

Federal Court



Cour fédérale

Date: 20221027

Docket: T-607-21

Docket: T-1168-21

Docket: T-732-22

Citation: 2022 FC 1473

Ottawa, Ontario, October 27, 2022

PRESENT: The Honourable Mr. Justice Southcott

BETWEEN:

Docket: T-607-21

APOTEX INC.

Plaintiff

and

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

Defendants

BETWEEN:

Docket: T-1168-21

DR. REDDY'S LABORATORIES LTD. and DR. REDDY'S LABORATORIES INC.

Plaintiffs

and

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

Defendants

BETWEEN:

Docket: T-732-22

PHARMASCIENCE INC.

Plaintiff

and

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

Defendants

PUBLIC ORDER AND REASONS

I. **Overview**

[1] This motion relates to three actions brought under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [Regulations]. In each action, the Plaintiff or Plaintiffs (Apotex Inc. (in Court File T-607-21) [Apotex]; Dr. Reddy's Laboratories Ltd and Dr. Reddy's Laboratories, Inc. (in Court File T-1168-21) [Dr. Reddy's]; and Pharmascience Inc. (in

Court File T-732-22) [PMS]) claim damages for lost sales of abiraterone acetate against the Defendants (Janssen Inc., Janssen Oncology, Inc., and BTG International Ltd [Janssen]).

[2] In this motion, Janssen moves under Rule 105 of the *Federal Courts Rules*, SOR/98-106 [Rules] to have heard together evidence on issues that it asserts are common to each of the section 8 actions.

[3] Some of the evidence adduced in this motion is subject to Confidentiality Orders, 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. Only PMS has proposed redactions, which are unopposed by the other parties. 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] For the reasons explained in greater detail below, Janssen's motion is dismissed. In summary, based on my conclusions surrounding the factors of commonality and prejudice that the Court is required to consider under Rule 105(a), the relief sought in this motion would not achieve the most efficient resolution of the matters in issue in the section 8 actions.

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] Each of the Plaintiffs sought to market a generic abiraterone acetate product, and each challenged the 422 Patent. In turn, Janssen commenced actions under section 6 of the Regulations against each of the Plaintiffs in respect of their abiraterone acetate products. The parties agreed to have the actions heard together at a common trial. On January 6, 2021, Justice Phelan dismissed Janssen's claims 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 actions crystallized causes of action for the Plaintiffs pursuant to section 8 of the Regulations. Each Plaintiff in turn commenced an action claiming damages for lost sales of their respective abiraterone acetate products. Those actions were commenced on the following dates:

- A. Apotex Action (T-607-21): April 12, 2021;
- B. Dr. Reddy's Action (T-1168-21): July 23, 2021; and
- C. PMS Action (T-732-22): April 8, 2022.

[8] The Dr. Reddy's Action and the Apotex Action are scheduled to be tried consecutively in June 2023. The PMS Action has not yet been set down for trial. In this motion, Janssen moves to have evidence on issues it asserts are common to each of these section 8 actions heard

together, starting in June 2023 or at a time to be fixed by the Court. The four common issues as articulated by Janssen are:

- A. The ability and motivation of five non-party generic manufacturers (Teva Canada Limited, Sandoz Canada Inc., Natco Pharma (Canada) Inc., Marcan Pharmaceuticals Inc., and JAMP Pharma Corporation [collectively, the Non-Parties]) to enter the abiraterone acetate market;
- B. The ability and motivation of the Plaintiffs to enter the abiraterone acetate market;
- C. Janssen's marketing of ZYTIGA (abiraterone acetate) and ERLEADA (apalutamide) post-genericization of the abiraterone acetate market; and
- D. The size of the total abiraterone acetate market post-genericization.

III. Issue

[9] As Janssen submits, the only issue on this motion is whether the Court should grant an order under Rule 105(a), directing that portions of the trials in the three section 8 actions be heard together.

IV. Analysis

A. *General Principles*

[10] The Court's authority to order that two or more proceedings be consolidated, heard together, or heard one immediately after another stems from Rule 105(a) of the Rules, which reads as follows:

Federal Courts Rules, SOR/98-106
Consolidation of proceedings

105 The court may order, in respect of two or more proceedings,

(a) that they be consolidated, heard together or heard one immediately after the other

Règles des Cours fédérales, DORS/98-106
Réunion d'instances

105 La Cour peut ordonner, à l'égard de deux ou plusieurs instances :

a) qu'elles soient réunies, instruites conjointement ou instruites successivement....

[11] Under Rule 105(a), the Court may also order that evidence on a subset of common issues be heard together, with the remainder of the trials taking place separately (see *Bayer Inc v Apotex Inc*, 2019 FC 191). This is the sort of relief that Janssen requests in this motion.

[12] For jurisprudential guidance on the manner in which the Court should apply Rule 105(a), the parties all rely on the decision of the Federal Court of Appeal in *Apotex Inc v Bayer Inc*, 2020 FCA 86 [*Bayer FCA*]. As explained at paragraph 45, the purpose of Rule 105(a) is to avoid a multiplicity of proceedings and promote an expeditious and inexpensive determination of those proceedings. The parties agree that the factors the Court must consider in deciding whether to grant an order under Rule 105(a) include: (a) the commonality of the parties, issues, facts and remedies; and (b) whether prejudice will result from the making of the order (*Bayer FCA* at paras 46-47).

[13] While prejudice is not the only factor to consider in making a determination under Rule 105, it carries great weight (*Bayer FCA* at para 46). With respect to prejudice, however, the parties disagree as to what the moving party must show. The Plaintiffs submit that the moving

party, here Janssen, has the burden of showing both: (a) that it would be prejudiced should the order not be granted; and (b) that it would not be abusive or prejudicial to the responding parties to make the order sought. In support of their position, the Plaintiffs rely on *Sanofi-Aventis Canada Inc v Novopharm Limited*, 2009 FC 1285 at paragraph 11 [*Ramipril*], which they submit has been endorsed in *Bayer FCA*.

[14] In contrast, Janssen takes the position that, in order to succeed in its motion, it is not required to show that it would be prejudiced in the absence of the relief sought. Janssen accepts that such prejudice is a relevant factor and that it bears the onus of establishing any prejudice that it says it would suffer if denied the requested relief. However, it submits that establishing such prejudice is not a precondition to obtaining an order under Rule 105(a). Rather, any such prejudice is only a factor to be balanced against prejudice to the responding parties if the relief were granted. Like the Plaintiffs, Janssen relies on in *Bayer FCA*, which it emphasizes did not expressly endorse the reasoning in *Ramipril* that required the moving party to establish prejudice on its part.

[15] To understand the parties' respective arguments, it is useful to review the portions of these decisions upon which they rely. In *Ramipril*, Justice Snider addressed a motion brought by the defendants to three section 8 claims to have their actions heard together with a common record (at para 1). In reviewing jurisprudence relevant to the assessment of prejudice, the Court stated as follows (at para 11):

11. With respect to prejudice, if the Court finds that one of the parties would suffer injustice or prejudice, this finding works against consolidation (*Boston Pizza*, above, at para. 11). Justice Rothstein (as he was then) held that the burden is on the party

seeking consolidation to prove that the responding parties would not suffer appreciable prejudice or injustice (see *Eli Lilly and Co. v. Novopharm Ltd.* (1994), 55 C.P.R. (3d) 429, 48 A.C.W.S. (3d) 31 at para. 6 (F.C.T.D.) (*Eli Lilly*)). In *Apotex-Wellcome*, Justice Mackay agreed with the jurisprudence that the onus also rests on the moving party (often the defendant) to prove that continuing the actions separately would be an abuse of process or would prejudice the moving party (above, at para. 15; see *Mon-Oil Ltd. v. Canada*, (1989) 27 F.T.R. 50, 26 C.P.R. (3d) 379 (F.C.T.D.) (*Mon-Oil*); *Fruit of the Loom Inc. v. Chateau Lingerie Mfg. Co. Ltd.* (1984), 79 C.P.R. (2d) 274). The moving party must prove a prejudice rather than a mere inconvenience (*Apotex-Wellcome*, above, at para. 15).

[16] *Bayer FCA* addressed two appeals from a decision of Justice Pentney (*Bayer Inc v Teva Canada Limited*, 2019 FC 1039 [*Bayer FC*]), which ordered that a trial of common issues be held together in three infringement actions under section 6 of the Regulations. The appellant generics argued that Justice Pentney had erred by failing to consider the application of Rule 105 and, as a result, failing to consider prejudice as a factor in his decision. Justice Pentney had framed his decision under the Court's inherent jurisdiction to control its proceedings and Rule 3, which required the interpretation of the Rules so as to secure the just, most expeditious, and least expensive determination of every proceeding on its merits (*Bayer FCA* at para 7).

[17] The Federal Court of Appeal held that Justice Pentney was right to consider Rule 3 but that Rule 105 was also relevant and applicable (at paras 41-42). In reviewing jurisprudence related to Rule 105, the Court provided the following explanation:

46. In determining whether an order sought under Rule 105 should be made, the Court must consider a number of factors, namely, the commonality of parties, issues, facts and remedies. The Court must also consider whether prejudice will result from the making of the order (*Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2009 FC 1285, 356 F.T.R. 235, at para. 9). In a number of decisions, the Federal Court has held that no order of

consolidation should be made where prejudice would result from the order. It is also well established that the onus rests with the moving party to show that it would not be abusive or prejudicial to make the order sought (*Global Restaurant; Ely Lilly and Company. v. Apotex Inc.*, 48 A.C.W.S. (3d) 31, [1994] 55 C.P.R. (3d) 429, at para. 6 (WL Can) (F.C.); *Apotex v. Wellcome Foundation Limited* (1993), 69 F.T.R. 178, 51 C.P.R. (3d) 480, at para. 15 (WL Can) (F.C.) [*Wellcome*]; *Mon-Oil Limited v. Canada* (1989), 26 C.P.R. (3d) 379, 27 F.T.R. 50, at para. 4 (WL Can) (F.C.)). Thus, it is clear that, while prejudice is not the only consideration relevant to a determination under Rule 105, it carries great weight. To this, I would add that the nature and severity of the prejudice are of obvious relevance.

[18] Janssen relies on the fact that this passage refers only to the significance of prejudice to the responding parties that would result from an order under Rule 105 and makes no reference to any requirement for the party seeking such an order to demonstrate it would suffer prejudice if the order were not granted.

[19] Janssen also notes that, in *Bayer FC*, Justice Pentney considered submissions by the moving party, Bayer, that it would be prejudiced in the absence of joinder by having to manage multiple proceedings (at para 12) but rejected that submission, as the number of proceedings was a natural consequence of Bayer's actions and the regime set out in the Regulations (at para 29). Although the Federal Court of Appeal ultimately allowed the appeal, based on the prohibition against joinder imposed by section 6.02 of the Regulations, it found no error in Justice Pentney's application of the jurisprudential principles surrounding Rule 105. Therefore, Janssen submits that *Bayer FCA* must be interpreted as having implicitly concluded that a party seeking Rule 105 relief need not demonstrate that it would suffer prejudice in the absence of that relief. Janssen takes the position that the imposition of such a requirement, as described in *Ramipril*, is no longer good law.

[20] In addition, Janssen emphasizes the particular relief that it seeks, an order providing for a trial of common issues, and argues that this is distinguishable from a full consolidation of proceedings or relief such as a stay of a particular proceeding. It submits that the nature of the particular relief sought under Rule 105 matters and that authorities (including those upon which *Ramipril* relies) that identify a requirement to demonstrate prejudice in the context of a full consolidation or stay do not necessarily apply to the motion at hand.

[21] I appreciate Janssen's point surrounding the spectrum of relief that may be sought by a party seeking to alter the usual progression of litigation. For instance, *Fruit of the Loom Inc v Chateau Lingerie Mfg Co Ltd* (1984), 79 CPR (2d) 274 (FCTD), the earliest of the authorities cited in *Ramipril*, involved an application for a stay of proceedings under s 50(1) of the *Federal Court Act*, RSC 1970, c 10 (2nd Supp). Both *Mon-Oil Ltd v Canada*, (1989), 26 CPR (3d) 379 (FCTD) [*Mon-Oil*] and *Apotex Inc v Wellcome Foundation Ltd* (1993), 51 CPR (3d) 480 (FCTD) [*Apotex-Wellcome*] involved motions to consolidate actions in the Federal Court. However, I also note the explanation in *Bayer FCA* that the principles explained in paragraph 46 (reproduced above) apply not only to orders for consolidation but also to orders that two or more proceedings be heard together either on all issues or on common issues only (at para 47). Consistent with that reasoning, I do not read the applicable jurisprudence as distinguishing between these different forms of relief.

[22] I also do not read *Bayer FCA* as signalling a departure from the principles governing prejudice explained in *Ramipril*. While I recognize that *Bayer FCA* does not expressly endorse the principle upon which the parties' positions diverge, I also note that, in its discussion of

prejudice, *Bayer FCA* cites not only *Ramipril* but also the decisions in *Mon-Oil* and *Apotex-Wellcome* upon which *Ramipril* relies. In my view, if the Federal Court of Appeal had intended to alter the principles in this line of jurisprudence, it would have done so expressly.

[23] Finally, I have considered Janssen's submission that its position on the disputed principle aligns with jurisprudence from Ontario (see *Robert A Cartier v Michaels Stocking (B-Dry)*, 2015 ONSC 3243 [*Cartier*]). However, given the volume of jurisprudence on this subject from the Federal Court and the Federal Court of Appeal, and as *Cartier* was decided under the particular civil procedure rules applicable in Ontario, I do not find this authority particularly instructive.

[24] All this said, my conclusion on this disputed principle is not determinative of the outcome of Janssen's motion. Janssen argues in the alternative that it would suffer prejudice if the common evidence that is the subject of its motion were heard at three separate trials. As will be explained in more detail later in these Reasons, my decision to dismiss Janssen's motion turns on the commonality assessment and balancing the relative adverse effects that would result from granting or dismissing the requested relief.

B. *Commonality of the Parties, Issues, Facts and Remedies*

[25] In support of the required commonality, Janssen argues that, in their respective section 8 actions, the Plaintiffs are claiming damages for lost sales of the same drug, against the same defendants, over essentially the same period. It submits that there will therefore be common legal and factual issues for the Court to consider across the three trials.

[26] In asserting such commonality, Janssen focuses upon four areas: (a) the ability and motivation of each of the five Non-Parties to enter the generic abiraterone acetate market; (b) the ability and motivation of each of the Plaintiffs to enter that market; (c) Janssen's allegation that, post-genericization of the abiraterone acetate market, it would have reduced its marketing of ZYTIGA (abiraterone acetate) and shifted these efforts to ERLEADA (apalutamide), another prostate cancer product marketed by Janssen; and (d) the effect of Janssen's decreased promotion of ZYTIGA upon the size of the total abiraterone acetate market. Janssen submits that there is no need for witnesses from each of the Non-Parties, the Plaintiffs, and Janssen itself to provide essentially the same evidence in three separate proceedings.

[27] Janssen acknowledges that the hypothetical or but-for world [BFW] underlying the required analysis in a section 8 action must be constructed separately in each of the three actions, and it accepts that the construction may be slightly different in each action, as each of the Plaintiffs alleges that it would have launched its generic product at a slightly different time. However, Janssen notes that Rule 105(a) does not require identical questions of fact and law, but rather only some commonality (see, e.g., *Ramipril* at para 10), and it submits that the core facts in each case are the same, *i.e.* the same companies seeking to launch the same products in overlapping time periods.

[28] Janssen also relies on the principle that the construction of the BFWs be based on events that occurred in the real world (see, e.g., *Teva Canada Ltd v Pfizer Canada Inc*, 2017 FC 332 at para 9). It submits that evidence from the Non-Parties, the Plaintiffs, and Janssen related to real world events will necessarily be the same in each action, such that it would be wholly duplicative

to have such evidence adduced three times. Janssen also raises concern that hearing evidence on the same issues multiple times could result in the Court making inconsistent findings of fact.

[29] In relation to the evidence of the Non-Parties in particular, Janssen also submits that the relief it seeks would avoid the need for the Non-Parties' representatives to be examined for discovery multiple times as well as the need for multiple motions to compel such discoveries and the production of related documentation.

[30] Each of the Plaintiffs advances largely similar arguments in opposition to Janssen's assertions of commonality. The Plaintiffs argue that Janssen bases such assertions on significant oversimplifications. To begin, the Plaintiffs emphasize that there is a lack of commonality in the parties to the three actions. While Janssen is a common Defendant in each, the Plaintiff in each action is a different, arm's-length competitor. In *Ramipril*, which considered a Rule 105 motion in the context of a similar party dynamic, Justice Snider held that the fact the actions involved different plaintiffs argued against consolidation, although not strongly so (at para 18).

[31] I find that conclusion on the commonality of the parties equally applicable to the case at hand. However, as I will explain later in these Reasons when assessing prejudice, the involvement of different and unrelated Plaintiffs, which may adopt different approaches to the litigation in the pursuit of their respective claims, militates more strongly against ordering a common issues trial.

[32] On the commonality of the issues and facts, the Plaintiffs emphasize that, as a matter of law, the Court will be required to analyse a different BFW in each of the three actions (*Apotex Inc v Sanofi-Aventis*, 2014 FCA 68 [*Ramipril FCA*] at para 163). I accept this point. However, as noted in Janssen's submission set out above, the application of Rule 105 does not require identical questions of fact or law (*Ramipril* at para 10).

[33] I find more compelling the Plaintiffs' argument surrounding the different factual dimensions to the BFWs to be assessed in the three actions. These differences relate to the combination of different time periods and different product dosages at issue in the three BFWs. The following factual parameters appear from the relevant patent hold letters and other evidence in the record in this motion:

- A. Dr. Reddy's claim relates solely to a 250 mg product, which was on patent hold as of May 27, 2019;
- B. Apotex's claim relates to both a 250 mg product and a 500 mg product, which were both on patent hold as of August 8, 2019;
- C. PMS's claim also relates to both a 250 mg product and a 500 mg product.
[REDACTED];
- D. Data protection on Janssen's ZYTIGA product under the *Food and Drug Regulations*, CRC, c 870, ended on July 27, 2019.

[34] The fact that two of the section 8 actions relate to two different product dosages, with the third action relating only to one of those dosages, detracts from the commonality of the issues and facts. I agree with the Plaintiffs' argument that, [REDACTED], the above details demonstrate larger differences, in the dates relevant to the BFWs to be constructed in the three actions, than suggested by Janssen's submissions. The fact that Dr. Reddy's was the only Plaintiff with an approvable product prior to the expiry of the data protection on ZYTIGA is also a potentially relevant distinguishing fact.

[35] In constructing the BFW for each of the section 8 actions, the Court will be required to determine the impact of the relevant Plaintiff hypothetically having been issued a notice of compliance for its generic abiraterone acetate product, taking into account the particular timing of that issuance and the particular dosage or dosages involved. That determination must also be performed against the backdrop of the other Plaintiffs being restrained by the Regulations from entering the market (*Ramipril FCA* at paras 159, 162).

[36] I appreciate that Janssen's pleadings indicate it intends to adduce evidence and argue at trial that it would have conducted itself in each of the BFWs in a manner that would have resulted in the other Plaintiffs being free of the constraints of the Regulations. (I am also conscious that Dr. Reddy's has filed a motion, not yet argued, seeking a determination that, as a matter of law, such an argument is not available to Janssen.) There is therefore a possibility that such evidence from Janssen, if permitted and accepted, could increase the level of commonality between the issues and the three actions. However, the evidence upon which Janssen proposes to

rely is not before the Court in this motion, and it would be premature for the Court to place any significant weight on such an outcome at this stage in the proceedings.

[37] I also agree with the Plaintiffs' submission that the differences in the factual parameters of the three actions have the potential to affect the evidence of the Non-Parties. While I take Janssen's point that the facts surrounding the Non-Parties' real-world activities in the generic market should be the same in each action, it does not necessarily follow that their evidence as to what their activities would have been in each of the BFWs will be the same. I will return to this point later in these Reasons when considering the prejudice factor.

[38] Similarly, I accept Janssen's submission that the facts surrounding its real-world activities should be the same in each action. However, this does not translate into a conclusion that its evidence on what its marketing efforts would have been, and the resulting effect on the size of the overall abiraterone acetate, will necessarily be the same in relation to the particular BFW in each action. As the Plaintiffs submit, changes in Janssen's marketing strategy could vary depending on which generic entered the market and the timing and dosage or dosages of such entry. Janssen has not filed any evidence in this motion to support a conclusion of commonality on this issue.

[39] In summary, Janssen has not satisfied me that that the level of commonality it asserts in support of its motion warrants a conclusion that ordering a common issues trial would be in the interests of achieving the most efficient resolution of the matters in issue in these section 8 actions.

C. *Prejudice*

[40] As previously noted, Janssen argues that it would suffer prejudice if the common evidence that is the subject of its motion is heard at three separate trials. It raises three categories of prejudice:

- A. At each trial, Janssen will be required to call evidence from five Non-Parties who are disinterested in the outcome of the litigation and have no incentive to cooperate. Janssen submits that this difficulty is exacerbated by having to call such evidence in a consistent manner across three different actions over a period of potentially 17 months based on the current scheduling or possible scheduling of the trials;
- B. Different burdens will apply to the introduction of the Plaintiff's evidence at each trial. For example, in the Apotex and Dr. Reddy's trials, Janssen will bear the burden to prove that PMS could and would have entered the abiraterone acetate market. However, in the PMS trial, PMS will bear the burden of proving those same facts; and
- C. Janssen will incur the expense of having its witnesses testify to its marketing practices three separate times.

[41] In response, the Plaintiffs submit that procedural and evidentiary requirements of this nature do not represent a form of prejudice under Rule 105. As explained in *Ramipril*, a party moving under Rule 105 must prove prejudice rather than a mere inconvenience (at para 11). As a Defendant to a section 8 action, Janssen bears the burden of proving elements of the BFW that it says favour its defence positions (*Pfizer Canada Inc v Teva Canada Ltd*, 2016 FCA 161 at para 63). In my view, the Plaintiffs' submission, that these circumstances do not qualify as prejudice for purposes of a Rule 105 analysis, is not without merit. Nevertheless, as explained later in these Reasons, I take these circumstances into account in balancing the adverse effects each party says would occur if it does not prevail in this motion.

[42] Finally, Janssen argues that it faces prejudice from the risk of inconsistent factual findings resulting from evidence being heard three times in the circumstances described above. In response, the Plaintiffs emphasize the explanation in *Ramipril* that inconsistency in findings of fact does not necessarily constitute prejudice (at para 12). In *Ramipril*, Justice Snider relied on the conclusion in *Mon-Oil* that the possibility of inconsistent findings of fact can be minimized by vigilant counsel and a vigilant court and, in any event, is not a sufficient ground to warrant consolidation.

[43] I accept those explanations but do not necessarily read them as suggesting that the risk of inconsistent findings can never represent prejudice for purposes of a Rule 105 analysis. As such, I take Janssen's argument into account later in these Reasons when considering whether the prejudice argued by the Plaintiffs to result from granting Janssen its requested relief would outweigh any prejudice to Janssen resulting from proceeding with the separate section 8 actions.

[44] Turning to the Plaintiffs' arguments, I find particularly compelling their submission surrounding prejudice that each would suffer as a result of the other two Plaintiffs' involvement in the examination of witnesses at a common issues trial. This concern is well expressed as follows in Apotex's written representations:

... with respect to the purported common evidence of what Janssen and the non-parties would have done in one or more of the hypothetical worlds, if this evidence is to be led (presumably all by Janssen) as part of the Dr. Reddy's s. 8 Action, then Apotex will effectively be forced to not only plan and rely on its own cross examination of that evidence but, also, it will be forced to accept (as part of Apotex's case) whatever cross-examination evidence that Dr. Reddy's and/or Pharmascience might choose to elicit – whether beneficial to Apotex or not. Put bluntly, Apotex does not wish to have non-party lawyers cross-examining adverse witnesses in Apotex's s.8 damages case.

[45] Dr. Reddy's describe similar concerns in its own written representations:

... Dr. Reddy's would suffer prejudice from having its own cross-examination strategy and theory subject to an otherwise-absent risk. If Dr. Reddy's action proceeds as it is presently scheduled, Dr. Reddy's can prepare its own theory and cross-examine any expert or fact witnesses as it chooses. If counsel for other section 8 claimants, with their own unique interests and theories of the BFW are permitted to participate and cross-examine expert or fact witnesses as part of a joint hearing, any useful testimony elicited in cross-examination by Dr. Reddy's as part of its case is at risk when counsel for another section 8 claimant conduct their cross-examination. Dr. Reddy's will have no control over questions that Apotex or Pharmascience may wish to ask as part of their theory of the case and cross-examination strategy, a prejudice that cannot be safeguarded or prevented.

[46] In considering these arguments, I have taken into account Janssen's submissions on the reasoning in *Apotex Inc v Shire LLC*, 2017 FC 139 [*Shire*], in which Justice Strickland dismissed an appeal by Apotex from an order of a prothonotary that partially consolidated a prohibition

application and an impeachment action, both involving the same parties. In particular, Janssen refers the Court to Justice Strickland's analysis of prejudice for purposes of Rule 105. As explained at paragraph 57, the Court was required to consider whether the prothonotary made a palpable and overriding error in concluding that consolidation was just and expeditious, which in that case which turned on the question of prejudice.

[47] In analysing this question, the Court considered Apotex's reliance on *Eli Lilly and Co v Novopharm Ltd*, [1994] FCJ No 680 (FCTD) [*Eli Lilly*] at paragraph 8, for the principle that loss of procedural or tactical advantage has been held to constitute the kind of prejudice that militates against the granting of a consolidation motion. Justice Strickland found *Eli Lilly* factually distinguishable and was not persuaded that it stands for the proposition that any loss of any tactical advantage is necessarily prejudicial and therefore precludes consolidation. Furthermore, *Eli Lilly* did not suggest that tactical considerations alone were sufficient to grant the refusal of a request for consolidation when the underlying policy considerations of resolving proceedings in an expeditious and least expensive way strongly militated toward some form of consolidation (at para 60).

[48] Before the prothonotary and on appeal, Apotex advanced arguments that it would suffer prejudice as to the effect of consolidation upon the differing burdens of proof that would apply in the proceeding, as well as resulting from the reversal of the order of evidence (at para 61). Justice Strickland regarded these arguments as related to the loss of tactical advantage, as had the prothonotary who concluded that the loss of this advantage was not sufficiently prejudicial to overcome the benefits of consolidation (at paras 61-66).

[49] I do not find *Shire* to particularly assist Janssen in responding to the Plaintiffs' prejudice arguments. I do not read *Shire* as standing for a proposition that a loss of tactical advantage cannot represent prejudice for purposes of a Rule 105 analysis. Indeed, *Eli Lilly* clearly found the contrary. Rather, *Shire* concluded only that a loss of tactical advantage was not necessarily prejudicial or sufficiently prejudicial on its own to warrant refusing a consolidation that was merited by other considerations. Moreover, Justice Strickland's dismissal of the appeal turned significantly on the standard of review applicable to a prothonotary's decision. The Court concluded that the prothonotary had not erred either in finding that any tactical disadvantage was unsubstantiated or otherwise in assessing Apotex's assertions of prejudice (at paras 67-68).

[50] I am also not convinced that the prejudice asserted by the Plaintiffs in the passages quoted above from their written representations necessarily falls within the category of a tactical advantage. *Shire* also refers to the principle that justice is not to be subordinated to expedition (at para 54). A party's interest in planning and controlling its approach to litigation in which it is involved, and therefore avoiding an adverse impact upon that approach caused by others who would not normally be party to that litigation, strikes me as engaging an aspect of the administration of justice more fundamental than a mere tactical advantage. Regardless, even if the concerns raised by the Plaintiffs are properly characterized as related to tactical advantage, I remain of the view that they represent prejudice of a sort and a significance appropriate to take into account in the Rule 105 analysis.

[51] I also find compelling the Plaintiffs' argument that requiring witnesses to testify in relation to the three different BFWs at a common hearing, instead of providing focused

testimony at each of three individual trials, would be inefficient because it would be potentially confusing for both witnesses and the Court. This concern is articulated as follows in Dr. Reddy's written representations:

Compiling the scenarios and potential variables across section 8 actions into one hearing where counsel and the Trial Judge are asked to transport themselves across different BFWs that involve different start dates, different potential dosages to launch, and different competitors with different head-start dates means that each proceeding will lack overlap in factual circumstances, but in totality the permutations will be overwhelming. Witnesses from a non-party generic will be examined or cross-examined on the basis of their willingness and ability to launch one dosage of abiraterone (and potentially two) in the Dr. Reddy's world starting July 27, 2019, and then will be cross-examined by counsel for Apotex and Pharmascience on entirely different scenarios. The complete lack of factual overlap between the scenarios will create unnecessary confusion.

[52] I agree with the Plaintiffs' submission that, in *Ramipril*, the complexity associated with an effort to join proceedings or components thereof was among the considerations militating against the requested relief. Justice Snider explained at paragraphs 31 to 32 her concern that such relief could result in a situation close to procedural paralysis.

[53] I also note the Plaintiffs' submission that the manner in which the litigation proceeded following the decision in *Ramipril* demonstrates how efficiency can potentially be achieved in the abiraterone acetate section 8 actions in the future, without the sort of concerns identified in *Ramipril* and by the Plaintiffs in the case at hand. Based on counsel's submissions and reported decisions, I understand that litigation progressed as follows. After the trial of the first section 8 action (brought by Teva), another section 8 claimant, Apotex, and the defendants agreed to a consent order. That order provided them leave for purposes of the upcoming second trial to rely

on the evidence of certain common witnesses as adduced at the first trial, although without precluding further evidence in chief, cross-examination, or evidentiary objections.

[54] I express no opinions on the merits of such an approach at a future stage in these proceedings, other than to note that it remains available to the parties, once an evidentiary record has been created in one proceeding, to agree to use components of that record in another proceeding and seek judicial endorsement of such an approach. As the Plaintiffs submit, such an approach would differ significantly from the relief currently sought by Janssen, as it would involve the parties making an informed decision in reliance on an existing evidentiary record.

[55] Finally, I note the particular submission on prejudice advanced by Pharmascience, the section 8 claimant whose trial has not yet been scheduled. Pharmascience's written representations state that a potential trial date of November 2024 has been discussed but not yet proposed to the Court. Such a date would be some 17 months following the Dr. Reddy's and Apotex trials scheduled for June 2023. Pharmascience observes that, in both the Apotex and Dr. Reddy's actions, first-round discoveries and motions to compel have been completed. In contrast, the current schedule adopted by the Court in the Pharmascience litigation provides for the first round of discoveries to be completed by November 30, 2022, with the proposed timetable for next steps to be provided by the end of 2022. Against this backdrop, Pharmascience submits that it would be unduly prejudicial to expect it to participate in a common issues trial in the June 2023 timeframe as proposed by Janssen.

[56] In response to this position, Janssen argues that, even if its motion is denied, representatives of Pharmascience will still be required to give evidence at the Dr. Reddy's and Apotex trials in June 2023. Janssen therefore submits that the timeframe within which Pharmascience will be required to prepare would not change in the event a common issues trial was instead taking place in the June 2023 timeframe. I do not find this argument particularly responsive to Pharmascience's position. Assuming that Pharmascience is compelled by other parties to give evidence at the Dr. Reddy's and/or Apotex trials in June 2023, this is different from imposing upon it a schedule that requires it to be prepared to participate in, and be bound by the results of, a June 2023 trial on the range of common issues identified in Janssen's motion.

[57] In summary on the subject of prejudice, I find the categories of prejudice advanced by the Plaintiffs and canvassed in the above analysis to militate strongly against granting the relief Janssen requests. Even accepting Janssen's arguments on the potential adverse effects of conducting three separate trials to constitute prejudice for purposes of the Rule 105 analysis, I consider each of the categories of prejudice advanced by the Plaintiffs sufficient individually to outweigh the prejudice advanced by Janssen. Cumulatively, those categories of prejudice clearly support a conclusion that the motion should be denied.

V. **Conclusion**

[58] In conclusion, I find, based on the factors the Court is required to consider under Rule 105(a), that the relief sought in this motion would not achieve the most efficient resolution of the matters in issue in the section 8 actions. The motion will therefore be dismissed.

VI. **Costs**

[59] At the conclusion of the hearing, I sought counsel's submissions on an appropriate lump-sum costs figure to be awarded to the successful party or parties in this motion. The parties proposed a figure of \$5000.00, although they were not necessarily aligned on whether this should be a cumulative figure, as opposed to each Plaintiff either bearing or benefiting from a \$5000.00 award.

[60] I find that, as the successful parties to the motion, the Plaintiffs in each of the actions should receive costs of \$5,000. Janssen's motion was brought in each of the three section 8 actions, and each of the Plaintiffs responded with substantive motion records, written representations, and authorities. While the Plaintiffs achieved efficiency in their oral submissions, so as not to be duplicative and in the interests of affording roughly equal time to the two sides of the dispute, it remains appropriate that each of the Plaintiffs receive costs in partial compensation for their efforts and expenses in responding to the motion. My Order will therefore award costs, in the all-inclusive lump sum amount of \$15,000.00, payable by Janssen as \$5000.00 to the Plaintiffs in each of the three section 8 actions.

PUBLIC ORDER IN T-607-21, T-1168-21 and T-732-22

THIS COURT ORDERS that:

1. The Defendants' motion is dismissed.
2. The Defendants shall pay costs of this motion in the all-inclusive lump-sum amount of \$15,000.00, payable as \$5000.00 to the Plaintiffs in each of these three proceedings.

“Richard F. Southcott”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-607-21, T-1168-21, T-732-22

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

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APPEARANCES FOR PLAINTIFFS - DR. REDDY'S LABORATORIES LTD. AND DR. REDDY'S LABORATORIES INC.

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