Typically, this is done by means of a notice of allegation (NOA) sent by a second person to a first person.

[4] The factual basis for the Second Person Allegation is a Teva Inter-Group License, Supply and Distribution Agreement dated January 1, 2014, between the plaintiff and a company called Teva Pharmaceutical Works Private Limited Company (Teva Hungary). This agreement is referred to hereinafter as the Inter-Group Agreement. The plaintiffs by counterclaim point to the following paragraph, among others, of that agreement to support arguments that Teva carries out the directions of Teva Hungary, that at the end of the day Teva Hungary directs and owns everything, and that even if Teva's NOC was obtained in its own name, the agreement provides that Teva merely obtained the NOC for Teva Hungary and the NOC will always be owned by Teva Hungary:

> 3.7. To the extent permitted under the laws applicable in the Territory, the Marketing Authorizations shall be applied for and obtained in the name of the Supplier, unless otherwise agreed between the Parties. All Marketing Authorizations – whether applied for and obtained in the name of the Supplier or whether, due to the law applicable in the Territory, in the name of the Distributor – shall be owned by the Supplier, and the Distributor shall utilize such Marketing Authorizations in accordance with the

> directions of the Supplier. On termination of this Agreement for any reason whatsoever, the Distributor shall cooperate with the Supplier to the fullest extent in connection with all activities which may be required by the Supplier with regard to the Marketing Authorizations, including without limitation, the cancellation thereof or the transfer thereof to such person or persons as the Supplier may specify at such time.

[5] It appears that the defendants in the main action, Millennium Pharmaceuticals Inc. and Janssen Inc., wish to establish that Teva Hungary is the beneficial owner of Teva's assets.

II. Applicable Legal Test

[6] The parties do not disagree substantially on the legal test to be applied in deciding a motion to amend a pleading. As a threshold issue, Janssen must satisfy the Court that the proposed amendment has a reasonable prospect of success: *Bauer Hockey Corp v Sport Maska Inc (Reebok-CCM Hockey)*, 2014 FCA 158 at para 13; *Teva Canada Limited v Gilead Sciences Inc*, 2016 FCA 176 at paras 29-31. The idea is that it would be a waste of resources to allow an amendment that is doomed to fail.

[7] If the threshold issue is satisfied, the Court then considers other factors such as whether allowing the amendment would (i) result in an injustice to the other party not capable of being compensated by an award of costs, and (ii) serve the interests of justice: *Canderel Ltd v Canada*, [1994] 1 FC 3 (CA) at p 10; *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2014 FCA 65 at para 13. Ultimately, it boils down to a consideration of simple fairness, common sense and the interest that the courts have that justice be done: *Merck & Co Inc v Apotex Inc*, 2003 FCA 488 at para 30; *Janssen Inc v Abbvie Corporation*, 2014 FCA 242 at para 3.

[8] In considering whether or not to grant leave to amend, the Court must assume that the facts pleaded in the amendments are true: *VISX Inc v Nidek Co* (1996), 72 CPR (3d) 19 (FCA) at para 16.

III. Analysis

[9] Teva's opposition to the present motion focuses on the threshold issue. Teva argues that the proposed amendment has no reasonable prospect of success, and therefore should not be allowed, for two reasons:

1. Having commenced proceedings against Teva, and having benefited from the stay period provided for in the *Regulations*, Janssen Inc. and Millennium Pharmaceuticals Inc. have accepted the liability provided for in section 8 of the *Regulations* and are estopped from denying liability now (referred to below as the estoppel issue); and
2. There is no dispute that Teva is the party that filed a submission for an NOC, sent a notice of allegation, was kept off the market for a time, and ultimately obtained an NOC, all as contemplated in the *Regulations*, and therefore Teva clearly satisfies the definition of "second person" therein.

A. *Estoppel Issue*

[10] Teva argues that the doctrines of election and estoppel prevent a party from avoiding liability under section 8 of the *Regulations* by arguing that the "second person" who was the object of a prohibition application under section 6 of the *Regulations* does not actually fit the definition of a "second person". The Federal Court of Appeal (FCA) addressed this issue in

Apotex Inc v Sanofi-Aventis, 2014 FCA 68. In that case, a ruling during the course of a prohibition application against Apotex had the effect of removing its status as a "second person". However, the prohibition application which kept Apotex from obtaining an NOC and from entering the market was not terminated until later. Sanofi argued that its liability for Apotex's damages under section 8 of the *Regulations* should end at the date that Apotex lost its status as a second person and not continue until termination of the proceedings. The FCA addressed this argument at paras 94, 99 and 100:

> [94] Though in this appeal Apotex appears to agree with Sanofi that it is not technically a "second person" with respect to the HOPE patents, it rightfully submits that in view of Sanofi's conduct throughout the litigation, it is precluded by the doctrines of election and estoppel from asserting that Apotex was not a "second person" for the purposes of section 8, at least until the NOC was issued to Apotex.
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> …
>
> [99] In this case, Sanofi listed the HOPE patents on the patent list maintained with respect to ramipril under section 4 of the *NOC Regulations* with the clear objective of forcing generic drug manufacturers (such as Apotex) which were seeking approval of copy-cat versions of ramipril to deal as "second persons" with those patents under the machinery of those Regulations. Sanofi moreover availed itself of subsection 6(1) of the *NOC Regulations* to initiate prohibition proceedings with respect to Apotex's notices of allegations concerning the HOPE patents, thus obtaining the benefit of the statutory stay provided under those Regulations. Had these prohibition proceedings not been initiated, Apotex would have received its NOC much earlier than it did. As a result, these prohibition proceedings in fact precluded Apotex from competing earlier with Sanofi in the ramipril market. Sanofi thus obtained considerable benefits under the *NOC Regulations* by treating Apotex as a "second person" through its prohibition proceedings concerning the HOPE patents.
>
> [100] The purpose of section 8 of the *NOC Regulations* is precisely to ensure that when an innovator drug manufacturer takes advantage of those Regulations by initiating unfounded prohibition proceedings, the generic drug manufacturer can then seek appropriate compensation for having been precluded from the

> market as a result. By initiating prohibition proceedings with respect to the HOPE patents and thereby precluding Apotex's market entry until December 12, 2006, Sanofi was clearly subject to section 8 compensation irrespective of whether the benefit it derived under the *NOC Regulations* was unjustified as later found in *AstraZeneca*. As a result, Sanofi cannot now claim that its own prohibition proceedings were null *ab initio* so as to deny to Apotex the benefit of section 8 compensation for the period during which those proceedings precluded it from entering the ramipril market.

[11] Justice Roger Hughes has, on more than one occasion, analogized liability under section 8 of the *Regulations* to an undertaking that is typically given by a party to secure an interlocutory injunction: that it will make good any losses suffered by the other party if it should fail in the end: *Apotex Inc v Merck & Co Inc*, 2008 FC 1185 at para 54; *Apotex Inc v Astrazeneca Canada Inc*, 2012 FC 559 at para 58.

[12] The plaintiffs by counterclaim seek to distinguish the foregoing jurisprudence on the basis that they do not seek to escape liability entirely, but rather seek to ensure that the correct party is claiming for the loss. They argue that the proposed new allegations lead to the conclusion that the "second person" who is entitled to compensation under section 8 of the *Regulations* is not Teva but Teva Hungary. Another consideration is that the Inter-Group Agreement was not revealed until the discovery phase of the present action. It was not known to Janssen Inc. during the underlying prohibition proceedings that gave rise to the present section 8 action. The plaintiffs by counterclaim also emphasize that it is not appropriate for the Court to decide the Second Person Allegation now. Rather, the Court should determine simply whether the Second Person Allegation has any reasonable prospect of success.

[13] In my view, the analogy to an undertaking given to obtain an interlocutory injunction is helpful and decisive. Whether Janssen Inc. was not in a position when it commenced the prohibition proceedings against Teva to allege that Teva was not a "second person" does not alter the fact that Janssen Inc. chose to employ the *Regulations* to benefit from keeping a potential competitor off the market, all while accepting the possibility of liability if it were unsuccessful. I see no distinction between the facts here and those in the jurisprudence sufficient to give rise to any reasonable prospect that the Second Person Allegation will be successful.

B. *Definition of "Second Person"*

[14] Teva's second principal argument against the proposed amendment is that, even accepting all of the facts as alleged in the Second Person Allegation, Teva remains a second person as defined in the *Regulations*, and has standing in the present action.

[15] It is not disputed that:

1. Teva filed a submission for an NOC in respect of a drug, which submission made reference to another drug which was the subject of a patent list that had to be addressed as contemplated in the *Regulations* before Teva could obtain its NOC;
2. Teva sent an NOA as contemplated in the *Regulations*;
3. Teva was the respondent in two prohibition applications commenced under the *Regulations* by Janssen Inc. in response to the NOA; and
4. Teva obtained the NOC once the prohibition applications had been dismissed.

[16] Based on the definition of "second person" which refers to subsection 5(1) of the *Regulations*, and based on Teva's involvement in the steps contemplated in the *Regulations*, and further considering the jurisprudence discussed above, I conclude that Teva is clearly a second person for the purposes of standing in the present action. Nothing to which my attention has been drawn in the Inter-Group Agreement alters this conclusion. Neither Teva Hungary's alleged interest in (or beneficial ownership of) Teva's assets nor its control of Teva's activities alters Teva's status as a second person based on the undisputed facts enumerated above.

[17] The plaintiffs by counterclaim argue that the Second Person Allegation is not only about Teva's standing but also encompasses the apportionment of damages to which Teva may be entitled. I am not convinced by this argument. The proposed paragraphs of the Second Person Allegation allege either that Teva lacks standing or that it is disentitled to any relief or that it suffered no damages. I see nothing in these paragraphs that suggests apportionment. Moreover, Teva notes that apportionment is already an issue in the action, questions having been asked and answered on the issue during discovery.

[18] In my view, Teva's clear status as a "second person" deprives the Second Person Allegation of any reasonable prospect of success.

IV. Conclusion

[19] It follows from the reasoning above that the proposed amendment to add the Second Person Allegation will not be permitted. That said, the other proposed amendments in the draft

Second Amended Statement of Defence and Counterclaim that accompanied the notice of motion, which are agreed to between the parties, will be permitted.

ORDER in T-944-15

THIS COURT ORDERS that:

1. The disputed aspect of the motion by the plaintiffs by counterclaim to amend their Amended Statement of Defence and Counterclaim is dismissed.

2. The plaintiffs by counterclaim may serve and file, within three days following the date of this Order, a Second Amended Statement of Defence and Counterclaim including the other amendments that have been agreed to between the parties.

3. Teva Canada Limited may serve and file, within seven days following service of the Second Amended Statement of Defence and Counterclaim, a Second Amended Reply and Defence to Counterclaim.

4. The plaintiffs by counterclaim shall pay costs of the motion in the amount of $1,000 to Teva Canada Limited.

"George R. Locke"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-944-15
STYLE OF CAUSE:	TEVA CANADA LIMITED v JANSSEN INC. AND MILLENNIUM PHARMACEUTICALS, INC.
PLACE OF HEARING:	OTTAWA, ONTARIO
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CONFIDENTIAL ORDER AND REASONS DATED:	MAY 2, 2017
PUBLIC ORDER AND REASONS DATE:	MAY 31, 2017

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