Federal Court Cour fédérale

Date: 20230214

Dockets: T-607-21
T-1168-21
T-732-22

Citation: 2023 FC 216

Ottawa, Ontario, February 14, 2023

PRESENT: The Honourable Mr. Justice Southcott

Docket: T-607-21

BETWEEN:

APOTEX INC.

Plaintiff

and

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

Defendants

Docket: T-1168-21

AND BETWEEN:

DR. REDDY'S LABORATORIES LTD. AND DR. REDDY'S LABORATORIES, INC.

Plaintiffs

and

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

Defendants

Docket: T-732-22

AND BETWEEN:

PHARMASCIENCE INC.

Plaintiff

and

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

Defendants

ORDER AND REASONS

I. Overview

[1] This decision relates to motions brought by the Defendants (Janssen Inc., Janssen Oncology, Inc., and BTG International Ltd. [together, Janssen]) in three actions under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-113 [Regulations]. In each action, the Plaintiff or Plaintiffs (Apotex Inc. [Apotex] in Court File T-607-21 [the Apotex Action]; Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. [together, DRL] in

Court File T-1168-21 [the DRL Action]; and Pharmascience Inc. [PMS] in Court File T-732-22 [the PMS Action]) claim damages for lost sales of abiraterone acetate against the Defendants.

[2] In each action, Janssen moves under Rule 233 and Rule 238 of the *Federal Courts Rules*, SOR/98-106 [Rules] for an order entitling it to document production and oral discovery in relation to the companies that are the Plaintiffs in the other two actions, as follows:

A. in the Apotex Action, Janssen seeks production from and discovery of DRL and PMS;
B. in the DRL Action, Janssen seeks production from and discovery of Apotex and PMS; and
C. in the PMS Action, Janssen seeks production from and discovery of Apotex and DRL.

[3] For the reasons explained in greater detail below, each of the motions is granted in part. Based on the applicable test and considering the discretionary factors under Rule 233, I find that Janssen should receive most, but not all, of the documentary production it requests in each action. I also find that Janssen has not satisfied the test under Rule 238, applicable to a motion for non-party discovery, as it has failed to demonstrate that it would be unfair not to allow it an opportunity to conduct such discoveries.

II. **Background**

[4] 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.

[5] 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). This decision was recently upheld on appeal (see *Janssen Inc v Apotex Inc*, 2022 FCA 184).

[6] Justice Phelan's dismissal of the section 6 actions crystallized causes of action for the Plaintiffs pursuant to section 8 of the Regulations. Each of the Plaintiffs 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. DRL Action (T-1168-21): July 23, 2021; and

C. PMS Action (T-732-22): April 8, 2022.

[7] The DRL 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.

[8] In each action, Janssen pleads that, if the Plaintiff(s) in that action had entered the market earlier than they did in the real world, they would have faced competition from several other

generic pharmaceutical companies in the but-for world [BFW]. In these motions, Janssen asserts in particular that the Plaintiff(s) in each action would have faced competition from the Plaintiffs in the other two actions.

[9] For example, Janssen asserts that, given that Apotex's product was approvable before or during the BFW time periods of each of DRL and PMS, the potential entry of Apotex into the abiraterone acetate market in those BFWs is relevant to assessing DRL's alleged damages in the DRL Action and PMS's alleged damages in the PMS Action. Janssen argues that the key questions to be addressed in relation to that defence assertion are whether the non-party generic (in this example, Apotex) had the ability and motivation to supply its abiraterone acetate product in the BFWs of the relevant Plaintiffs (in this example, DRL in the DRL Action and PMS in PMS Action). On this basis, Janssen seeks, in each of the DRL Action and the PMS Action, documentary production by Apotex and discovery of the individual(s) at Apotex primarily responsible for deciding whether and when Apotex would have launched an abiraterone product in the relevant BFW.

[10] Similarly, Janssen seeks documentary production and discovery in relation to DRL in the Apotex Action and the PMS action, and likewise seeks documentary production and discovery in relation to PMS in the Apotex Action and the DRL Action.

[11] On November 2, 2022, Janssen served three motion records on each of Apotex, DRL, and PMS. Each of its Notices of Motion (which are materially the same) is filed in two of the section 8 actions and seeks relief against the company that is not a party to either of those actions (*i.e.*,

the Plaintiff in the other section 8 action) [the Non-Party]. Each Notice of Motion seeks the following relief:

A. an order pursuant to Rule 233 directing that the Non-Party produce the documents listed at Schedule "A" to the Notice of Motion (which lists 10 categories of documents);

B. an order pursuant to Rule 238 granting Janssen leave to examine for discovery the individual(s) at the Non-Party primarily responsible for deciding whether and when the Non-Party would have launched an abiraterone product;

C. in the alternative:

    i. an order requiring production of transcripts from examinations for discovery of the Non-Party (that took place in the section 8 action in which the Non-Party is the Plaintiff) and select productions identified by Janssen as Confidential Information-CEO (meaning "counsel's eyes only") pursuant to an existing Protective Order; and

    ii. an order granting Janssen leave to examine for discovery the individual(s) at the Non-Party primarily responsible for deciding whether and when the Non-Party would launch an abiraterone product on relevant topics not canvassed in the transcript and documents produced pursuant to the alternative relief.

[12] As will be explained in more detail later in these Reasons, Janssen's counsel advised at the hearing of these motions that it was prepared to withdraw the requests for alternative relief described above.

[13] On January 16, 2023, each of Apotex, DRL, and PMS served responding motion records in the actions in which it was not a party (*i.e.*, responding to Janssen's motion seeking to have it make non-party production and submit to non-party discovery). On January 20, 2023, each of Apotex, DRL, and PMS served responding motion records in the action in which it is the Plaintiff (*i.e.*, responding to Janssen's motion seeking non-party production and non-party discovery in its section 8 action). In their written representations and their oral submissions at the hearing of these motions on January 31, 2023, each of Apotex, DRL, and PMS adopted the others' submissions in opposing the relief Janssen requests.

III. **Issue**

[14] Having considered the various arguments advanced by the parties in support of their positions, and the parties' respective articulations of the issues, I conclude that their arguments can be analyzed under the following issues:

A. Whether Janssen's motions represent, or if granted its requested relief would represent, a breach of the implied undertaking applicable to evidence obtained by compulsion from a party to litigation;

B. Whether the Non-Parties should be compelled to produce any of the documents sought by Janssen; and

C. Whether Janssen should be granted leave to examine any individuals at the Non-Parties.

IV. **Analysis**

A. *General principles*

[15] Before turning to the parties' arguments, it is useful to review general principles that apply to Janssen's motions. I do not understand any of these principles to be in dispute.

[16] As previously noted, Janssen brings its motions under Rule 233 and Rule 238. These Rules are somewhat related, as both address pre-trial discovery of a person who is not a party to an action. Rule 233 relates to production of documents by a non-party, and Rule 238 relates to examination for discovery of a non-party. The portions of these Rules relevant to the arguments in these motions read as follows:

Production from non-party with leave	***Production d'un document en la possession d'un tiers***
233 (1) On motion, the Court may order the production of any document that is in the possession of a person who is not a party to the action, if the document is relevant and its production could be compelled at trial.	**233 (1)** La Cour peut, sur requête, ordonner qu'un document en la possession d'une personne qui n'est pas une partie à l'action soit produit s'il est pertinent et si sa production pourrait être exigée lors de l'instruction.
….	….
Examination of non-parties with leave	***Interrogatoire d'un tiers***
238 (1) A party to an action may bring a motion for leave to examine for discovery any person not a party to the action, other than an expert witness for a	**238 (1)** Une partie à une action peut, par voie de requête, demander l'autorisation de procéder à l'interrogatoire préalable d'une personne qui n'est pas une partie autre qu'un témoin expert d'une partie, qui

party, who might have information on an issue in the action.	pourrait posséder des renseignements sur une question litigieuse soulevée dans l'action.
….	….
Where Court may grant leave	***Autorisation de la Cour***
238 (3) The Court may, on a motion under subsection (1), grant leave to examine a person and determine the time and manner of conducting the examination, if it is satisfied that:	**238 (3)** Par suite de la requête visée au paragraphe (1), la Cour peut autoriser la partie à interroger une personne et fixer la date et l'heure de l'interrogatoire et la façon de procéder, si elle est convaincue, à la fois :
(a) the person may have information on an issue in the action;	a) que la personne peut posséder des renseignements sur une question litigieuse soulevée dans l'action;
(b) the party has been unable to obtain the information informally from the person or from another source by any other reasonable means;	b) que la partie n'a pu obtenir ces renseignements de la personne de façon informelle ou d'une autre source par des moyens raisonnables;
(c) it would be unfair not to allow the party an opportunity to question the person before trial; and	c) qu'il serait injuste de ne pas permettre à la partie d'interroger la personne avant l'instruction;
(d) the questioning will not cause undue delay, inconvenience or expense to the person or to the other parties.	d) que l'interrogatoire n'occasionnera pas de retards, d'inconvénients ou de frais déraisonnables à la personne ou aux autres parties.

[17] Orders under both Rule 233 and Rule 238 are discretionary and indeed "exceptional" remedies that require a stranger to the litigation to involve themselves in a proceeding before the Court (see *Janssen Inc v Pfizer Canada Inc*, 2019 FCA 188 [*Janssen*] at para 5; *Guides, Inc v Videotron GP*, 2019 FCA 321 [*Rovi FCA*] at para 16). *Rovi*

[18] Rule 233 establishes two threshold requirements. For the Court to grant an order under this Rule, the moving party must establish both that the documents sought are relevant and that they would be compellable at trial. To be relevant, the requested documents must relate to the issues between the parties, be useful, and be likely to contribute to resolving the issues (see *Tippett v Canada*, 2020 FC 714 at para 22).

[19] However, because an order under Rule 233 is discretionary, establishing the relevance and compellability of the documents sought is necessary, but not sufficient, for the Court to order production. Merely establishing these two threshold criteria does not entitle a litigant to a production order (*O'Leary v Ragone*, 2021 FC 185 [*O'Leary*] at paras 13-14). Given the exceptional nature of the remedy sought, the Court must still exercise its discretion to determine whether it should grant the remedy in the circumstances (*O'Leary* at para 14).

[20] In *O'Leary*, Associate Judge Tabib noted that there is no set list of factors that the Court must, or can, consider in exercising its discretion on a Rule 233 motion. However, she identified the following factors that had been previously identified in the jurisprudence as being potentially relevant (at para 15):

A. Whether the information can be obtained from another party or source;

B. The necessity of the order;

C. Whether an order is premature;

D. The necessity and probative value of the documents in light of documents already disclosed;

E. The privacy interests of, or prejudice to, other non-parties;

F. Confidentiality concerns;

G. Public interest in disclosure;

H. Delay, cost or disruption in the proceedings;

I. The non-party's involvement in the matter under dispute;

J. The specificity of the request for production; and

K. Any costs to the producing party.

[21] Applicable jurisprudence also establishes that Rules 233 and 238 should not be regarded as prescribing two insular sets of requirements or criteria. The fact that certain factors, such as fairness between the parties, are expressly set out in Rule 238, but not in Rule 233, does not foreclose their consideration on a motion for production under Rule 233 (*Janssen* at para 10; *O'Leary* at para 17).

[22] Rule 238 governs the discovery examination of non-parties. To obtain leave under Rule 238 for discovery of a person who is a non-party, the moving party must at a minimum satisfy the Court of the following four requirements expressly enumerated in Rule 238(3) (see *Rovi Guides, Inc v Videotron GP*, 2019 FC 1220 [*Rovi*] at para 48, aff'd *Rovi FCA*):

A. The person may have information on an issue in the action;

B. The party has been unable to obtain the information informally from the person or from another source by any other reasonable means;

C. It would be unfair not to allow the party an opportunity to question the person before trial; and

D. The questioning will not cause undue delay, inconvenience or expense to the person or to the other parties.

[23] Once the moving party has satisfied the Court of these requirements, the Court again retains discretion to dismiss a Rule 238 motion (*Rovi FCA* at para 17). I understand the parties to properly agree that, in exercising that discretion, the Court can look to the factors identified in *O'Leary.*

B. *Whether Janssen's motions represent, or if granted its requested relief would represent, a breach of the implied undertaking applicable to evidence obtained by compulsion from a party to litigation*

[24] Before turning to the parties' arguments specific to Rules 233 and 238, it is necessary for the Court to consider a threshold issue raised by the Non-Parties that they submit should preclude Janssen from being granted any relief in these motions. The Non-Parties argue that, if Janssen is granted its requested relief, it would give rise to a breach of the implied undertaking applicable to evidence obtained by compulsion from a party to litigation. Indeed, they go further in arguing that Janssen has already breached that undertaking by bringing these motions.

[25] The Federal Court of Appeal explained the nature of the implied undertaking rule in its recent decision in *FibroGen, Inc v Akebia Therapeutics, Inc*, 2022 FCA 135 [*FibroGen*], at paragraph 45:

> 45. The implied undertaking rule applies to both documentary and oral information obtained on discovery: such evidence is not to be used except for the purpose of that litigation unless and until the undertaking is varied by court order (*Juman* at para. 4) or until the documents are admitted into evidence and become part of the public court record. Whether documents produced or answers given are privileged and confidential is irrelevant to the undertaking (*Juman* at para. 27).

[26] This passage from *FibroGen* references the decision of the Supreme Court of Canada in *Juman v Doucette*, 2008 SCC 8 [*Juman*], which explained the rationale for the implied undertaking rule (at paras 24-27). Pre-trial discovery is an invasion of a private right to be "left alone with your thoughts and papers." While the public interest in getting at the truth in a civil action outweighs the examinee's privacy interest, the latter is nevertheless entitled to a measure of protection. Moreover, a litigant who has some assurance that the documents and answers will not be used for a purpose collateral or ulterior to the proceedings in which they are demanded will be encouraged to provide a more complete and candid discovery.

[27] Before using information or documents subject to the implied undertaking rule, the party seeking to use the information or documents must apply to the Court for leave to do so and must specify the purpose or purposes for using the information and explain the reasons why relief is justified, with both parties being heard on the application (*Juman* at para 30).

[28] Each of the Non-Parties asserts that Janssen's motions breach, or if granted would give rise to a breach, of the implied undertaking rule, because Janssen is using or seeking to use evidence, obtained by compulsion from the Non-Party through documentary production or discovery examination in the section 8 action in which it is the Plaintiff, outside the section 8 proceeding in which the evidence was provided. The Non-Parties argue that the breach of the rule is particularly apparent in the alternative relief sought in Janssen's Notices of Motion, in which Janssen expressly seeks the production of discovery examination transcripts and documentary evidence that were generated in another proceeding.

[29] The Non-Parties refer the Court to Justice Manson's recent decision in *Janssen Inc v Apotex Inc*, 2022 FC 1746 (a piece of litigation that involves some of the same parties, but is unrelated, to the present matters), in which Janssen wished to use documents and information, that had been compelled from Apotex in one proceeding, in separate subsequent proceedings. Janssen brought a motion to vary the confidentiality order, governing the proceeding in which the evidence had been produced, to allow that evidence to be used in the subsequent proceedings. Relying on *FibroGen* and the fact that the evidence had never been tendered in open court at trial, Justice Manson held that the evidence was still subject to the implied undertaking rule and

that it would be inappropriate to vary the confidentiality order until Janssen had sought relief from its undertaking (at paras 15 and 20).

[30] Each Non-Party takes the position that, before Janssen can seek the Rule 233 and Rule 238 relief advanced in these motions, it must seek relief from the implied undertaking in the section 8 action in which the Non-Party (in its capacity as Plaintiff) has provided documentary production and discovery evidence under compulsion.

[31] In the matters at hand, Janssen does not dispute that the documentary production and discovery evidence it has obtained from the Plaintiffs in each of the section 8 actions is subject to the implied undertaking rule. Indeed, in apparent recognition of the application of the rule to the alternative relief sought in its Notices of Motion, Janssen's counsel advised at the hearing of these motions that Janssen was prepared to withdraw its request for the alternative relief. I am therefore not required to rule on that request. However, in the interests of explaining my reasoning in relation to the implied undertaking arguments, I note that I would have had little difficulty concluding that the implied undertaking would have been engaged by that alternative relief. In that relief, Janssen sought to use in one proceeding the particular evidence that was generated under compulsion in another proceeding.

[32] In contrast, as explained below, I am not convinced that the principal relief (and now the only relief) that Janssen seeks in these motions similarly engages the implied undertaking rule.

[33] As I understand the Non-Parties' position, they assert that Janssen is already in possession of evidence of the sort that it seeks through these motions and that it is therefore necessarily making collateral use of that evidence in presenting these motions. The Non-Parties rely in particular on the following statement by Janssen in paragraph 22 of its written representations in support of these motions (the following quote being, by way of example, from the written representations seeking production and discovery of Apotex):

> 22. Given Apotex's burden to prove that it could and would have entered the abiraterone market as early as [patent hold date] in the Apotex Section 8 Action, these issues have been the subject of documentary and oral discovery in the Apotex Section 8 Action.
> …

[34] Reading the paragraphs in Janssen's representations that precede paragraph 22, it is clear that the "issues" referenced in the statement are Apotex's ability and motivation to supply its abiraterone product. This statement forms part of Janssen's explanation of attempts it had made, through dialogue between the parties, to acquire consensually the evidence it seeks. Janssen explains that it proposed to Apotex using the discovery examination and document productions from the Apotex Action as non-party production and discovery in the DRL Action and PMS Action. Effectively, Janssen was proposing a negotiated result comparable to the alternative relief that it subsequently advanced, and then withdrew, in these motions. However, it received no response to its proposal.

[35] In response to the Non-Parties' argument based on paragraph 22 of its representations, Janssen submits that it cannot be inferred from this statement that it is making use of evidence obtained in another proceeding for purposes of seeking documentary production and discovery

under Rules 233 and 238. Janssen argues that stating that Apotex was discovered in its section 8 action on its ability and motivation to supply its abiraterone product is comparable to stating that a party to a negligence action was discovered on the applicable duty and standard of care. While perhaps not a perfect parallel, I take Janssen's point that a section 8 claimant's ability and motivation to supply its product are typical issues in a section 8 action (see *Eli Lilly Canada Inc v Teva Canada Limited*, 2018 FCA 53 at paras 85-88). Moreover, given the fact that Janssen made the statement (at paragraph 22 of its written representations) in the context of explaining its efforts to negotiate the alternative relief, I do not infer from that statement that it is relying on the evidence already in its possession in seeking orders under Rules 233 and 238.

[36] That said, in my view there is merit to the Non-Parties' position that a litigant, which is in possession of evidence that is subject to the implied undertaking in one proceeding, must be cautious in how it approaches another proceeding in which the same evidence may be relevant. Clearly, a litigant need not have actually produced the evidence in another proceeding in order to have breached the undertaking.

[37] For example, in *Goodman v Rossi*, 1995 CarswellOnt 146, 125 DLR (4th) 613 (Ont CA) [*Goodman*], one of the authorities upon which the Non-Parties rely, the plaintiff commenced a defamation action based on a document she obtained from the defendant in another piece of litigation in which she had sued the defendant for wrongful dismissal. The defendant sought to stay the defamation action, because it was based on evidence obtained in the other proceeding. Before the Court of Appeal for Ontario, the issue was whether the relevant document was subject

to an implied undertaking and, if so, whether the plaintiff should be granted relief from the undertaking in order to permit pursuit of the defamation proceeding (see paras 1-3).

[38] In recognizing the existence of an implied undertaking, the Court of Appeal noted that the jurisprudential prohibition against using a document for a "collateral or ulterior purpose" does not use that phrase in a pejorative sense, but rather prohibits use for any purpose different from that which was the only reason that the document was provided in a civil action (at para 47). *Goodman* does not appear to set out an express analysis and conclusion that the plaintiff's commencement of the defamation action represented a use of the relevant document in breach of the undertaking. However, it is clear that this was the Court's conclusion, as it analysed and ultimately dismissed the Plaintiff's request for relief from the implied undertaking (at paras 59-71).

[39] While *Goodman* involved a fact pattern far different from the matter at hand, and therefore offers limited instruction on whether Janssen's motions give rise to a breach of the implied undertaking, the Non-Parties also rely on *Quenneville v Robert Bosch GmbH*, 2018 ONSC 6775 [*Quenneville*], which involved a motion for non-party documentary discovery. *Quenneville* arose in the context of a class action against the defendant, Robert Bosch GmbH [the Bosch Action], the supplier of software to a number of Volkswagen entities [VW] in an alleged conspiracy to install deceptive emissions measurement devices in diesel engine automobiles sold in Canada. The plaintiffs in the Bosch Action had previously commenced, and in turn settled, a class action against VW in relation to the same subject matter [the VW Action]. The same class counsel represented the plaintiffs in both actions.

[40] In the VW Action, VW produced some 3 million documents, which were subject to a protective order issued in that matter. Following settlement of the VW Action, the plaintiffs moved in the Bosch Action for an order requiring VW (a non-party in that action) to produce the same 3 million documents. In rejecting the plaintiffs' motion, the Court relied in part on a conclusion that they had breached rule 30.1.01(3) of the Ontario *Rules of Civil Procedure* [Ontario Rules] (at para 8). (This rule, called the deemed undertaking rule, is a codification of a principle comparable to the implied undertaking that exists as a matter of common law in the Federal Court's jurisprudence.) Indeed, the Court stated that, when class counsel received these documents for purposes of the VW Action, they were simultaneously receiving the documents for purposes of the Bosch Action and thereby in breach of the protective order and the deemed undertaking (at para 25).

[41] Ultimately, the Court's dismissal of the motion appears to have turned on both the breach of the undertaking and other factors relevant to a motion seeking non-party production (at paras 40-53). This reasoning included the Court's concern that the larger portion of the 3 million documents produced in the VW Action were not relevant to the Bosch Action, and class counsel had made no attempt to tailor or refine their request (at paras 42-43).

[42] In oral submissions, Janssen's counsel questioned the reasoning (in *Quenneville* at para 25) that class counsel had breached the deemed undertaking, just by receiving the documents, due to their role as counsel in both the VW Action and the Bosch Action. I also struggle with that particular reasoning. However, elsewhere in the decision, the Court describes the breach as resulting from the fact that class counsel had undertaken not to use the information other than for

the VW action (at para 27). That reference to “use” of the information is consistent with the Court’s summary of its reasoning that it was the bringing of the motion that represented the breach of the deemed undertaking (at para 8).

[43] *Quenneville* would be a particularly relevant authority for the Court to consider if Janssen were advancing its request for the alternative relief set out in in its Notices of Motion. It illustrates the concern inherent in the implied undertaking about seeking to use documents, produced under compulsion in one proceeding, in a separate proceeding, without first seeking relief from the undertaking. However, in my view, moving for orders under Rules 233 and 238, where neither the relief sought nor the evidentiary support for the relief is framed in terms of evidence that was produced in another matter, does not represent a breach of the undertaking.

[44] In further support of its position that it is not using evidence subject to the implied undertaking in bringing the present motions, Janssen argued at the hearing that the terms of the relief sought against the Non-Parties is essentially the same as that which was sought in the Rule 233 and Rule 238 motions previously filed by Janssen and directed at other generic abiraterone manufacturers who are not parties to section 8 litigation with Janssen.

[45] The record before the Court in the current motions confirms that, in these section 8 proceedings, Janssen moved for non-party discovery of six other pharmaceutical companies, which motions were resolved and did not proceed to a hearing [the Other Motions]. The motion materials in the Other Motions are not themselves included in the records filed by the parties in the current motions. However, those materials form part of the Court’s files in these

proceedings, and Janssen's counsel took the position at the hearing of the current motions that the Court is entitled to review those materials to confirm Janssen's assertion. Counsel for the other parties did not dispute this position and indeed did not dispute Janssen's assertion that the Other Motions sought relief on essentially the same terms as the current motions.

[46] In the absence of any detailed argument comparing the terms of the relief sought in the Other Motions to that sought in the motions at hand, I decline to engage in such an analysis. However, the fact that Janssen pursued the Other Motions in support of Rule 233 and Rule 238 relief in relation to other pharmaceutical companies, which had not been the subject of previous documentary oral discovery, supports a conclusion that Janssen need not be relying on evidence that is subject to the implied undertaking to be seeking such relief in the present motions.

[47] Moreover, Janssen's written representations in support of these motions do not rely on any such evidence in support of the relevance of the requested information. Rather, they rely on applicable jurisprudence to the following effect:

A. in section 8 cases, a significant factor in quantifying the claimant's lost profits is the presence of competitors in the BFW, which affects the claimant's market share and pricing (*Apotex Inc v Merck Canada Inc*, 2012 FC 1235 [*Alendronate*] at paras 43-44 and 51; *Apotex Inc v Takeda Canada Inc*, 2013 FC 1237 at para 61); and

B. in assessing whether a competitor could and would have entered the market, relevant factors include when the competitor would have received its Notice of Compliance [NOC], whether it had the capacity to manufacture or acquire the product, and whether it

was motivated or dissuaded from entering the marketplace (*Alendronate* at para 44; *Apotex Inc v Sanofi-Aventis*, 2012 FC 553 [*Apotex Ramipril*] at paras 151-152, rev'd on other grounds 2014 FCA 68).

[48] In conclusion, the record in these motions does not support a conclusion that Janssen's motions represent, or will give rise to, a breach of the implied undertaking through use in other proceedings of the evidence previously provided by the Non-Parties as Plaintiffs in their section 8 actions.

C. *Whether the Non-Parties should be compelled to produce any of the documents sought by Janssen*

[49] As explained earlier in these Reasons, the threshold requirements prescribed by Rule 233 are relevance and compellability.

(1) Relevance

[50] One of the principal arguments advanced by the Plaintiffs in opposing Janssen's Rule 233 motion (as well as its Rule 238 motion) is that Janssen has failed to establish the relevance of the documentary production it seeks. Rule 233 imposes on the moving party the burden to establish such relevance. As explained above in these Reasons, to discharge this burden, Janssen relies on authorities identifying the significance of market competition, and the factors to be considered in assessing such competition, when quantifying a section 8 claimant's lost profits. Janssen also provides more detailed submissions explaining why it considers the 10 categories of documents

it is seeking to be relevant to regulatory hurdles faced by the Non-Parties, their capacity to manufacture or acquire product, or their motivation to launch their product.

[51] I do not understand the Plaintiffs to take issue with Janssen's position on the factors that are relevant to assessing market competition. They do advance submissions challenging the relevance of the particular categories of documents that Janssen seeks, to which submissions I will return later in these Reasons. However, more fundamentally, they argue that Janssen has failed to satisfy the relevance requirement because its pleadings do not identify the Non-Parties as competitors and do not identify the circumstances that Janssen asserts would have permitted the Non-Parties to enter the BFW that is constructed in each of the section 8 actions.

[52] The Plaintiffs are correct that Janssen's pleadings do not identify any of the Non-Parties by name as relevant competitors. By way of example, in the Apotex Action, the pleading upon which Janssen relies to establish relevance is paragraph 22(a) of its Amended Statement of Defence, which reads as follows:

> 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:
>
> > a. If Apotex had entered the market in Canada prior to January 11, 2021, several other generic pharmaceutical companies would have also entered the market in Canada at or about the same time as Apotex;

[53] Janssen's pleading references "several other generic pharmaceutical companies" and does not identify either DRL or PMS by name. Janssen's Amended Statement of Defence in each of

the DRL Action and PMS Action is similarly constructed. However, I have difficulty concluding that this lack of specificity renders any of these pleadings deficient in establishing the relevance of evidence that bears upon market competition and the effect of that competition upon the quantification of the section 8 claims.

[54] I appreciate that insufficiently defined pleadings can represent a basis for the Court to decline a motion to compel discovery from third parties (see *Eli Lilly Canada Inc v Sandoz Canada Incorporated*, 2009 FC 345 at para 25). However, to the extent the Plaintiffs in the section 8 actions are taking the position that Janssen's failure to plead by name specific generic competitors deprived it of an understanding of Janssen's defence, I agree with Janssen's argument that it was available to the Plaintiffs to move for better particulars.

[55] It was also available to the Plaintiffs to discover Janssen on the identities of the generic competitors that were the subject of Janssen's defence. No discovery evidence has been filed in these motions, and I understand that discoveries have not yet taken place in the PMS Action. However, by way of example, I note that an earlier interlocutory decision by this Court in the DRL Action (in which DRL sought determination of a question of law under Rule 220) reflects that, during discovery in that action, Janssen identified Apotex and PMS as two of the generic companies that it asserts are relevant under section 8(5) and 8(6) of the Regulations (see *Dr. Reddy's Laboratories Ltd v Janssen Inc*, 2022 FC 1672 at para 11 [the Rule 220 Decision]).

[56] As identified above, the Plaintiffs also argue that Janssen's pleadings are deficient in that they do not identify the circumstances that Janssen asserts would have permitted the Non-Parties

to enter the BFW that is constructed in each of the section 8 actions. In advancing this argument, the Plaintiffs rely on *Apotex Inc v Sanofi-Aventis,* 2014 FCA 68 [*Apotex Ramipril FCA*], aff'd 2015 SCC 20. In *Apotex Ramipril FCA,* the Federal Court of Appeal considered whether, in a circumstance where a patentee has exercised its right under section 7 of the Regulations to a statutory stay against generic entry and does not resolve or renounce that right in relation to certain generics in the real world, it is available to the patentee when subsequently defending a claim for section 8 damages to argue that such generics (other than the section 8 claimant) would have entered the market in the BFW free of that obstacle to entry (at paras 155-162 and 186-187).

[57] I pause to note my understanding that the interpretation, and significance to the facts of the present actions, of authorities including *Apotex Ramipril FCA* that have interpreted section 8 of the Regulations will be an issue for determination at trial. As reflected in the Rule 220 Decision, DRL takes the position that, in the circumstances considered in *Apotex Ramipril FCA*, it is as a matter of law unavailable to the patentee to argue that generics who were subject to the statutory stay in the real world would have entered the market in the BFW. In contrast, Janssen takes the position that *Apotex Ramipril FCA* and other authorities establish that, while there is a legal presumption in a section 8 proceeding that a patentee would have taken the same steps in the BFW that it did in the real world, it is open to the patentee (or any party) to lead evidence that events in the BFW would have unfolded differently than they did in the real world. As the Rule 220 Decision dismissed DRL's motion, this legal issue remains to be resolved at trial, and I will not presently elaborate any further upon that issue.

[58] However, independent of how this legal issue may ultimately be resolved at trial, the Plaintiffs challenge the relevance of Janssen's Rule 233 production request on the basis that it does not explain in its pleading or in any evidence adduced on this motion how the Non-Parties in any of the section 8 actions would escape operation of the Regulations so as to become market participants in the applicable BFW.

[59] In support of their position that Janssen's motion should be denied in the absence of sufficient evidentiary support, the Plaintiffs refer the Court to *Apotex Ramipril* at paragraph 149, which held that the defendant in a section 8 action cannot simply allege that other generics would have entered the market without leading evidence in support of such assertions. However, *Apotex Ramipril* was the trial decision in a section 8 action, in which the Court was addressing the evidential burden at trial. *Apotex Ramipril* does not support a conclusion that a party faces such a burden on a production motion.

[60] The Plaintiffs also argue that support for their position can be found in this Court's decision in an earlier Rule 105 motion, brought by Janssen in these section 8 actions, seeking to have heard together evidence on issues that it asserted were common to all three actions (see *Apotex Inc v Janssen Inc*, 2022 FC 1473 [the Rule 105 Decision] at para 36):

> 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.

[61] I do not find the Plaintiffs' argument on this point compelling. In the Rule 105 Decision, one of the factors the Court was required to consider was the commonality of the parties, issues, facts and remedies in the three section 8 actions in which Janssen is a defendant (at para 12). Paragraph 36 of the Rule 105 Decision refers to Janssen's argument that such commonality would result from its intention to adduce evidence at trial to support a conclusion that Apotex and PMS would have been able to enter the BFW in DRL's section 8 claim. Without Janssen presenting such evidence on the Rule 105 motion, this argument was afforded little weight in the Court's assessment of commonality. However, in the present motions, the Court is required to assess relevance, and relevance is determined by reference to the pleadings (see Rule 240(a); *Apotex Inc v Pfizer Canada Inc*, 2006 FC 262 at para 9; *Proctor & Gamble Co v Kimberly-Clark of Canada Ltd* (1990), 35 CPR (3d) 321 (FCTD) at para 14).

[62] This Court considered this principle in *Apotex Inc v Janssen Inc*, 2022 FC 1476, an interlocutory decision in the Apotex Action that addressed a motion by Janssen under Rule 51, appealing an order of the Case Management Judge that had declined on the basis of relevance to compel Apotex to answer certain discovery questions [the Rule 51 Decision]. As noted in the Rule 51 Decision, the Court's task is to assess relevance by reference to the facts pleaded by the parties, not by reference to the evidence that has previously been produced in the litigation (at para 41).

[63] That said, there is potentially a role for evidence in informing an assessment of relevance, as the Court may decline to compel answers to questions that it considers to represent a fishing expedition (Rule 51 Decision at para 42). However, I find no basis to conclude that the categories of documents that Janssen seeks in the present motions represent a fishing expedition. Subject to consideration, later in these Reasons, of the challenges to the relevance of the individual categories, their relevance is grounded in authorities noted above, identifying the ability and motivation of competitors to enter the market as relevant to quantifying a section 8 claimant's lost profits.

[64] At the hearing of these motions, Janssen's counsel responded to the Plaintiffs' position that Janssen's motions are deficient for failing to include evidence establishing the basis for its assertion that the Non-Parties in each section 8 action would not have been prevented by the Regulations from entering the market in the applicable BFW. I understand Janssen to recognize that it will bear the burden at trial of adducing evidence supporting that assertion, which will be a condition precedent to the Court considering evidence of the Non-Parties' presence in the BFWs. However, Janssen argues that the Plaintiffs have offered no authority for the proposition that it must now, in these motions, adduce the evidence in support of the condition precedent in order to establish the relevance of evidence related to generics' ability and motivation to enter the market. I agree with this submission and find that neither Janssen's pleadings nor its evidentiary records in these motions are insufficient to establish such relevance.

[65] While I am not convinced by the arguments broadly challenging the relevance of Janssen's production requests, I recognize that the Plaintiffs/Non-Parties have also made

particular submissions related to the relevance of the individual categories of documents Janssen seeks. As those submissions are not only framed in terms of the relevance of the categories but also advance other arguments related to discretionary considerations such as overbreadth and confidentiality concerns, I will consider them later in these Reasons, after addressing the parties' broad arguments surrounding the discretionary factors.

(2) Compellability

[66] While Rule 233 provides that the Court may order non-party production of a document only if the document could be compelled at trial, the parties' submissions do not focus on this requirement. I do not understand the Plaintiffs/Non-Parties to be arguing that the documents sought by Janssen would not be compellable at trial, for instance for reasons of privilege. I find that they would be compellable, such that this requirement is not an impediment to the relief Janssen seeks.

(3) Discretionary Factors

[67] I now turn to the discretionary factors identified in *O'Leary* upon which the parties made submissions. In the interests of efficiently addressing those submissions, I have reorganized and combined the factors to some extent.

(a) *Whether the information can be obtained from another party or source; necessity of the order; necessity and probative value of the documents in light of documents already disclosed*

[68] In relation to the documentation that Janssen seeks from each of the Non-Parties, it submits that the Non-Party is the only source of that information. As for necessity, Janssen refers to the evidence in its motion records as to its unsuccessful efforts to seek voluntary production.

[69] The Plaintiffs/Non-Parties argue that Janssen already has available to it significant information responsive to its requests, through both public sources and voluntary disclosure by the Plaintiffs in their respective section 8 actions. They submit, for instance, that each Non-Party's ability to supply abiraterone in the real world is available through real world market data (e.g., IQVIA data). In relation to regulatory status, they argue that the patent hold dates, which are the earliest dates each Non-Party could have obtained regulatory approval to launch its products, are also available. In relation to motivation to launch, they argue that their service of notices of allegations, proceeding to trial, and launching abiraterone products in the real world provides Janssen with all the evidence it needs.

[70] I do not find these submissions compelling. I accept Janssen's response that it has received no commitment from the Plaintiff in each section 8 action that it will not argue at trial that Janssen has failed to adduce other evidence, in addition to the information above identified by the Plaintiffs, necessary to meet its burden to establish generic competition in the BFW at the relevant time.

[71] The Plaintiffs/Non-Parties also submit that, in every section 8 case decided to date, any non-party discovery was voluntary, with non-party generics being called by the defendants to testify at trial (see, *e.g.*, *Apotex Ramipril* at paras 151-154; *Teva Canada Limited v Pfizer*

Canada Inc, 2017 FC 332 at para 95). They argue that Janssen has not explained how the present actions are any different, such that the extraordinary remedy of a Rule 233 order is necessary for the first time in this case.

[72] I agree with Janssen's response that the fact that non-party documentary production is frequently available on a voluntary basis supports, rather than detracts from, the merits of its Rule 233 motion. While it may not always be the case, it is reasonable to assume that decisions to make voluntary disclosure are in at least some instances influenced by the backdrop of the Rules.

[73] The Plaintiffs/Non-Parties refer the Court to its decision in *Hospira Healthcare Corporation v Kennedy Institute of Rheumatology*, 2018 FC 992 [*Hospira*] at paragraph 17, aff'd 2019 FCA 188, to the effect that the necessity of an order under Rule 233 is demonstrated only where there is no other practical source of the information sought. In that context, they submit that the Plaintiff in each section 8 action has produced to Janssen documentation that would represent another source of the information it seeks. They argue that, rather than bringing the Rule 233 motion, Janssen should have sought relief from the implied undertaking so as to be able to use that information.

[74] I accept that seeking relief from the implied undertaking may have been another avenue available to Janssen. However, given the Non-Parties' arguments in relation to the implied undertaking, as canvassed earlier in these Reasons, it is reasonable to conclude that Janssen would have encountered significant resistance to a motion seeking such relief. I do not find these

circumstances comparable to those in *Hospira*, where the evidence indicated that the plaintiff was prepared to request the relevant third-party information, to which it appeared to be entitled, and in turn make that production to the party that unsuccessfully moved for Rule 233 relief.

[75] In relation to the necessity factor, the Plaintiffs/Non-Parties also make the point that the three section 8 trials will take place in sequence such that, by the time the second and third trials commence, Janssen will already have the benefit of documents and testimony introduced into evidence by the Plaintiff(s) in the earlier trial or trials. They argue that counsel for all parties will then be able to discuss and determine which transcripts and documents, if any, are necessary and can be used in the subsequent trial or trials. The Plaintiffs/Non-Parties refer to this possibility having been raised by the parties in the context of Janssen's Rule 105 motion (see the Rule 105 Decision at paras 53-54).

[76] As expressed in the Rule 105 Decision, such an approach is an available possibility (at para 54). However, until an evidentiary record has been created in a particular proceeding, it cannot be known whether it will include the evidence that Janssen is seeking to discharge its burden that the Plaintiff in that proceeding would have been a participant in the BFWs of the other Plaintiffs.

[77] Having considered the above arguments, I find that these factors favour Janssen's motion.

(b) *Whether an order is premature*

[78] Janssen's principal submission on this factor is that it should not be obliged to wait until the resolution of DRL's Rule 220 motion before it is provided with non-party production. I understand this submission to be a response to an argument previously advanced by the Plaintiffs/Non-Parties to the effect that Janssen's present motion should not be entertained until after the outcome of the Rule 220 motion was known. As explained earlier in these Reasons, the Rule 220 Decision has since been issued. As such, the Plaintiffs/Non-Parties did not advance that argument at the hearing of the present motions.

[79] The Plaintiffs/Non-Parties also argue that an order on these motions would be premature, because Janssen is in breach of its implied undertaking. However, I rejected this argument earlier in these Reasons.

[80] I find that this factor favours Janssen's motion.

(c) *Confidentiality concerns*

[81] In relation to confidentiality concerns, Janssen submits that the Protective Order issued in each section 8 action protects documentation produced by the Non-Parties through a Confidential Information–CEO provision.

[82] Notwithstanding the benefit of the "counsel eyes only" provisions in the Protective Orders, the Non-Parties remain concerned about being required to produce confidential information. They note that, under the terms of the Protective Orders, the individuals entitled to access documentation designated as Confidential Information–CEO includes in-house counsel

for the parties to the particular section 8 action. The effect is that, if any of Apotex, DRL or PMS is ordered to produce documents as a Non-Party pursuant to Janssen's Rule 233 motions, those documents will be available not only to Janssen's in-counsel but to in-house counsel for two of its competitors in the generic abiraterone market. While the Non-Parties recognize that the Protective Orders constrain the use and disclosure of such documents by in-house counsel, and they are not intending to impugn counsel's integrity, they are nevertheless concerned that in-house counsel will be aware of this information when providing advice to their employers in the future.

[83] The Plaintiffs/Non-Parties submit that this concern is particularly acute in the context of Janssen's request for detailed financial documents. As will be explained later in these Reasons, category 10 of Janssen's requests seeks production of documents showing the aggregate amount of rebates, professional allowances, discounts, trade-spend, free goods, or any other benefit, payment, or reimbursement provided to customers in respect of a Non-Party's abiraterone product from the date of first sale through to the present, on a monthly basis.

[84] The Non-Parties note that Janssen's request for financial documents is based on assertions that rebates are higher in a multi-generic market than a sole-generic market and that manufacturers providing higher rebates may obtain greater market share. In relation to their confidentiality concern, the Non-Parties argue that the information in the detailed financial documents Janssen has requested is extremely sensitive, as it represents competitive intelligence that, if Janssen's request is granted, would end up being provided to companies with which each

Non-Party is actively competing in the generic market for abiraterone. The Non-Parties therefore submit that the Court should reject Janssen's request for these particular materials.

[85] I find the Non-Parties' arguments on this factor compelling, particularly in relation to the category 10 financial documents, and conclude that this factor militates against granting Janssen's motion.

(d) *Delay, cost or disruption in the proceedings*

[86] The Plaintiffs take the position that Janssen has delayed unreasonably in bringing this motion. They note that, while Janssen first approached the Non-Parties seeking discovery on May 3, 2022, it did not perfect its motions until November 2, 2022, weeks before expert reports were due in the DRL Action in December 2022 and in the Apotex Action in January 2023. Discovery examinations of the parties' witnesses in those actions have been completed, and the first section 8 trial (in the DRL Action) is scheduled to commence in less than four months, followed immediately by the trial in the Apotex Action. (In the PMS Action, no dates have yet been set for discoveries, production of expert reports, or indeed a trial.)

[87] Addressing more broadly the combination of the Rule 233 and Rule 238 relief Janssen seeks, the Plaintiffs raise concern about the combination of the time required to complete the requested production, first by the Non-Parties to Janssen and then by Janssen to the relevant Plaintiffs, along with scheduling and conducting Non-Party discovery examinations following production and potentially further discovery of Janssen that could then result. The Plaintiffs argue that such relief would augment the discovery record after their expert reports have already

been filed, and they submit that they will be prejudiced because they are not entitled to file reply expert reports as a matter of right. They refer the Court to *Rovi* at paragraph 52 (aff'd *Rovi FCA*), which held that delay by a party in seeking non-party production and discovery can be a sufficient reason to dismiss a Rule 238 motion.

[88] I agree that, with less than four months remaining before the commencement of the first section 8 trial, the timing of this motion is less than ideal. However, the present circumstances are not comparable to those in *Rovi*, in which counsel for the moving party acknowledged that, should its motion be granted even in part, the trial would necessarily have to be adjourned (at para 53). None of the Plaintiffs has made such an assertion in the motions at hand.

[89] Nor have the Plaintiffs dimensioned in any detailed way how the steps required by the relief Janssen seeks would resonate through the existing schedules for steps leading to trial. Moreover, as will be explained later in these Reasons, my Order will dismiss Janssen's motion for non-party discovery under Rule 238. In the absence of at least some aspects of the compounded effect described by the Plaintiffs, surrounding the scheduling and conduct of oral discovery examinations following documentary production, I am not convinced that this factor militates against granting the requested production.

(e) *The non-party's involvement in the matter under dispute*

[90] Janssen submits that the Non-Parties are not strangers to the section 8 claims in which production is sought, given that each is a Plaintiff in its own section 8 claim. The Non-Parties disagree, arguing that each Non-Party had nothing to do with the other Plaintiffs' service of

notices of allegation, Janssen's commencement of its section 6 actions against those Plaintiffs, those Plaintiffs' ability and motivation to enter the abiraterone market in the real world, or those Plaintiffs' ability and motivation to enter the abiraterone market in their respective BFWs.

[91] To the extent this factor focuses upon the proceeding in which the Rule 233 motion is brought, obviously each of the Non-Parties is not involved, other than as a target of the motion and potentially as a witness at trial. However, given that Apotex, DRL and PMS are competitors in the generic abiraterone market and each is a claimant against Janssen in its own section 8 proceeding, this is not a circumstance in which any of those companies can be considered a true stranger to the issues in the others' litigation. In my view, this factor favours Janssen.

(f) *The specificity of the request for production*

[92] Janssen submits that its requests are focused, as it has identified specific categories of documents that it requires in order to prove that each Non-Party could have and would have entered the market during the relevant BFW. The Plaintiffs/Non-Parties disagree, arguing that it is clear from Janssen's list of requested documents that it has not made any attempt to tailor its documentary request to what is actually needed for trial. They rely on *Rovi FCA* at paragraph 17, in which the Federal Court of Appeal held that the Federal Court was entitled to be concerned that the Rule 233 motion before it was insufficiently targeted.

[93] I accept that, in considering this discretionary factor, a surgical request favours the requesting party more than one that is broad and sweeping. However, I am not convinced that the overall manner in which Janssen has formulated its request is itself problematic. While the

requests are framed as categories, in my view the necessary assessment is the degree of precision with which each category is formulated. I will return to this factor later in these Reasons, when considering the submissions of the Plaintiffs/Non-Parties that certain categories are overbroad.

(g) *Any costs to the producing party*

[94] The Non-Parties argue that they should be compensated for any costs resulting from complying with any production or discovery order (see *Voltage Pictures LLC v John Doe*, 2015 FC 1364 at paras 36-38). They have not presented any evidence or detailed argument surrounding such costs. However, with the potential for compensation of any such costs, this factor does not militate against granting the requested production.

(h) *Fairness*

[95] When I turn to consideration of Janssen's motion seeking non-party discovery examination under Rule 238, I will address its arguments that it would be unfair not to afford it such discovery rights. I will explain in that portion of these Reasons that Janssen has not established the unfairness required by a Rule 238 motion.

[96] For purposes of its Rule 233 motion, I adopt the same conclusion. However, unlike under Rule 238 where establishing unfairness is a requirement (*Rovi* at para 48), it is not a prerequisite to success under Rule 233. Rather, as noted earlier in these Reasons, it is a discretionary factor that the Court is entitled to take into account (*Janssen* at para 10; *O'Leary* at para 17). This

factor favours dismissing the Rule 233 motion, but will be balanced along with the other factors canvassed above in the exercise of the Court's discretion.

(4) Categories of Documents Sought by Janssen

[97] I now turn to the individual categories of documents sought by Janssen and the submissions of the parties in relation thereto. In responding to the motions, these submissions were advanced principally by PMS, in its capacity as a Non-Party. However, as previously noted, each of the Plaintiffs/Non-Parties has adopted the submissions of the others.

[98] Janssen has requested 10 categories of documents. It frames categories 1-3 as related to regulatory hurdles faced by the Non-Party, categories 4-8 as related to the Non-Party's capacity to manufacture or acquire product, and categories 9-10 as related to the Non-Party's motivation to launch.

(a) *Category 1 - Notifiable changes*

[99] Janssen seeks any notifiable change documents submitted to Health Canada in respect of the Non-Party's Abbreviated New Drug Submission(s) for its abiraterone product between the earliest patent hold date and the real-world launch date. In reliance on a Guidance Document published by Health Canada and attached to Janssen's deponent's affidavit, Janssen describes notifiable changes as changes made to a drug that have the potential to impact safety, efficacy, quality and/or effective use. Janssen further submits that, while notifiable changes do not require the issuance of an NOC, Health Canada must issue a no objection letter before they can be

implemented, and notifiable changes can occur after a drug product is considered approvable by Health Canada. As such, Janssen submits that any notifiable changes for a Non-Party's abiraterone product are relevant to the Non-Party's ability to launch even after its product was considered approvable.

[100] The Non-Parties note Janssen's submissions that notifiable changes do not require the issuance of an NOC and therefore argue that a Non-Party's absence or presence on the market in a section 8 claimant's BFW cannot be impacted by any notifiable change that occurred in the real world. The Non-Parties refer the Court to *Eli Lilly Canada Inc v Teva Canada Limited*, 2017 FC 88 [*Teva Olanzapine*], rev'd in part 2018 FCA 53, in which the Court rejected evidence of a notifiable change as relevant to the date a section 8 claimant could have entered the market.

[101] I agree with Janssen's response that the determination in *Teva Olanzapine* is fact-specific, based on the particular notifiable change in that matter, involving an alternative manufacturing process, in a circumstance where the claimant had already received an NOC (at paras 30-36). I accept the relevance of Janssen's requested inquiry into developments between the patent hold date and the real-world launch date that could have affected timing of market entry.

[102] However, I also agree with another submission, made by PMS in particular, arising from the fact that the two different dosages of its product (250 mg and 500 mg) were on patent hold as of different dates. PMS argues logically that, for the 500 mg dosage that was on later patent hold,

documents related to the submission for that dosage prior to its patent hold date are irrelevant. Janssen has not responded to this particular argument, which I accept.

[103] Finally, I regard this particular requested category as sufficiently targeted and precise that the specificity factor favours Janssen. As such, the only discretionary factors militating against ordering production are confidentiality, which is to some extent mitigated by the effect of the Protective Orders, and the fact that Janssen has not demonstrated that unfairness would arise if it was deprived of production. Balancing the discretionary factors, I am satisfied that the Court should order production of this category of documentation, although my Order will limit the production of documentation related to PMS's 500 mg dosage to the period after the patent hold date for that dosage.

(b) *Category 2 - Correspondence with Health Canada regarding deficiencies*

[104] Janssen seeks any correspondence between the Non-Party and Health Canada regarding deficiencies or other issues with the Non-Party's submission after its abiraterone product was first placed on patent hold and before the real-world launch date. It argues that such material will indicate whether and when the Non-Party could have received its NOC in the BFWs. Janssen notes that it has narrowed its request to those documents created after the Non-Party's product became approvable, so as to identify any potential problems with its submission that arose after its patent hold date.

[105] The Non-Parties argue that Janssen has not established the existence of any correspondence that would be responsive to this request or referred to any jurisprudence to

support this request. They also submit that such information would have no probative value, as the relevant patent hold dates have already been disclosed.

[106] As with category 1, I accept Janssen's argument as to the relevance of documents that identify issues between the patent hold date and the real-world launch date that could have affected timing of market entry. I do not regard the absence of specific jurisprudential support for a particular category of documentation to represent an impediment to a finding of relevance. I appreciate that Janssen has adduced no evidence suggesting that there were issues arising after the patent hold date. However, the Non-Parties have not suggested that Janssen would have a means of acquiring such evidence other than through non-party discovery. If there are no documents responsive to this request, then no production will be required.

[107] As with category 1, PMS also submits that the request is overbroad because it covers the period from the earliest patent hold date to the real world launch date. Again, I accept that, for the 500 mg dosage that was on later patent hold, documents that relate to the period prior to its patent hold date are irrelevant. Otherwise, I regard this particular request category as sufficiently targeted and precise that the specificity factor favours Janssen.

[108] I regard the balancing of discretionary factors to be the same as for category 1. I am satisfied that the Court should order production of the category 2 documentation, although again limiting the production of documentation related to PMS's 500 mg dosage to the period after the patent hold date for that dosage.

(c) *Category 3 – Life cycle management table*

[109] Janssen requests the most recent life cycle management table for the Health Canada dossier relating to all regulatory submissions in respect of the Non-Party's abiraterone product. Referencing a further Guidance Document published by Health Canada, Janssen describes the life cycle management table as an index of correspondence between Health Canada and the Non-Party. Janssen submits that the most recent table will show the status of the Non-Party's abiraterone submission at various points in time, which status will in turn indicate whether and when the Non-Party would have been approved in the BFWs and what, if any, regulatory hurdles it faced at any point in time.

[110] The Non-Parties note that the life cycle management table would include information from prior to the patent hold dates and after the real world launch date, which they argue would be irrelevant. They also submit that the existence of regulatory hurdles is not relevant given that Janssen has been provided with the applicable patent hold dates. Janssen responds that knowing the patent hold dates is not sufficient, as it must be able to explore potential regulatory impediments to a product launch. It submits that, without the benefit of that evidence, it may face (and be unable to respond to) arguments from the Plaintiffs at trial that it has failed to meet its burden to establish that a particular Non-Party would have been present as a competitor in the applicable BFWs.

[111] I find Janssen's argument the more compelling. I understand the logic of the Non-Parties' submission that information pre-dating the patent hold date and post-dating the real-world launch date is unlikely to be instructive. However, in the absence of evidence or argument that it is

practicable to produce the information in the life cycle management table in relation to only a particular range of dates, I accept that the document is relevant and not lacking in precision.

[112] I regard the balancing of discretionary factors to be the same as for categories 1 and 2. I am satisfied that the Court should order production of the category 3 documentation.

(d) *Categories 4 and 5 – Sections 2.3.S.2.1 and 2.3.P.3.1 of Certified Product Information Document - Chemical Entities; names of other API suppliers*

[113] Again relying on a Health Canada Guidance Document, Janssen notes that, as part of their submission to Health Canada, generic manufacturers must produce a Certified Product Information Document - Chemical Entities [CPID], sections 2.3.S.2.1 and 2.3.P.3.1, which must identify any suppliers of active pharmaceutical ingredient [API] or finished product. Janssen seeks production of these excerpts from the CPID as relevant to the Non-Parties' ability to make or acquire sufficient abiraterone product.

[114] Janssen also requests the names of any entities, other than those identified in the CPID, from which the Non-Parties purchased abiraterone API used in the manufacture of any commercial sale batches of abiraterone product between the patent hold date and the real-world launch date.

[115] The Non-Parties refer the Court to *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2012 FC 552 [*Teva Ramipril*], a section 8 decision which held that the identity of a non-party generic competitor's API supplier was not relevant (at para 157). However, this conclusion

turned on the evidence in that particular case surrounding the availability of API in the market generally. The Non-Parties' reliance on *Teva Ramipril* does not convince me that categories 4 and 5 of Janssen's request are irrelevant.

[116] As with category 1, PMS also submits that these requests are overbroad because they cover the period from the first patent hold date to the real world launch date. Again, I accept that, for the 500 mg dosage that was on later patent hold, documents that relate to the period prior to its patent hold date are irrelevant (although it is not clear to me whether the responses to categories 4 and 5 differ as between the two dosages).

[117] I regard the balancing of discretionary factors to be the same as for previous categories. I am satisfied that the Court should order production of the category 4 and 5 documentation. To the extent the documentation differs as between PMS's two dosages, the production of documentation related to PMS's 500 mg dosage will be limited to the period after the patent hold date for that dosage.

(e) *Category 6 - Access to supply of API and/or finished product*

[118] Janssen seeks documents relating to the Non-Parties' access to the supply of abiraterone API and/or finished product from the entities named in the CPIDs from three months prior to the patent hold date to present, including any supply agreements for abiraterone API or finished abiraterone tablets.

[119] Again, the Non-Parties rely on *Teva Ramipril*, in which the non-party's ability to supply was established through the evidence of a witness, and reference to a single document, subpoenaed at trial. However, the introduction of such evidence at trial in *Teva Ramipril* supports the conclusion that it is relevant. The fact that the section 8 claimant in that case relied upon particular evidence to establish the non-party's ability to supply in the BFW does not mean that other evidence is not relevant to the same issue.

[120] The Non-Parties also argue that this request is overbroad as it seeks the production of "documents" without defining the scope of the request, and because it is seeking information to the present date. I agree that the request for "documents relating to access to the supply of abiraterone acetate active ingredient, and/or finished product from the entities named in the CPID …" is insufficiently precise. However, the request is also framed as "… including any supply agreements …" which seeks a more targeted category of documents. As I understand that the Plaintiffs are seeking damages to present, I do not regard the category 6 request as overbroad for seeking information to the present date.

[121] Other than the imprecision concern related to the specificity factor, I regard the balancing of discretionary factors to be the same as for previous categories. I will order production of the category 6 documentation, but limited to supply agreements.

(f) *Category 7 - Plant capacity and utilization rates*

[122] Janssen seeks documents showing each Non-Party's plant capacity and utilization rates for all manufacturing plants/lines that the Non-Party could have used to manufacture its

abiraterone product, on a quarterly or annual basis, from three months prior to the date of its earliest patent hold letter for its abiraterone product to present. Janssen argues that such documents are relevant to determining the portion of the Canadian market that the Non-Party could have supplied in the BFWs.

[123] In relation to this category, I agree with the Non-Parties' position that the request is insufficiently precise, as it is framed only in terms of what the requested documents would show. Balancing the discretionary factors, including this lack of specificity, I decline to order production of this category of documentation.

(g) *Category 8 - Validation reports and/or validation justification reports*

[124] Janssen seeks production of validation reports and/or justification reports in respect of each Non-Party's abiraterone product and any amendments to same completed between the earliest patent hold date and the real-world launch date. It notes that, prior to launching a drug product, manufacturers are required to validate their manufacturing process to verify that the product is consistently reproducible and meets quality requirements. Janssen submits that documents relating to a Non-Party's real-world validation for its abiraterone product are relevant to determining whether and when it could have completed this required step in the BFWs. It references the consideration of this process in *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 248 [*Venlafaxine*] at paragraph 98.

[125] The Non-Parties argue that they were able to launch within days of receiving an NOC in the real world and that, as Janssen has made no allegation about the date that validation was

completed, the requested documents have no probative value. I disagree. As explained in *Venlafaxine*, the question is when validation could have been completed in the BFW, and I am satisfied that the requested reports can inform consideration of this question.

[126] I regard this request as framed with sufficient precision and, as with other such categories, I conclude that the balancing of discretionary factors favours Janssen. I will order production of the category 8 documentation.

(h) *Category 9 - Launch plans and forecasts*

[127] Janssen seeks any launch plans, forecasts, reports, or slideshow presentations that were current to three months before a Non-Party's abiraterone product became approvable through to present and which contain analysis on: (a) the potential for profitability of the abiraterone product; or (b) the launch of the abiraterone product. Janssen argues that such documents predating the NOC can show the factors the Non-Party was considering when deciding whether and when to launch its product. It submits that having several launch plans or forecasts contemporaneous with the BFW periods will permit tracking of how the Non-Party's motivations changed (if at all) over time and is probative of when, if ever, the Non-Party would have launched its product.

[128] The Non-Parties argue that these documents are irrelevant, because their launch plans were prepared in the context of the real world, where the market was genericized only following the dismissal of Janssen's infringement actions, with several generic companies entering the market at approximately the same time. I accept that the real world market conditions are

different from the hypothetical conditions the Court will be required to consider in the BFWs in the section 8 actions. However, real-world conditions can inform conclusions as to those that would have existed in the BFWs (see *Eli Lilly v Apotex Inc*, 2019 FC 1463 at para 23, aff'd 2021 FCA 149). I am satisfied that this category of documentation is relevant.

[129] The Non-Parties also argue that this request is overly broad and has no probative value, because it seeks information up to the present date. They note that there can be no question of motivation to launch from the real-world launch date to present, when the Non-Party has actually been on the market. I agree with this submission. Otherwise, I am satisfied that this category is framed with sufficient specificity.

[130] Balancing the discretionary factors applicable to this category, I am satisfied that production should be ordered, although limited to documentation current to the real-world launch date.

(i) *Category 10 – Rebates and other benefits, payments, or reimbursements to customers*

[131] Janssen seeks production of documents showing the aggregate amount of rebates, professional allowances, discounts, trade spend, free goods, or any other benefit, payment, or reimbursement provided to customers in respect of a Non-Party's abiraterone product from the date of first sale through to present, on a monthly basis. It submits that such evidence will assist the Court in assessing the Plaintiff's market share in the BFW and the rebates the Plaintiff may have to pay to compete with the Non-Party in the BFW. Janssen notes that the Court has

recognized that as a response to competitive forces, trade spend is much higher in a multi-generic market than a sole-generic market (*Teva Ramipril* at para 271).

[132] I have identified earlier in these reasons the Non-Parties' concerns about the confidentiality of this financial information. They also submit that, consistent with that confidentiality, each of Apotex, DRL and PMS would not have been aware of rebates paid by the others, in either the real world or the BFWs. The Non-Parties also argue that Janssen has not identified the specific documents it seeks.

[133] I find the Non-Parties' arguments compelling. Taking into account the lack of specificity in this category of request, and the enhanced concerns explained earlier in these Reasons surrounding the confidentiality and commercial sensitivity of this particular information, I find the balancing of the discretionary factors favours declining to order production of this category of documentation.

D. *Whether Janssen should be granted leave to examine any individuals at the Non-Parties*

[134] As previously explained, Rule 238 prescribes four threshold requirements. However, before turning to those requirements, I must first address an argument raised by the Plaintiffs/Non-Parties related to the fact that Janssen's motion does not identify the witness of whom it seeks discovery examination.

(1) Identity of Witness

[135] The portion of Janssen's Notices of Motion seeking relief under Rule 238 is framed as follows:

> 2. An Order pursuant to Rule 238 granting Janssen leave to examine for discovery the individual(s) at [the Non-Party] primarily responsible for deciding whether and when [the Non-Party] would have launched an abiraterone product for use in [Court file numbers] within 45 days;

[136] Janssen explains that it does not know the identity of the individual or individuals employed by each of the Non-Parties who would know the answers to the questions it wishes to ask on discovery related to the launch of the Non-Party's abiraterone product in the BFWs. Janssen therefore seeks an order that would require the Non-Party to identify such individual or individuals and produce them for discovery.

[137] The Plaintiffs/Non-Parties take the position that Rule 238 does not contemplate relief of this nature. Rule 238(1) permits a motion for leave to examine for discovery "any person not a party to the action", and Rule 238(3) authorizes the Court to grant leave to examine "a person". The Plaintiffs/Non-Parties submit that non-party discovery examination pursuant to this Rule contemplates examination of natural persons, to explore evidence within their personal knowledge, not an examination of a corporate representative of the sort permitted by Rule 237, in which the corporation nominates the representative.

[138] In support of their position, the Plaintiffs/Non-Parties rely on various provisions of the Rules which, in their submission, demonstrate the difference between a discovery examination of a representative of a corporate party and a non-party discovery examination:

A. Rule 237(1) requires a corporation that is to be examined for discovery to select a representative to be examined on its behalf;

B. Rule 239(5) provides that a person being examined under Rule 238 (*i.e.*, in a non-party discovery) shall not be cross-examined and shall not be required to give hearsay;

C. Rule 239(6) provides that the testimony of such a person shall not be used as evidence at trial, other than in cross-examination if the person is a witness at trial; and

D. Rule 241 requires a person who is to be examined for discovery to become informed by making inquiries of any present or former officer, servant, agent or employee of the party who might be expected to have knowledge relating to any matter in question in the action. However, persons to be examined under Rule 238 (*i.e.*, in a non-party discovery) are excluded from the operation of Rule 241.

[139] The Plaintiffs/Non-Parties submit that the combination of these Rules demonstrates that non-party discovery under Rule 238 involves discovery of a natural person as a witness in an individual capacity, not discovery of such a person as a corporate representative. They argue that this distinction between non-party discovery and discovery of a corporation that is a party to litigation supports their position that a motion under Rule 238 must identify the individual that the moving party seeks to discover, rather than seeking to have a non-party corporation identify the individual.

[140] The Plaintiffs/Non-Parties submit that their position, that Rule 238 is limited to examination of natural persons, is consistent with the decision in *Bayside Towing Ltd v Canadian Pacific Railway*, [2000] FCJ No 1122 (FCTD) [*Bayside Towing*] at paragraph 8. The Plaintiffs/Non-Parties acknowledge that there is a decision to the opposite effect in *Bauer Nike Hockey Inc v Easton Sports Canada Inc*, 2006 FC 1084 [*Bauer*] at paragraphs 29-35, but they submit that this authority was wrongly decided and conducted no analysis of the interactions of relevant provisions of the Rules as set out above.

[141] Janssen does not agree that *Bauer* was wrongly decided. However, it explained at the hearing that it is not seeking discovery of an individual or individuals at the Non-Parties as corporate representatives of the sort contemplated by Rule 237. It wishes to discover a witness or witnesses with responsibility for deciding whether and when the Non-Party would have launched an abiraterone product. However, it is not seeking to discover that witness beyond the scope of their own personal knowledge.

[142] As such, it is not necessary for the Court to resolve the jurisprudential point raised in *Bayside Towing* and *Bauer*. However, it is still necessary to address the Non-Parties' position that Janssen's Rule 238 motion is deficient for failing to identify the person(s) it wishes to discover. The argument that best supports the Non-Parties' position is based on the requirement in Rule 238(2) that a Rule 238 motion be served not only on the other parties but personally on the person to be examined. As the Non-Parties submit, this service requirement affords such person an opportunity to make representations on the motion. In the present circumstances, the Non-Parties themselves were served and responded to Janssen's motions. However, the

particular witness or witnesses who could be the subject of a Rule 238 order were not identified in Janssen's motions and were therefore neither served nor afforded the opportunity to make representations.

[143] In my view, this deficiency precludes Janssen succeeding in its Rule 238 motions as framed.

(2) Requirements under Rule 238

[144] More substantively, Janssen's Rule 238 motions must also fail because it has not satisfied the requirements of the Rule. As previously explained, Rule 238(3) prescribes four requirements that must be met in order to obtain leave to discover a non-party and, if those requirements are met, the Court must conduct an analysis of discretionary factors comparable to that under Rule 233. Much of the analysis conducted earlier in these Reasons under Rule 233 would apply to the Rule 238 motions as well, informing consideration of both the requirements of Rule 238(3) and the application of discretionary factors. However, as telegraphed in my comments on unfairness in the Rule 233 analysis, I regard the unfairness requirement in Rule 238(3) as an impediment to Janssen's success in seeking leave for examination for discovery.

[145] Under paragraph (c) of Rule 238(3), in order to obtain leave to examine a person who is not a party to the action, Janssen must satisfy the Court that it would be unfair not to allow it an opportunity to question that person before trial. Janssen argues that this requirement is met because the Non-Parties are adverse in interest to Janssen in the section 8 actions in which they are themselves Plaintiffs and, in the absence of the discoveries it seeks, it will not in advance of

trial have evidence that it can use to satisfy its burden to establish generic competition in the applicable BFW. It similarly asserts that it wishes to conduct discoveries to identify in advance of trial who would be the appropriate witnesses from the Non-Parties to call at trial in the discharge of its burden.

[146] The difficulty with these arguments is that they conflate the unfairness requirement with other requirements in Rule 238(3), that the person of whom discovery is sought may have information on an issue in the action and the party seeking discovery has been unable to obtain the information informally from the person or from another source by any other reasonable means. In other words, given that it is a separate requirement under the Rule, unfairness must entail something other than establishing that the witness has relevant evidence that the moving party will not otherwise be able to obtain in advance of trial.

[147] As the Plaintiffs submit, this interpretation is supported by the analysis in *Actava TV, Inc v Matvil Corp*, 2021 ONCA 105 [*Actava TV*] at paragraphs 94-95. Referencing the provision of the Ontario Rules governing issuance of an order for production from a non-party, which includes an unfairness requirement, the Court of Appeal for Ontario referenced the exceptional nature of such relief and explained that, by its terms, the rule assumed that requiring a party to go to trial without the forced production of relevant documents in the hands of non-parties is not *per se* unfair. While *Actava TV* is not binding on this Court and addressed the Ontario Rules, I find its reasoning equally applicable to this Court's Rules.

[148] The Plaintiffs also reference *O'Leary* as demonstrating the sort of analysis engaged by the unfairness requirement, in which the Court concluded that the parties were all on the same informational footing with respect to the evidence sought from a non-party in that matter (at paras 25-26). In the case at hand, the Plaintiffs submit that they have no more information than Janssen with respect to the Non-Parties in their respective section 8 actions.

[149] While *O'Leary* addressed unfairness in terms of informational asymmetry, this analysis was a function of the particular unfairness arguments raised by the moving parties and was included among analyses of other arguments surrounding unfairness. I would not regard informational asymmetry as the only means by which a moving party can establish unfairness necessary to succeed in a Rule 238 motion. However, other than identifying its wish to obtain relevant evidence and information as to its sources in advance of being required to meet its burden at trial, Janssen has not explained how it would be unfair not to afford it that opportunity.

[150] As the unfairness requirement is not satisfied, Janssen's motions under Rule 238 must be dismissed.

V. **Conclusion**

[151] I will issue an Order in each of the three section 8 actions, ordering each of the two Non-Parties in each action to make documentary production consistent with the analysis in these Reasons. I note that, in the interests of comprehensibility, each Order will employ the same document category numbering as in Schedule "A" attached to the applicable Notice of Motion

and in these Reasons, notwithstanding that some of the categories from Schedule “A” are not included in the Order.

VI. **Costs**

[152] As the parties have met with divided success in these motions, I will order no costs of the motion, other than that each Non-Party shall be entitled to recovery from Janssen of its reasonable costs incurred in making documentary production in response to the Orders.

ORDER in T-607-21

THIS COURT ORDERS that:

A. The Defendants' motion under Rule 233 is allowed in part and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. [together, DRL] shall within 20 days of the date of this Order produce the following documents for use in this proceeding:

1. any Notifiable Change documents submitted to Health Canada in respect of DRL's Abbreviated New Drug Submission(s) for REDDY-ABIRATERONE between the earliest patent hold date and the real-world launch date;

2. any correspondence between DRL and Health Canada regarding deficiencies or other issues with DRL's submission (such as Clarifaxes, information requests, and product monograph updates) after REDDY-ABIRATERONE was first placed on patent hold and before the real-world launch date;

3. the most recent life cycle management table for the Health Canada dossier related to all regulatory submissions in respect of REDDY-ABIRATERONE;

4. excerpted sections 2.3.S.2.1 and 2.3.P.3.1 from the Certified Product Information Document - Chemical Entities [CPID] identifying manufacturers of REDDY-ABIRATERONE and abiraterone acetate active ingredient used in the manufacture of REDDY-ABIRATERONE that was in force when REDDY-

ABIRATERONE was first placed on patent hold and any amendments made regarding the identities of the manufacturers referred to in the sections thereafter;

5. to the extent different than those entities set out in the response to #4, provide the names of the entities from whom DRL purchased abiraterone acetate active ingredient used in the manufacture of any commercial sale batches of REDDY-ABIRATERONE between the patent hold date and the real-world launch date;

6. any supply agreements for abiraterone acetate active ingredient or finished REDDY-ABIRATERONE tablets from the entities named in the CPIDs from three months prior to DRL's patent hold date to present;

7. validation reports and/or validation justification reports in respect of REDDY-ABIRATERONE, and any amendments to same completed between the earliest patent hold date and the real-world launch date; and

8. any launch plans, forecasts, reports, or slideshow presentations that were current to three months before REDDY-ABIRATERONE became approvable through to the real-world launch date and which contain analysis on: (a) the potential profitability of REDDY-ABIRATERONE; or (b) the launch of REDDY-ABIRATERONE.

B. The Defendants' motion under Rule 233 is allowed in part and Pharmascience Inc. [PMS] shall within 20 days of the date of this Order produce the following documents for use in this proceeding:

1. any Notifiable Change documents submitted to Health Canada in respect of PMS's Abbreviated New Drug Submission(s) for each dosage of PMS-ABIRATERONE between the patent hold date for the dosage and its real-world launch date;

2. any correspondence between PMS and Health Canada regarding deficiencies or other issues with PMS's submission (such as Clarifaxes, information requests, and product monograph updates) for each dosage after PMS-ABIRATERONE was first placed on patent hold for the dosage and before its real-world launch date;

3. the most recent life cycle management table for the Health Canada dossier related to all regulatory submissions in respect of PMS-ABIRATERONE;

4. excerpted sections 2.3.S.2.1 and 2.3.P.3.1 from the Certified Product Information Document - Chemical Entities [CPID] identifying manufacturers of PMS-ABIRATERONE and abiraterone acetate active ingredient used in the manufacture of PMS-ABIRATERONE that was in force when PMS-ABIRATERONE was first placed on patent hold for each dosage and any amendments made regarding the identities of the manufacturers referred to in the sections thereafter;

5. to the extent different than those entities set out in the response to #4, provide the names of the entities from whom PMS purchased abiraterone acetate active ingredient used in the manufacture of any commercial sale batches of PMS-

ABIRATERONE between the patent hold date for each dosage and the real-world launch date;

6. any supply agreements for abiraterone acetate active ingredient or finished PMS-ABIRATERONE tablets from the entities named in the CPIDs from three months prior to PMS's patent hold date to present;

7. validation reports and/or validation justification reports in respect of PMS-ABIRATERONE, and any amendments to same completed between the earliest patent hold date and the real-world launch date; and

8. any launch plans, forecasts, reports, or slideshow presentations that were current to three months before PMS-ABIRATERONE became approvable through to the real-world launch date and which contain analysis on: (a) the potential profitability of PMS-ABIRATERONE; or (b) the launch of PMS-ABIRATERONE.

C. The Defendants' motion under Rule 238 is dismissed.

D. No costs are awarded in these motions other than that:

1. the Defendants shall pay DRL its reasonable costs incurred in making documentary production in response to paragraph A of this Order; and

2. the Defendants shall pay PMS its reasonable costs incurred in making documentary production in response to paragraph B of this Order.

ORDER in T-1168-21

THIS COURT ORDERS that:

A. The Defendants' motion under Rule 233 is allowed in part and Apotex Inc. [Apotex] shall within 20 days of the date of this Order produce the following documents for use in this proceeding:

1. any Notifiable Change documents submitted to Health Canada in respect of Apotex's Abbreviated New Drug Submission(s) for APO-ABIRATERONE between the earliest patent hold date and the real-world launch date;

2. any correspondence between Apotex and Health Canada regarding deficiencies or other issues with Apotex's submission (such as Clarifaxes, information requests, and product monograph updates) after APO-ABIRATERONE was first placed on patent hold and before the real-world launch date;

3. the most recent life cycle management table for the Health Canada dossier related to all regulatory submissions in respect of APO-ABIRATERONE;

4. excerpted sections 2.3.S.2.1 and 2.3.P.3.1 from the Certified Product Information Document - Chemical Entities [CPID] identifying manufacturers of APO-ABIRATERONE and abiraterone acetate active ingredient used in the manufacture of APO-ABIRATERONE that was in force when APO-

ABIRATERONE was first placed on patent hold and any amendments made regarding the identities of the manufacturers referred to in the sections thereafter;

5. to the extent different than those entities set out in the response to #4, provide the names of the entities from whom Apotex purchased abiraterone acetate active ingredient used in the manufacture of any commercial sale batches of APO-ABIRATERONE between the patent hold date and the real-world launch date;

6. any supply agreements for abiraterone acetate active ingredient or finished APO-ABIRATERONE tablets from the entities named in the CPIDs from three months prior to Apotex's patent hold date to present;

7. validation reports and/or validation justification reports in respect of APO-ABIRATERONE, and any amendments to same completed between the earliest patent hold date and the real-world launch date; and

8. any launch plans, forecasts, reports, or slideshow presentations that were current to three months before APO-ABIRATERONE became approvable through to the real-world launch date and which contain analysis on: (a) the potential profitability of APO-ABIRATERONE; or (b) the launch of APO-ABIRATERONE.

B. The Defendants' motion under Rule 233 is allowed in part and Pharmascience Inc. [PMS] shall within 20 days of the date of this Order produce the following documents for use in this proceeding:

1. any Notifiable Change documents submitted to Health Canada in respect of PMS's Abbreviated New Drug Submission(s) for each dosage of PMS-ABIRATERONE between the patent hold date for the dosage and its real-world launch date;

2. any correspondence between PMS and Health Canada regarding deficiencies or other issues with PMS's submission (such as Clarifaxes, information requests, and product monograph updates) for each dosage after PMS-ABIRATERONE was first placed on patent hold for the dosage and before its real-world launch date;

3. the most recent life cycle management table for the Health Canada dossier related to all regulatory submissions in respect of PMS-ABIRATERONE;

4. excerpted sections 2.3.S.2.1 and 2.3.P.3.1 from the Certified Product Information Document - Chemical Entities [CPID] identifying manufacturers of PMS-ABIRATERONE and abiraterone acetate active ingredient used in the manufacture of PMS-ABIRATERONE that was in force when PMS-ABIRATERONE was first placed on patent hold for each dosage and any amendments made regarding the identities of the manufacturers referred to in the sections thereafter;

5. to the extent different than those entities set out in the response to #4, provide the names of the entities from whom PMS purchased abiraterone acetate active ingredient used in the manufacture of any commercial sale batches of PMS-ABIRATERONE between the patent hold date for each dosage and the real-world launch date;

6. any supply agreements for abiraterone acetate active ingredient or finished PMS-ABIRATERONE tablets from the entities named in the CPIDs from three months prior to PMS's patent hold date to present;

7. validation reports and/or validation justification reports in respect of PMS-ABIRATERONE, and any amendments to same completed between the earliest patent hold date and the real-world launch date; and

8. any launch plans, forecasts, reports, or slideshow presentations that were current to three months before PMS-ABIRATERONE became approvable through to the real-world launch date and which contain analysis on: (a) the potential profitability of PMS-ABIRATERONE; or (b) the launch of PMS-ABIRATERONE.

C. The Defendants' motion under Rule 238 is dismissed.

D. No costs are awarded in these motions other than that:

1. the Defendants shall pay Apotex its reasonable costs incurred in making documentary production in response to paragraph A of this Order; and

2. the Defendants shall pay PMS its reasonable costs incurred in making documentary production in response to paragraph B of this Order.

ORDER in T-732-22

THIS COURT ORDERS that:

A. The Defendants' motion under Rule 233 is allowed in part and Apotex Inc. [Apotex] shall within 20 days of the date of this Order produce the following documents for use in this proceeding:

1. any Notifiable Change documents submitted to Health Canada in respect of Apotex's Abbreviated New Drug Submission(s) for APO-ABIRATERONE between the earliest patent hold date and the real-world launch date;

2. any correspondence between Apotex and Health Canada regarding deficiencies or other issues with Apotex's submission (such as Clarifaxes, information requests, and product monograph updates) after APO-ABIRATERONE was first placed on patent hold and before the real-world launch date;

3. the most recent life cycle management table for the Health Canada dossier related to all regulatory submissions in respect of APO-ABIRATERONE;

4. excerpted sections 2.3.S.2.1 and 2.3.P.3.1 from the Certified Product Information Document - Chemical Entities [CPID] identifying manufacturers of APO-ABIRATERONE and abiraterone acetate active ingredient used in the manufacture of APO-ABIRATERONE that was in force when APO-

ABIRATERONE was first placed on patent hold and any amendments made regarding the identities of the manufacturers referred to in the sections thereafter;

5. to the extent different than those entities set out in the response to #4, provide the names of the entities from whom Apotex purchased abiraterone acetate active ingredient used in the manufacture of any commercial sale batches of APO-ABIRATERONE between the patent hold date and the real-world launch date;

6. any supply agreements for abiraterone acetate active ingredient or finished APO-ABIRATERONE tablets from the entities named in the CPIDs from three months prior to Apotex's patent hold date to present;

7. validation reports and/or validation justification reports in respect of APO-ABIRATERONE, and any amendments to same completed between the earliest patent hold date and the real-world launch date; and

8. any launch plans, forecasts, reports, or slideshow presentations that were current to three months before APO-ABIRATERONE became approvable through to the real-world launch date and which contain analysis on: (a) the potential profitability of APO-ABIRATERONE; or (b) the launch of APO-ABIRATERONE.

B. The Defendants' motion under Rule 233 is allowed in part and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. [together, DRL] shall within 20 days of the date of this Order produce the following documents for use in this proceeding:

1. any Notifiable Change documents submitted to Health Canada in respect of DRL's Abbreviated New Drug Submission(s) for REDDY-ABIRATERONE between the earliest patent hold date and the real-world launch date;

2. any correspondence between DRL and Health Canada regarding deficiencies or other issues with DRL's submission (such as Clarifaxes, information requests, and product monograph updates) after REDDY-ABIRATERONE was first placed on patent hold and before the real-world launch date;

3. the most recent life cycle management table for the Health Canada dossier related to all regulatory submissions in respect of REDDY-ABIRATERONE;

4. excerpted sections 2.3.S.2.1 and 2.3.P.3.1 from the Certified Product Information Document - Chemical Entities [CPID] identifying manufacturers of REDDY-ABIRATERONE and abiraterone acetate active ingredient used in the manufacture of REDDY-ABIRATERONE that was in force when REDDY-ABIRATERONE was first placed on patent hold and any amendments made regarding the identities of the manufacturers referred to in the sections thereafter;

5. to the extent different than those entities set out in the response to #4, provide the names of the entities from whom DRL purchased abiraterone acetate active ingredient used in the manufacture of any commercial sale batches of REDDY-ABIRATERONE between the patent hold date and the real-world launch date;

6. any supply agreements for abiraterone acetate active ingredient or finished REDDY-ABIRATERONE tablets from the entities named in the CPIDs from three months prior to DRL's patent hold date to present;

7. validation reports and/or validation justification reports in respect of REDDY-ABIRATERONE, and any amendments to same completed between the earliest patent hold date and the real-world launch date; and

8. any launch plans, forecasts, reports, or slideshow presentations that were current to three months before REDDY-ABIRATERONE became approvable through to the real-world launch date and which contain analysis on: (a) the potential profitability of REDDY-ABIRATERONE; or (ii) the launch of REDDY-ABIRATERONE.

C. The Defendants' motion under Rule 238 is dismissed.

D. No costs are awarded in these motions other than that:

1. the Defendants shall pay Apotex its reasonable costs incurred in making documentary production in response to paragraph A of this Order; and

2. the Defendants shall pay DRL its reasonable costs incurred in making documentary production in response to paragraph B of this Order.

"Richard F. Southcott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-607-21, T-1168-21, T-732-22
STYLE OF CAUSE:	APOTEX INC. v. JANSSEN INC., JANSSEN ONCOLOGY INC. AND BTG INTERNATIONAL LTD. DR. REDDY'S LABORATORIES LTD. AND DR. REDDY'S LABORATORIES, INC. v. JANSSEN INC., JANSSEN ONCOLOGY INC. AND BTG INTERNATIONAL LTD. PHARMASCIENCE INC. v. JANSSEN INC., JANSSEN ONCOLOGY INC. AND BTG INTERNATIONAL LTD.
PLACE OF HEARING:	HELD BY VIDEOCONFERENCE
DATE OF HEARING:	JANUARY 31, 2023
ORDER AND REASONS:	SOUTHCOTT J.
DATED:	FEBRUARY 14, 2023

APPEARANCES

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Mr. Marcus Klee	FOR THE PLAINTIFF PHARMASCIENCE INC.
Mr. Jonathan Giraldi	FOR THE PLAINTIFFS DR. REDDY'S LABORATORIES LTD. AND DR. REDDY'S LABORATORIES, INC.

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