Federal Court Cour fédérale

Date: 20221027

Docket: T-607-21

Citation: 2022 FC 1477

Ottawa, Ontario, October 27, 2022

PRESENT: The Honourable Mr. Justice Southcott

BETWEEN:

APOTEX INC.

Plaintiff

and

JANSSEN INC., JANSSEN ONCOLOGY INC. and BTG INTERNATIONAL LTD.

Defendants

PUBLIC ORDER AND REASONS

I. Overview

[1] This decision relates to a motion by Janssen Inc., Janssen Oncology Inc., and BTG International Ltd., [together, Janssen], the Defendants in the within action brought under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-113 [the Regulations].

In the underlying action, the Plaintiff, Apotex Inc. [Apotex], claims against Janssen damages for lost sales of abiraterone acetate.

[2] In this motion, Janssen moves, under Rule 75 of the *Federal Courts Rules*, SOR/98-106 [the Rules], to amend its Statement of Defence. Apotex opposes the motion.

[3] Some of the evidence adduced in this motion is subject to a Confidentiality Order, in order to protect commercially sensitive confidential information of the parties. A draft confidential decision was therefore sent to the parties on October 7, 2022, to allow them to propose any redactions required for the issuance of the public version of the decision. The parties have jointly proposed redactions. As these redactions will not affect the intelligibility of the decision, I am satisfied that they appropriately balance the interests of protecting confidential information and the public interest in open and accessible court proceedings. As such, two versions of this decision, one public and the other confidential, will be issued simultaneously.

[4] As explained in greater detail below, Janssen's motion is granted, because I find that allowing the amendment will serve the interests of justice, by fulfilling the purpose of determining the real questions in controversy between the parties without resulting in an injustice to Apotex not capable of being compensated by an award of costs.

II. **Background**

[5] Janssen markets the prostate cancer drug abiraterone acetate in Canada as ZYTIGA and listed Canadian Patent No. 2,661,422 [the 422 Patent] on the Patent Register in respect of ZYTIGA.

[6] Apotex sought to market a generic abiraterone acetate product and challenged the validity of the 422 Patent. In turn, Janssen commenced an action under section 6 of the Regulations against Apotex in respect of its abiraterone acetate products. On January 6, 2021, Justice Phelan dismissed Janssen's claim and declared the 422 Patent to be invalid (see *Janssen Inc v Apotex Inc*, 2021 FC 7).

[7] Justice Phelan's dismissal of the section 6 action crystallized a cause of action for Apotex pursuant to section 8 of the Regulations. On April 12, 2021, Apotex commenced the within action claiming damages against Janssen for lost sales of Apotex's abiraterone acetate product. This action is scheduled for trial beginning on June 19, 2023.

[8] Apotex's Statement of Claim alleges that, but for Janssen's conduct, it would have received its Notice of Compliance [NOC] from Health Canada and sold its abiraterone acetate products in Canada on August 8, 2019. As a result, Apotex alleges that its sales were delayed from August 8, 2019 until January 11, 2021, when it ultimately received its NOC in the real world [the Delay Period]. Apotex's Statement of Claim seeks compensation for all losses suffered from August 8, 2019. That is, its claim extends to future losses beyond the Delay Period.

[9] In response, Janssen pleaded in its Statement of Defence that Apotex did not have the ability and/or capacity to manufacture and supply sufficient quantities of Apotex's abiraterone acetate product to satisfy the Canadian generic market for this drug. Apotex denied this allegation in its Reply.

[10] The parties have completed the first round of examinations for discovery. Shortly prior to its discovery of Apotex's representative, Janssen produced documentation [that the parties refer to as the US Data Document] purporting to contain data in relation to sales of abiraterone acetate products in the US. Janssen alleges this data shows that Apotex suffered a supply disruption beginning in and around March 2019, as a result of which it could not manufacture sufficient quantities of its abiraterone acetate product to satisfy the US market.

[11] During its examination for discovery of Apotex's representative, Janssen's counsel asked a number of questions that Janssen considers to be relevant to whether Apotex could have supplied the Canadian market starting in August 2019 in the but-for world. Apotex refused to answer several questions of this sort, following which Janssen brought a motion to compel answers to these questions and others.

[12] In an Order dated June 14, 2022 [the Order], Prothonotary Milczynski (now Associate Judge Milczynski), who is case managing this action [the Case Management Judge], ordered Apotex to answer several questions but dismissed Janssen's motion with respect to certain questions that focused upon Apotex's sales in the US market and its relationship to the Canadian market [the Disputed Questions]. Janssen has moved under Rule 51 to appeal this portion of the

Order. The parties argued that appeal on the same day as the hearing of this motion by Janssen to amend its Statement of Defence. I have addressed the Rule 51 motion in a separate decision of today's date, in which I have allowed Janssen's appeal [the Rule 51 Decision]. As will be apparent from a review of both the present decision and the Rule 51 Decision, there is some overlap in the arguments raised by the parties in both motions.

[13] The relevant portion of Janssen's current Statement of Defence reads:

> 22. In the alternative, Janssen relies upon subsections 8(5) and 8(6) of the Amended Regulations and pleads that the following relevant factors should be taken into account by the Court when assessing the amount of compensation, if any, to be awarded to Apotex:
>
> ….
>
> b. Apotex did not have the ability and/or capacity to manufacture or obtain any quantities of Apo-Abiraterone, let alone sufficient amounts to satisfy the Canadian generic abiraterone acetate marketplace;

[14] In this motion, Janssen seeks to amend paragraph 22b to read as follows:

> b. Apotex did not have the ability and/or capacity to manufacture or obtain any quantities of Apo-Abiraterone, let alone sufficient amounts to satisfy the Canadian generic abiraterone acetate marketplace~~;~~, including as a result of the following:
>
> i. Apotex's Canadian facilities manufacture and supply Apo-abiraterone for Canada and other markets. Apotex has experienced supply disruptions in other markets and in Canada, both before and after August 8, 2019, including (as non-limiting examples):
>
> 1. Apotex experienced supply disruptions in the U.S., starting from approximately March 2019 and was unable to meet market demand in the U.S.;
>
> 2. As a result of supply disruptions starting in approximately March 2019, Apotex was unable to sell its U.S. customers

> sufficient quantities of Apo-abiraterone to meet market demand, causing some of Apotex's U.S. customers to seek other suppliers for abiraterone acetate tablets;
>
> 3. Apotex again experienced a disruption in the manufacture of its 500 mg tablet for Canada starting from approximately March 31, 2022 and lasting at least until May 16, 2022 and was unable to meet market demand in Canada; and
>
> 4. To date, Apotex has not obtained regulatory approval for its 500 mg tablet in the U.S.
>
> ii. Apotex would not have been able to manufacture and/or supply sufficient quantities of Apo-abiraterone continuously as of August 8, 2019. Had Apotex launched in August 2019, it either:
>
> 1. would not have had sufficient supply for the Canadian market as it would have channelled all of its available supply to the U.S. market in order to address its shortfall; or
>
> 2. would have supplied the Canadian market at the expense of supplying other markets (including the U.S. market) and would have suffered losses as a result.

III. **Issue**

[15] The sole issue on this motion is whether this Court should grant Janssen leave to serve and file its Amended Statement of Defence.

IV. **Analysis**

A. *General Principles*

[16] Rule 75 provides the Court with the discretion to allow a party to amend its pleadings on such terms as will protect the rights of all parties.

[17] The general principle is that an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties and to facilitate the Court's consideration of the true substance of the dispute on its merits (*McCain Foods Limited v JR Simplot Company*, 2021 FCA 4 at para 20 [*McCain*]; *Apotex Inc v Bristol-Myers Squibb Co*, 2011 FCA 34 at para 33 [*BMS*]). However, the Court must guard against granting amendments that would result in an injustice to the other party not capable of being compensated by an award of costs, or that would not serve the interests of justice (*McCain* at para 20).

[18] In conducting this assessment, the Court will determine whether the proposed amendment (in the context of a Statement of Defence) discloses a defence with a reasonable prospect of success (*Teva Canada Limited v Gilead Sciences Inc*, 2016 FCA 176 at para 31 [*Teva*]; *McCain* at para 20). This is a threshold issue (*Teva* at para 31). It can be helpful for the Court to ask itself whether the amendment, if it were already part of the pleadings, would be a plea capable of being struck out (*McCain* at para 22). For purposes of this analysis, the facts pleaded are assumed to be true (*McCain* at para 20; *Houle v Canada*, [2001] 1 FC 102 [*Houle*] at para 18).

[19] Once it has been established that a proposed amendment has a reasonable prospect of success, consideration will be given to other factors consonant with the interests of justice. Such factors include: (a) the timeliness of the motion to amend; (b) the extent to which the proposed amendments would delay the expeditious trial of the matter; (c) the extent to which a position taken originally by one party has led another party to follow a course of action in the litigation which it would be difficult or impossible to alter; and (d) whether the amendments sought will

facilitate the Court's consideration of the true substance of the dispute on its merits. These factors are non-exhaustive and not limiting; a balancing exercise is required with no single factor intended to predominate. Consideration will also be given to simple fairness, common sense and the interest that the courts have that justice be done (*Sunovion Pharmaceuticals Canada Inc v Taro Pharmaceuticals Inc*, 2021 FC 37 at para 34, citing *Janssen Inc v Abbvie Corporation*, 2014 FCA 242 at para 3).

[20] Ultimately, the determination of whether an amendment should be granted under the Rules is a matter of discretion for the trial judge, to be guided by the judge's assessment of where justice lies (*Canderel Ltd v Canada*, [1994] 1 FC 3 (FCA) at paras 10, 13).

B. *Jurisprudential Dispute*

[21] While the parties appear to agree on the general principles set out above, they disagree on the current state of the jurisprudence as to the ease with which a party can obtain leave to amend its pleading even at a relatively advanced stage in a proceeding.

[22] Janssen submits that the law contemplates motions for leave to amend being allowed even in extreme cases of negligence, carelessness, or undue delay by the party seeking the proposed amendment (none of which Janssen considers to apply in the present case), provided the amendment can be made without injustice to the other party. In its written submissions, Janssen cites the decision of the Federal Court of Appeal in *Visx Inc v Nidek Co*, [1998] FCJ No 1766 (FCA) [*Visx*] at paragraph 1 in support of its position.

[23] Apotex argues that, particularly in the context of complex high-stakes litigation including in the pharmaceutical sphere, the law has evolved since *Visx* to place additional emphasis on the requirement for the parties to develop and pursue their positions timely and efficiently. Apotex relies on *BMS*, in which the Federal Court of Appeal overturned a decision that had allowed a pleading amendment and explained as follows (at para 37):

> 37. Complex, high-stakes intellectual property proceedings are governed by procedural rules aimed at fairness, full and timely disclosure, and efficiency. Purposeful, strategic conduct involving non-disclosure, non-clarification or inaction, as the Prothonotary and the Federal Court judge found here, disrespects these rules and their aims. Those who disrespect the rules and their aims can hardly expect courts to smile upon them when they look for a favourable exercise of discretion under those rules.

[24] Janssen disagrees with Apotex's submission that *BMS* represents a change in the law. It argues that the outcome in *BMS* is to be understood as driven by the particular facts in that case. I agree with Janssen's interpretation. *BMS* acknowledged that pleading amendments should be allowed for the purpose of determining the real questions in controversy. The Court noted that pleading amendments can be made at any time to achieve that purpose, even after a trial has begun. Indeed, the Court stated that, even in a case such as the one before it, where a major new issue had been sprung in the proceeding at the last minute with no justification, the Court was obliged to give significant weight to the need for the real questions in controversy to be determined (at para 33).

[25] *BMS* nevertheless rejected the proposed amendment because of the particular history of the applicant's conduct in that case. The Court explained that, for roughly a decade, the applicant had conducted itself in a way that suggested that the issues it was seeking to plead were not real

questions in controversy. The applicant was attempting to raise these issues years after the exchange of pre-trial memoranda, and without any significantly new developments in the litigation. Moreover, even on the eve of trial, the applicant was not able to articulate with acceptable particularity the supposedly real questions in controversy that it wished to raise (at para 34). The Court further concluded that the applicant had purposefully and strategically decided not to clarify earlier its position on these issues, an approach which was contrary to the right of the parties to the orderly progression of matters to trial (at para 36).

[26] Certainly, *BMS* is an instructive decision, as it emphasizes that a party should not assume that requested pleading amendments will be granted automatically, without some scrutiny of the litigation history and the parties' conduct therein. However, in my view, *BMS* does not represent a departure from the principles governing pleading amendments canvassed above in these Reasons. As Janssen notes, the explanation of those principles in the relatively recent decision in *McCain* significantly post-dates *BMS*.

C. *Real Controversy / Reasonable Prospect of Success*

(1) Janssen's Position

[27] Janssen submits that one of the central issues in dispute in this action is whether Apotex could have launched its abiraterone acetate product on August 8, 2019, in quantities sufficient to supply the Canadian generic market. Paragraph 22b of Janssen's Statement of Defence currently pleads that Apotex did not have the ability and/or capacity to manufacture or obtain any quantities of abiraterone acetate, let alone sufficient amounts to satisfy the Canadian generic

marketplace. It argues that its proposed amendments merely particularize material facts it wishes to plead in relation to this central issue - Apotex's ability to supply the market. The proposed amendments relate to Apotex's real world experiences in both the US and Canadian markets, which experiences Janssen argues are relevant to the but-for world at issue in this action.

[28] Janssen submits that Apotex's US experience is relevant for two reasons. First, it explains its position that Apotex's US abiraterone acetate tablets appear to have been manufactured [redacted]. In support of this submission, Janssen relies on what it describes as public documentation surrounding US labelling, which it submits confirms that Apotex manufactures its abiraterone acetate product for the US market at what it refers to as the Signet plant. [redacted]. Janssen also references a documentary production by Apotex in this litigation, which it submits demonstrates that the active pharmaceutical ingredient [API] for Apotex's abiraterone acetate product for the US and Canadian markets was shipped to the [redacted] plant.

[29] Second, based on the US Data Document, Janssen submits that Apotex experienced a sudden and precipitous decline in sales in the US market for its 250 mg tablets in the months preceding August 8, 2019. Based on the combination of these facts related to the US market, Janssen alleges that Apotex experienced supply issues that would have impacted its ability to come to market in Canada. Janssen wishes to particularize its paragraph 22d pleading by reference to these facts.

[30] In relation to the Canadian market, Janssen asserts that Apotex experienced supply disruptions for its 500 mg tablets for that market, starting in March 2022. In support of this assertion, Janssen relies on what it describes as public reports that emerged around the time of examination for discoveries in March 2022 and identified that Apotex had encountered a disruption of the manufacture of its 500 mg abiraterone acetate tablet in Canada, which disruption lasted until May 20, 2022. While this disruption post-dates the Delay Period, Janssen submits that it is relevant to Apotex's claim, because the claim seeks losses extending beyond the Delay Period.

[31] Janssen's proposed amendments also include the allegation that Apotex has not yet received approval for 500 mg tablets in the US. Janssen submits that this fact, which could be a function of Apotex's capacity to manufacture its product to the standard necessary to achieve regulatory approval, supports Janssen's position that Apotex has experienced manufacturing and/or supply issues with its 500 mg tablet, which would have affected its ability to increase its manufacture and/or supply of product to supply the Canadian market in the but-for world.

(2) Apotex's position

[32] In opposing Janssen's motion, Apotex relies significantly on evidence it has produced in this litigation, through documentary discovery, its representative's testimony during examination for discovery by Janssen's counsel, and subsequent answers to discovery undertakings.

[33] The documentary evidence includes a chart setting out the annual production capacities of Apotex's Signet plant, and another alternative plant in Etobicoke, from 2017 to 2021, which

Apotex submits includes both plants' theoretical maximum capacities and actual output. Apotex argues that this evidence establishes that its Signet facility had more than sufficient excess capacity to satisfy the entire Canadian market for abiraterone acetate. Apotex also produced a spreadsheet setting out its actual billings, which it argues support its position that it entered the market immediately after it received its NOC and made sales of abiraterone acetate continuously through to the day the spreadsheet was generated in July 2021.

[34] The oral discovery evidence upon which Apotex relies includes confirmation that [redacted]. Apotex also confirmed that it manufactured its Canadian abiraterone acetate product in the real world at its [redacted] facility but that it could also have used its [redacted] facility if needed. It further confirmed that it experienced no delays or difficulties in obtaining any of the excipients or non-API ingredients for its product, and it provided supplier invoices and an inventory log for the supply of product for its abiraterone tablets. Apotex submits that this evidence shows that it had [redacted] of available API in the relevant period.

[35] Finally, Apotex notes that, in the course of Janssen's motion to compel answers to the questions that had been refused on discovery, Apotex agreed to provide additional information regarding its Canadian manufacturing capabilities, which Apotex argues will further speak to Apotex's ability to supply the Canadian market in the relevant time period.

[36] Against the backdrop of this evidence, Apotex argues that the Court has a robust record of the information provided by Apotex to date in respect of its manufacturing capabilities during

the Delay Period, which information addresses and dispels in full the purported controversies that Janssen seeks to inject into this action. Based on this information, Apotex submits that it is clear that Janssen's arguments cannot succeed and that there exists no controversy or dispute with respect to Apotex's ability to manufacture its abiraterone acetate tablets and supply the Canadian market in the but-for world at the relevant time. Apotex argues that Janssen's proposed pleading is therefore forlorn and frivolous, and would be capable of being struck, because it stands in contrast to the known factual matrix in this proceeding as revealed through the discovery process.

[37] Apotex also submits that, as in *BMS*, the proposed pleading is contrary to a position taken by Janssen earlier in this litigation. In advancing this submission, Apotex focuses upon the proposed pleading as it relates to facts following the Delay Period. Apotex refers the Court to developments during the motion to compel before the Case Management Judge, in which Apotex submits that Janssen initially moved on questions relating to post-Delay Period facts but later dropped those questions, representing an acknowledgement that they were not relevant.

[38] While Apotex acknowledges that it is claiming for future losses following the Delay Period, it argues that facts following the Delay Period are not relevant to this claim. It submits that these losses flow from being deprived of its opportunity to be the first to market a generic abiraterone acetate in Canada. That is, it argues that the future losses flow strictly from events and related losses that occurred during the Delay Period.

(3) Evidentiary arguments

[39] At this point in the analysis, it is also necessary to identify arguments advanced by each of the parties surrounding deficiencies in the other's evidence. Apotex takes the position that Janssen is unable to rely on the US Data Document and other documentary evidence in support of its motion, because it has not proven either the documents or their contents. The documents form part of the record on this motion as exhibits to an affidavit of a law clerk in Janssen's counsel's law firm, who swears only that he is attaching particular documentation. While Apotex's evidentiary argument focuses significantly upon the US Data Document, I understand it to take the same position in relation to the US labelling document, which Janssen relies upon to establish that Apotex manufactures abiraterone acetate for the US market at the Signet plant, and what Janssen describes as a public report of Apotex experiencing disruption of the manufacture of its 500 mg abiraterone acetate tablet.

[40] In response to this position, Janssen identifies what it considers to be deficiencies in Apotex's evidence in this motion. Janssen refers the Court to *South Yukon Forest Corporation v Canada*, 2004 FC 1645 [*South Yukon*], which addressed a motion seeking leave to amend a statement of claim and upheld the defendant's objection to the plaintiff's efforts to rely upon extracts from the discovery examination of the plaintiff's representative. The Court explained that the Rules allow use of discovery evidence by an adverse party but do not contemplate such use by the party whose representative gave that evidence on discovery (at paras 11-13).

[41] Janssen argues that, if Apotex is unable to rely on its own discovery evidence, the only other evidence in support of its position is documentary evidence attached to an affidavit sworn

by a law clerk in the office of Apotex's counsel. Janssen submits that this is no different from the manner in which Janssen introduced its documentary evidence.

[42] Apotex responds that the concern identified in *South Yukon* does not apply in the circumstances in which it has relied on its representative's discovery evidence. It submits that Janssen has relied on portions of the discovery examination of Apotex's representative and that Apotex is therefore entitled to complete the record by providing additional evidence from the discovery.

[43] The parties made similar arguments in the Rule 51 motion. In the Rule 51 Decision, I arrived at conclusions on these evidentiary arguments similar to those explained below.

(4) Analysis

[44] In support of its objection to Janssen's reliance on documentary evidence attached to a law clerk's affidavit, Apotex refers the Court to *Hoffman-La Roche Limited v Sandoz Canada Inc*, 2021 FC 384 [*Hoffman*] at paragraphs 48 to 54, in which Justice Manson held an affidavit from a law clerk attaching prior art to be inadmissible. As Justice Manson explained, the evidence sought to be introduced through a law clerk's affidavit related to the probative value of the prior art. This evidence was inadmissible, as it failed to meet the requirements of the best evidence rule (at para 48).

[45] In my view, Apotex's reliance on this authority demonstrates the weakness in its evidentiary argument. *Hoffman* is a trial decision. The parties were therefore required to prove

documentary evidence for authenticity and the truth of their contents in order to establish the merits of their respective positions on the substantive issues at trial. The same evidentiary requirements do not apply in a motion to amend a pleading. As explained earlier in these Reasons, the facts that a party wishes to plead in a proposed amendment are assumed to be true for purposes of the analysis as to whether the pleading identifies a real controversy between the parties and has a reasonable prospect of success.

[46] Indeed, in *Houle*, the Court referred to a general principle that it ought not to accept evidence on a motion to amend a pleading unless it is necessary to clarify the nature of the amendment (at para 18). As I understand Janssen's arguments in this motion, it relies on the documentary evidence in its motion materials for purposes of identifying information that has come to its attention and has prompted its effort to particularize its defence pleading. This evidence is arguably unnecessary for purposes of the Court's analysis as to whether, assuming the facts pleaded to be true, the defence has a reasonable prospect of success.

[47] However, I accept that the evidence provides context, which assists the Court in understanding the nature of the amendment. Reliance on this evidence is therefore consistent with the principle referenced in *Houle*. It is also consistent with that principle that Janssen is not required to prove that evidence in the manner that would be required if it was offered to establish facts at trial. As I explained in the Rule 51 Decision (at para 45), the pleadings define the scope of discovery, and the purpose of discovery is to enable a party to obtain evidence that it does not yet have. This purpose would be thwarted if the Court were to impose too high an evidentiary standard upon a party seeking to explain why it wishes to amend its pleading. In addition, while

Apotex has not expressly acknowledged the accuracy of information in the documentary evidence upon which Janssen relies, and I appreciate that Apotex disputes the significance of this information, I do not understand it to be arguing the information is incorrect.

[48] Turning to Janssen's objections to Apotex's reliance upon its own discovery evidence, and again consistent with my reasoning in the Rule 51 Decision, my conclusion is that the evidence is properly before the Court. I accept Apotex's argument that, given Janssen's reliance on Apotex's representative's discovery evidence in support of this motion, Apotex is entitled to complete the record before the Court by reference to other portions of that same evidence that are responsive to the evidence and arguments upon which Janssen relies.

[49] However, in my view, Apotex's evidence does not support a conclusion that the proposed amendment is frivolous. The analysis the Court is required to perform, in considering whether the amendment speaks to a real question in controversy between the parties and has a reasonable prospect of success, does not involve considering the extent to which the amendment is consistent with other evidence that has been produced in the litigation thus far. The Court should identify whether there is an issue in controversy, not assess which party is likely to prevail on that issue. As explained in *Houle*, it is not the Court's role to anticipate at this juncture whether the amendment will be successful at trial (at para 18).

[50] I turn to Apotex's argument that Janssen's proposed amendments represent a reversal of position. In support of that argument, Apotex refers to a disputed discovery question, in which Janssen asked Apotex's representative to advise whether any of the manufacturing facilities in

Canada that make its abiraterone acetate product had to slow down production or shut down at any point from 2018 to the date of the examination, March 8, 2022. Apotex submits that it subsequently offered to provide an answer for 2019 and 2020, the two years it was kept off the market, and that Janssen accepted that offer, as crystallized in the Case Management Judge's Order. Apotex argues that, in accepting this narrow timeframe, Janssen effectively conceded that Apotex's manufacturing capabilities in March to May 2022 were irrelevant to the issues in this action.

[51] The only information on this point captured in the Order is in a recital stating that, as agreed in Apotex's responding motion record or during oral argument, it will provide an answer to this question from 2019 and 2020. The records that the parties placed before the Court in this motion do not include the motion records or oral arguments before the Case Management Judge in the motion to compel. The information in the Order does not provide sufficient detail to support a conclusion that Janssen conceded that Apotex's manufacturing capabilities following the Delay Period were irrelevant. Certainly, I cannot conclude that Janssen's position in the present motion demonstrates it resiling from a previous position in a manner similar to that identified in *BMS*, where the Federal Court of Appeal explained that the applicant had conducted itself in a particular manner on substantive issues for roughly an entire decade (at para 34).

[52] I also disagree with Apotex's argument that the portions of Janssen's proposed amendments related to events following the Delay Period have no reasonable prospect of success, because such events cannot be relevant to its claim for future losses. Janssen accepts that the damages claimed in the underlying action must flow from what happened during the

Delay Period. However, it submits that real-world events that occurred following the Delay Period can affect the calculation of those damages. Janssen also submits that, as authorities upon which Apotex relies were decided under the version of the Regulations predating the 2017 amendments, they are limited in their application to this point, because of restrictions to the damages that could be claimed under the earlier version. Without reaching any conclusions on a point that may arise at trial, I find Janssen's submissions sufficiently compelling to conclude that it is not frivolous for it to plead post-Delay Period facts in support an argument that these real-world events potentially affect the damages calculation.

[53] In conclusion, I accept Janssen's broader position that its proposed amendments represent particularizations of its existing pleading that speak to real questions in controversy between the parties, surrounding alleged real-world events that have the potential to affect Apotex's damages in the but-for world. I emphasize that whether Janssen will succeed in establishing these facts or their potential significance is an issue for trial, not for assessment on this motion. However, I am satisfied that the amendments are not frivolous and that they have a reasonable prospect of success within the meaning of the jurisprudence canvassed earlier in these Reasons.

D. *Interests of Justice*

[54] I therefore turn to consideration whether other factors consonant with the interests of justice support allowing the amendments. Principally, Apotex argues that Janssen has brought its motion too late in this proceeding, that it deliberately delayed doing so for strategic reasons, and that Apotex and the orderly progression of this matter to trial will be prejudiced as a result.

[55] I accept that this matter is marching towards trial, which is scheduled to commence in less than nine months in June 2023, and that a pleading amendment at this stage has the potential to be disruptive. As Apotex submits, the parties are at a stage in the proceeding where the first round of discoveries and the resulting refusals motion are complete, the second round of discoveries is scheduled to commence in mid-October 2022, and it is reasonable to assume that the parties are working with their experts in the preparation of expert reports. However, I have very little in the way of evidence or detailed argument that would assist the Court in dimensioning the extent of any disruption that may be caused by the amendments. Certainly, I have no basis to conclude at this stage that the particularization of Janssen's defence position as represented by the amendments will result in loss of the trial dates.

[56] Nor is there evidence to support a conclusion that Janssen has deliberately and strategically delayed its pursuit of these amendments. Apotex has been aware that Janssen was pursuing defence arguments related to an alleged manufacturing disruption, said by Janssen to be evidenced by the US Data Document, since the discovery of Apotex's representative in March 2022. Janssen has subsequently advanced its pursuit of those arguments through its motion to compel and its Rule 51 appeal. The allegation that Apotex experienced a disruption in the manufacture of its 500 mg tablet for Canada relates to events alleged to have began only in the spring of 2022. While the motion to amend was heard only in September 2022, this was at least in part a function of the Court's schedule, as Janssen's motion is dated July 15, 2022.

[57] Taking into account these considerations and the jurisprudential principles canvassed above, I consider the interests of justice to support allowing the proposed amendments, as they

will permit Janssen to pursue real questions in controversy between the parties without resulting in an injustice to Apotex not capable of being compensated by an award of costs. I will return to the issues of costs shortly.

[58] I note that, in arriving at this conclusion, I have considered an additional argument advanced by Apotex that Janssen's amendment motion represents an effort to sidestep the Case Management Judge's Order. Referencing the combination of Janssen's motion to compel, Rule 51 appeal, and present amendment motion, Apotex refers the Court to authority to the effect that litigants ought not to be faced with multiple motions on similar subjects, as such an approach is contrary to judicial economy (*Harris v R*, 2001 FCT 758 at para 23; *Webster v Canada (AG)*, 2003 FCT 296 at para 9). Apotex characterizes the present motion as Janssen's "third kick at the can." However, in my view, the fact that Janssen has succeeded in its Rule 51 appeal reduces the strength of Apotex's argument. Moreover, there are elements of the relief sought in the present motion, unrelated to the events alleged to be demonstrated by the US Data Document, that do not overlap with the relief sought in the motion to compel and related appeal.

V. **Conclusion**

[59] In conclusion, I am prepared to grant Janssen leave to serve and file its proposed Amended Statement of Defence, and my order will so provide.

VI. **Costs**

[60] Janssen seeks costs of $5000.00 on this motion, an amount which it notes exceeds the $3000.00 it sought in its Rule 51 appeal, and it requests that those costs be made payable by Apotex forthwith. It takes the position that this result is warranted, because Apotex should have consented to its proposed amendment, which would have avoided the necessity for this motion.

[61] In support of that position, at the hearing of this motion, Janssen informed the Court that, in another section 8 action against it by Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. [together, Dr. Reddy's] involving abiraterone acetate, in Court File No. T-1168-21, Dr. Reddy's consented to Janssen amending its Statement of Defence to include particularized allegations similar to those at issue in this motion.

[62] On the subject of costs, Apotex relies on a principle to the effect that the costs of a pleading amendment should typically be borne by the party seeking the amendment. Janssen references the Rules in support of this principle.

[63] As Janssen has prevailed in this motion, I am satisfied that costs of the motion itself should follow the event, and I will award Janssen $3000.00. I do not find the fact that Dr. Reddy's consented to a similar amendment in another proceeding to represent a basis for awarding a higher amount of costs or ordering costs payable forthwith.

[64] I am also conscious of the costs principle raised by Janssen. Rule 410(1) contemplates the costs occasioned by an amendment to a pleading being borne by the party making the amendment, unless the Court orders otherwise. This Rule refers to an amendment made without

leave, which is not the case in the matter at hand. However, this principle is consistent with applicable jurisprudence (*e.g.*, *Apotex Inc v Pfizer Canada Inc*, 2017 FC 951; *The Brick Warehouse Corp v Canada (Minister of National Revenue)*, 2004 FC 309). I do not currently have a basis to conclude that Apotex will incur any particular costs as a result of Apotex's amendments. However, my order will preserve Apotex's right to claim any such costs that it may identify in the future, with the result of any such claim to be in the discretion of the Court.

PUBLIC ORDER IN T-607-21

THIS COURT ORDERS that:

1. The Defendants' motion is granted.

2. The Defendants are granted leave to serve and file their proposed Amended Statement of Defence in the form attached as Schedule "A" to their Notice of Motion.

3. The Defendants are awarded costs of this motion in the amount of $3000.00.

4. The Plaintiff's right to claim any costs occasioned by the Defendants' amendments is reserved, with the result of any such claim to be in the discretion of the Court.

"Richard F. Southcott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-607-21
STYLE OF CAUSE:	APOTEX INC. v. JANSSEN INC., JANSSEN ONCOLOGY INC. and BTG INTERNATIONAL LTD.
PLACE OF HEARING:	HEARD VIA VIDEOCONFERENCE
DATE OF HEARING:	SEPTEMBER 22, 2022
PUBLIC ORDER AND REASONS:	SOUTHCOTT J.
DATED:	OCTOBER 27, 2022

APPEARANCES FOR PLAINTIFF - APOTEX:

Mr. Jerry Topolski	FOR THE PLAINTIFF

APPEARANCES FOR DEFENDANTS - JANSSEN INC. AND BTG INTERNATIONAL LTD.

Mr. Peter Wilcox	FOR THE DEFENDANTS

APPEARANCES FOR DEFENDANT - JANSSEN ONCOLOGY, INC.

Mr. David Yi	FOR THE DEFENDANT

SOLICITORS OF RECORD:

Goodmans LLP Toronto, Ontario	FOR THE PLAINTIFF
Bellmore Neidrauer LLP & Norton Rose Fulbright Canada LLP Toronto, Ontario	FOR THE DEFENDANTS