Federal Court  Cour fédérale

Date: 20240229

Docket: T-732-22

Citation: 2024 FC 335

Toronto, Ontario, February 29, 2024

PRESENT: Associate Judge Trent Horne

BETWEEN:

PHARMASCIENCE INC.

Plaintiff / Moving Party

and

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

Defendants / Responding Parties

PUBLIC ORDER AND REASONS

(Confidential Order and Reasons issued February 29, 2024)

I. Background

[1] This is a discovery motion within an action brought under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("Regulations"). In these reasons, all references to section numbers are to sections of the Regulations, unless otherwise indicated.

[2] The drug in issue is abiraterone, which is used to treat prostate cancer. Abiraterone, or more specifically listed Canadian patent 2,661,422, ("422 Patent") has been the subject of considerable litigation.

[3] In November 2017, Janssen Inc and Janssen Oncology, Inc commenced an application against Apotex Inc ("Apotex") under the former Regulations to prohibit the issuance of a notice of compliance for its 250 mg abiraterone product. Janssen was successful in its application (*Janssen Inc v Apotex Inc*, 2019 FC 1355; aff'd *Apotex Inc v Janssen Inc*, 2021 FCA 45).

[4] On January 10, 2019, Janssen Inc, Janssen Oncology, Inc, and BTG International Ltd (collectively "Janssen") commenced a section 6 action against Apotex for its 250 and 500 mg abiraterone tablets (Court file T-84-19).

[5] Janssen commenced a section 6 action against Pharmascience Inc ("PMS") on January 25, 2019 in respect of PMS' 250 mg abiraterone product (Court file T-182-19). Janssen commenced a second section 6 action (T-1893-19) against PMS on November 22, 2019 in respect of PMS' 500 mg abiraterone product.

[6] Janssen commenced a further section 6 action relating to abiraterone against Dr Reddy's Laboratories Ltd and Dr Reddy's Laboratories, Inc ("Dr Reddy's") on June 14, 2019 (Court file T-978-19).

[7] The trials of the proceedings against Apotex, PMS, and Dr Reddy's were conducted together. The actions were collectively dismissed on the basis that the patent is invalid (*Janssen Inc v Apotex Inc*, 2021 FC 7); the decision was upheld on appeal (*Janssen Inc v Apotex Inc*, 2022 FCA 184).

[8] In each of the section 6 actions against Apotex, PMS, and Dr Reddy's, Janssen did not renounce the 24-month statutory stay under section 7.

[9] Apotex, Dr Reddy's and PMS each commenced section 8 actions against Janssen.

[10] The Apotex section 8 case (T-607-21) was concluded by way of consent judgment on April 11, 2023. The Dr Reddy's section 8 case (T-1168-21) was concluded by way of consent judgment dated April 28, 2023.

[11] Janssen also reached settlements with other generics for their abiraterone products.

[12] At a very high level, the "loss suffered" by PMS will be determined by assessing a "but-for world" where PMS would have received a notice of compliance ("NOC") and commenced sales of its abiraterone product an earlier date because it was not blocked by the operation of the Regulations.

[13] The assessment of this loss requires the Court to:

1. determine the duration of the period of liability (the relevant period);

2. determine the overall size of the abiraterone market during the relevant period (the abiraterone market);
3. determine the portion of the abiraterone market that would have been retained by Janssen, and the portion that would have been held by generic manufacturers during the relevant period (the generic market);
4. determine the portion of the generic market that would have been held by PMS (PMS' lost volumes); and
5. quantify the damages that would have been suffered by PMS in respect of PMS' lost volumes (PMS' net lost profits).

(*Apotex Inc v Sanofi-Aventis*, 2012 FC 553 at para 11)

II. The Motion

[14] PMS has divided the disputed questions into categories and sub-categories with letter designations. The questions were identified using item numbers. In this order, I will use the same category and item descriptions as in the motion materials.

[15] In their responding motion materials, Janssen stated that they would provide answers to items 49–53, 55–57, 60–63, 69–73, 76–83, 85, 89, 95–96, and 98–99 (category BTG K). In correspondence to the Court dated January 18, 2024, PMS withdraw items 13-14, 16, 18, 31, and 47 from the BTG discovery. No order need be made in respect of these items.

[16] Certain items were adjudicated during the hearing, and reasons were given for the outcome. Other categories were taken under reserve. These reasons set out the disposition of the items taken under reserve, one category that was adjudicated at the hearing, and categories of questions that were not spoken to at the hearing.

A. *Settlement Agreements*

[17] Categories B, BTG A, BTG B, and BTG C seek production of settlement agreements that PMS believes Janssen entered into with Apotex and Dr Reddy's for the purposes of settling their section 8 cases, together with related documents and information.

[18] For this part of the motion, Apotex and Dr Reddy's were put on notice of the relief sought, and their counsel attended the hearing. For the motion as a whole, the vast majority of materials have been designated as confidential pursuant to the terms of a protective order. I issued a direction on December 12, 2023 stating that confidential materials could be filed under seal. Other than when counsel for Apotex and Dr Reddy's were present, the hearing was held *in camera*. There was no issue at the hearing, but it bears repeating, that all materials filed on the motion maintain their confidential designations. All of the material that was filed under seal remains under seal, and is not part of the public record. Excepting the time when counsel for Apotex and Dr Reddy's were in attendance, none of the submissions made during the motion are part of the public record.

[19] A significant issue in this category of questions is whether settlement privilege applies to the documents and information requested, and if so, whether Janssen has waived that privilege. Of particular interest to PMS is the amount paid by Janssen under any settlement agreement.

[20] "The purpose of settlement privilege is to promote settlement. The privilege wraps a protective veil around the efforts parties make to settle their disputes by ensuring that communications made in the course of these negotiations are inadmissible" (*Sable Offshore Energy Inc v Ameron International Corp*, 2013 SCC 37 ("*Sable*") at para 2).

[21] It has long been recognized as a policy interest worth fostering that parties be encouraged to resolve their private disputes without recourse to litigation, or, if an action has been commenced, encouraged to effect a compromise without resort to trial (Sidney N Lederman, Michelle K Fuerst & Hamish C Stewart, *Sopinka, Lederman & Bryant: The Law of Evidence in Canada*, 6th ed. (Toronto: LexisNexis, 2022) at 105 at para 14.367). Settlement privilege is an effective tool to ameliorate the "stubbornly endemic delays", expense and stress of litigation (*Sable* at para 1).

[22] Settlement privilege applies broadly to settlement negotiations. The privilege applies whether or not a settlement is reached, and if a settlement is reached, the negotiated amount (*Sable* at paras 17-18).

[23] The conditions that must be present for settlement privilege to be recognized are:

1) litigation was commenced or in the parties' contemplation;

2) the communication was made with the intent it not be disclosed if settlement negotiations failed; and

3) the purpose of the communication was to achieve settlement.

(*Nova Scotia (Attorney General) v Nova Scotia Teachers Union*, 2020 NSCA 17 at para 49)

[24] There are exceptions. To come within those exceptions, the party seeking disclosure "must show that, on balance, 'a competing public interest outweighs the public interest in encouraging settlement'. These countervailing interests have been found to include allegations of misrepresentation, fraud or undue influence, and preventing a plaintiff from being overcompensated" (*Sable* at para 19, citations omitted).

[25] While Janssen has not admitted that there is an agreement with Apotex or Dr Reddy's, the publicly available judgments dismiss the respective section 8 actions on consent of the parties. I have no difficulty assuming that sophisticated pharmaceutical companies had some form of discussion, and reached some form of agreement, in advance of presenting a consent judgment to the Court. It is reasonable to assume that these parties wrote down the terms of any agreement.

[26] On the assumption that there is some form of agreement between Janssen and Apotex, and Janssen and Dr Reddy's, it is self-evident that those agreements, and the negotiations leading up to them, are protected by settlement privilege. The parties had claims before the Court, and a mutually acceptable resolution was reached before adjudication. Janssen, Apotex, and Dr Reddy's have opposed every effort by PMS to compel disclosure of the existence or terms of

any agreement, demonstrating an intention that the communications not be disclosed. The purpose of the communication was clearly to achieve a settlement. These are precisely the kinds of communications that settlement privilege is intended to protect.

[27] I cannot conclude that any of the exceptions in *Sable* apply to situations where one section 8 plaintiff is trying to determine what other section 8 plaintiffs litigating the same drug settled for. There are no allegations of misrepresentation, fraud, or undue influence in this action. Further, there is no competing public interest that outweighs the public interest in encouraging settlement. It is not unusual for multiple generics to have contemporaneous section 8 claims; denying the protection of privilege to settlement negotiations as a matter of course would be a disincentive to settle any one of them.

[28] A section 8 case requires the construction of a hypothetical but-for world ("BFW"), and quantifies a loss in circumstances that did not actually happen. A number of variables may be presented, particularly in respect of what other generics (if any) will be in the BFW generic market. Here, the BFW will be considered in about 2019. Assuming Apotex and Dr Reddy's reached a settlement with Janssen shortly before the issuance of the consent judgments, that happened four years later.

[29] Section 8 cases are different than cases like *Sable*. In *Sable,* there was a claim that paint was defective. If liability was found, the plaintiff sustained a certain amount of damage. In section 8 cases, damages do not arise from what did happen in the real world, but what would

have happened in various hypothetical scenarios. In light of these differences, the public interest in encouraging settlement outweighs other interests.

[30] The parties are not aware, and neither am I, of a decision where a defendant in a section 8 case was obliged to disclose settlement agreements it reached with other generics in other section 8 proceedings relating to the same drug. I am not persuaded that I should be the first, and conclude that settlement privilege applies to any agreements between Janssen and Apotex and Janssen and Dr Reddy's to resolve those section 8 abiraterone claims, as well as the negotiations leading up to any agreement.

[31] PMS asserts that Janssen has waived any privilege that attaches to these communications. "The onus of establishing waiver of privilege rests with the party asserting the waiver" (*Rakuten Kobo Inc v Canada (Commissioner of Competition)*, 2017 FC 382 ("*Rakuten*") at para 56).

[32] A phrase that comes up with some frequency in the context of privilege and waiver is "fairness and consistency."

[33] This phrase appears to have its root in *S & K Processors Ltd v Campbell Ave Herring Producers Ltd*, 1983 CanLII 407 ("*S & K Processors*"), a decision of Justice McLachlin (as she then was) of the Supreme Court of British Columbia. In that decision, she held at para 6:

> Waiver of privilege is ordinarily established where it is shown that the possessor of the privilege: (1) knows of the existence of the privilege; and (2) voluntarily evinces an intention to waive that privilege. However, waiver may also occur in the absence of an intention to waive, where fairness and consistency so require. Thus waiver of privilege as to part of a communication

> will be held to be waiver as to the entire communication. Similarly, where a litigant relies on legal advice as an element of his claim or defence, the privilege which would otherwise attach to that advice is lost.

[34] For class privileges such as settlement privilege, fairness and consistency are considered when determining whether privilege has been waived, not whether it exists.

[35] The analysis in this respect begins with the importance that has been attached to creating and maintaining class privileges. The importance and public policy for settlement privilege has been discussed above.

[36] Generally, a waiver of privilege can be express, where a party voluntarily discloses all or part of a privileged communication, or implied, where the party – again voluntarily – relies on the privileged communication as an element of its claim or defence or where it puts in issue legal advice it has received (*Apotex Inc v Canada (Minister of Health)*, 2004 F.C.J. No 1431). Here is where fairness and consistency come into play. Where a partial waiver has been established, whether by express disclosure or implication, the interests of fairness and consistency may dictate that the privilege be waived in its entirety (*K F Evans v Canada (Minister of Foreign Affairs)*, [1996] F.C.J. No 30, at para 23-24; see also the unreported decision of case management judge Tabib in *Teva Canada Limited v Pfizer Canada Inc.* dated December 21, 2017 in Court file T-1194-12 ("*Amlodipine*") where she determined that no matter how relevant a communication might be, a party may not be deprived of its right to claim privilege unless it has acted in a manner inconsistent with that right).

[37] Put another way, the Court cannot compel a party to waive settlement privilege on a case by case basis. For PMS to be successful on waiver, it must demonstrate that Janssen took a step or has acted in a manner that is inconsistent with its rights of privilege.

[38] Production of settlement agreements was before Justice O'Reilly in *Pharmascience Inc v Pfizer Canada ULC*, 2020 FC 1176. There, on an appeal of an order of an associate judge, PMS sought an order compelling Pfizer to produce unredacted copies of settlement agreements between Pfizer and Teva. The disputed redactions in the two agreements related to financial information, in effect, the amounts for which the parties agreed to settle. Justice O'Reilly found that "the question of settlement privilege provides a complete answer to Pharmascience's submissions" (para 5) and dismissed the appeal.

[39] PMS argues that the pleadings in this proceeding should lead to a different result. I cannot agree. In this case, paragraph 15 of Janssen's statement of defence pleads that certain factors should be taken into account when assessing any compensation to PMS. The first of these factors is:

> a. If PMS had received a NOC prior to January 8, 2021, several other generic pharmaceutical companies would have also entered the market in Canada before PMS, or in the alternative on or about the same time as PMS.

[40] In the matter before Justice O'Reilly, the second amended statement of defence stated:

> 19. If Pharmascience had received a NOC for any Pregabalin product prior to February 15, 2013, some or all of the other generic pharmaceutical manufacturers would also have received NOCs for the sale of generic versions of Pregabilin prior to the dates on which they actually received those NOCs.

[41] I do not see a meaningful difference in these pleadings, and no difference that would compel me to reach a different conclusion than Justice O'Reilly.

[42] A similar issue was before the Court in *Amlodipine*, which dealt with the issue of waiver page 3:

> Pfizer, at paragraph 92(a) and (c)(ii) to (iv) of its Second Amended Statement of Defence, merely pleads that GenMed, it is own generic brand, would have entered the market at the same time as Teva and that once a generic manufacturer had begun selling amlodipine besylate tablets, Pfizer would have immediately consented to other generics entering the market, discontinued all existing prohibition applications and not commenced new ones in relation to amlodipine besylate, and started supplying certain particular generics with amlodipine besylate products for resale.
>
> These allegations refer to actions that Pfizer would have taken in response or reaction to a given factual circumstance: the entry of a first generic on the amlodipine besylate market. They do not refer to or rely on legal advice Pfizer might have sought or received to justify, prompt or support those actions. It is quite likely that Pfizer would, as many sophisticated corporations might be expected to do, have sought legal advice prior to or as part of its implementation of the strategies. However, I am satisfied that by pleading the hypothetical adoption of certain strategies, Pfizer has not relied on the legal advice it has received in connection with the strategies or put that advice at issue. A party that pleads that it would have taken certain steps, even if the steps include commencing or discontinuing litigation, cannot be said to have waived privilege over the legal advice related to the adoption or consideration of the steps unless it also indicates an intention to rely on legal advice received as justification for taking these steps.

[43] I am therefore not satisfied that paragraph 15a. of Janssen's statement of defence results in express or implied waiver of any privilege over its settlement discussions and any agreement with Apotex and Dr Reddy's, particularly the amount of any settlement.

[44] On discovery, PMS asked for Janssen's knowledge, information and belief with respect to what [redacted]. In response to an undertaking, Janssen advised that, under these hypothetical facts, Janssen believes that [redacted].

[45] PMS asserts that it should be able to explore what actually happened in the real world with Apotex and Dr Reddy's so it can assess and challenge what Janssen says would have happened with these entities in the BFW, particularly in light of the Court's observation that what happened in the real world is very important to what would have happened in the BFW (*Apotex Inc v AstraZeneca Canada Inc*, 2018 FC 181at para 66).

[46] I am not satisfied that Janssen's answers to undertakings constitute an express waiver. Janssen does not rely on the fact that, in the real world, it reached a settlement with Apotex and Dr Reddy's, or the terms of any agreement, as a defence to PMS' claim. Rather, it says that certain agreements would have been concluded in the hypothetical BFW.

[47] I am also not satisfied that Janssen has waived privilege by implication. By giving a discovery answer in response to a hypothetical question about what it believes would have happened in 2019, Janssen has not mentioned, referred to, or relied on any settlement agreement that may have been reached in 2023. The source of PMS' information about any settlement of the Apotex/Dr Reddy's section 8 cases appears to be the Court file, not documents and

information provided in the discovery process by Janssen. I therefore do not see any partial waiver by Janssen, specifically when there has been no disclosure of *some* information that would then open the door to production of *further* information based on principles of fairness and consistency. This is consistent with *Rakuten* at paragraph 61 where the Chief Justice stated that, where there has been partial disclosure, it must be demonstrated that, without the further information in respect of which privilege has not been waived, the disclosed information is somehow misleading.

[48] PMS relies on *Ministry of Correctional Services v McKinnon*, 2010 ONSC 3896 at para 4 for the principle that an exception to settlement privilege is where the settlement documentation is necessary for the proper disposition of a proceeding. What is necessary for the proper disposition of the matter may be relevant to whether the privilege exists, and whether the exceptions to the privilege set out in *Sable* are present, however I do not accept that, where settlement privilege has been found to exist, and there is no partial waiver, I can use the interests of justice as a justification to deem a waiver.

[49] It is easy to see why PMS wants this information, and has strived in this proceeding and others to learn the details of settlement agreements entered into by its competitors. But any agreements between Janssen and Apotex/Dr Reddy's, and the negotiations leading up to them, are protected by settlement privilege. Janssen has not waived that privilege in whole or in part, expressly or by implication.

[50] Specific questions in this category address Janssen's expectations in the litigation, including whether it was surprised at the result. I have difficulty seeing how Janssen could answer these questions without getting into advice that it received from counsel. These questions in these categories will not be ordered answered.

B. *Cooperation Agreements*

[51] PMS believes that Apotex and Dr. Reddy's are assisting Janssen in the present litigation. PMS argues that the willingness and ability of Dr Reddy's and Apotex to enter the abiraterone market as asserted by Janssen is a central issue in this proceeding, and that the existence of cooperation agreements between Janssen and Dr Reddy's/Apotex is relevant to assessing the weight to be afforded to the evidence regarding their actions in the BFW.

[52] The disputed questions in categories G and BTG D ask whether the section 8 settlement agreements include an obligation to cooperate with Janssen, whether a separate cooperation agreement exits, whether any compensation will be paid in return for cooperation, and whether cooperation extends to trial testimony. The production requests extend to any agreements and related communications.

[53] My analysis on settlement privilege above applies to this section as well. To the extent this category of questions address what is contained in any section 8 settlement agreements, or the negotiations leading up to them, those agreements and communications are protected by settlement privilege.

[54] In support of an argument that, as a general principle, cooperation agreements must be disclosed, PMS relies on *Bilfinger Berger (Canada) Inc v Greater Vancouver Water District*, 2014 BCSC 1560 ("*Bilfinger*"), *Seaspan International Ltd v Ewa (Ship)*, 2004 FC 124 ("*Seaspan*"), *BC Children's Hospital v Air Products Canada Ltd*, 2003 BCCA 177 ("*BC Children*"), *Mendlowitz & Associates Inc v Chiang*, 2014 ONSC 2651 ("*Mendlowitz*"), and *Middelkamp v Fraser Valley Real Estate Board* (1992), 45 CPR (3d) 213 ("*Middlecamp*"). Each of these authorities can be distinguished on their facts, particularly that none of them address a cooperation agreement with a non-party.

[55] *Bilfinger* involved an agreement between co-defendants (para 1); *Seaspan* involved settlement agreements (which apparently did not exist) between plaintiffs (para 18); *BC Children* involved settlement agreements with former defendants (para 1); in *Mendlowitz* settlement privilege for one paragraph of one email gave way to a competing public interest (risk of misleading the court) (para 92); and *Middlecamp* referred to the principle that opposite parties are entitled to know about any arrangements which are made about evidence. I do not agree with PMS that, as a general principle, cooperation agreements *with non-parties* must be disclosed.

[56] I am not aware of an instance where a Court has expanded the principle that an agreement dealing with evidentiary arrangements between parties to extend to include evidentiary agreements between a party and a witness, and then compelled production of related agreements and documents. The distinction between a party and a witness is a meaningful difference.

[57] I agree with Janssen's submissions that, in multi-party litigation, if a plaintiff enters into an agreement with one defendant, this is an obvious change in the expected adversarial relationship and significant unfairness could result from a lack of disclosure. Similarly, if two defendants with crossclaims enter into a settlement agreement, that would be an unexpected change (even though they are otherwise aligned against the plaintiff), because they were formerly adverse to each other, at least as it related to the crossclaims.

[58] If there are cooperation agreements between Janssen and Apotex/Dr Reddy's (and I make no finding as to whether such agreements exist), the terms of any such agreement would not alter the apparent relationships between any parties in this litigation that would otherwise be assumed from the pleadings (see *Aviaco International Leasing Inc v Boeing Canada Inc*, 2000 CanLII 22777 (ONSC) at para 23). There has been no change in the adversarial landscape *in this action*, and no re-alignment of interests among the parties *in this action*.

[59] I am not satisfied there is a risk that the Court will be misled in the event any cooperation agreements between Janssen and Apotex/Dr Reddy's are not disclosed, particularly when PMS can ask questions on cross-examination as to the circumstances leading to the testimony, including whether the evidence was voluntary or truly compelled by subpoena. The questions in this category were properly refused, and will not be ordered answered.

C. *Waiver*

[60] Category A is described as abiraterone litigation assessment, and involves issues of waiver.

[61] Janssen was asked who would have made a decision to reach a settlement (or not) with Dr Reddy's at a certain time and in a certain scenario in the BFW. For Janssen Inc, Janssen responded to an undertaking by stating that a decision would have been made by one person before a specific date, and by another person after that date "with advice from Diane Yee and Jen Reda." Both are lawyers. PMS argues that the discovery question did not go to advice received, and this information was therefore "voluntarily injected" by Janssen. PMS submits this is a textbook example of reliance on legal advice to support a defence. Since Janssen did not settle with Dr Reddy's in the real world, PMS argues that by necessary implication Diane Yee or Jen Reda would have given different advice to guide Janssen to make a different decision on whether to settle, when to settle, and on what terms as between the real world and the BFW. PMS therefore asserts that it should be able to probe that advice.

[62] Solicitor-client privilege is "fundamental to the proper functioning of our legal system and a cornerstone of access to justice. […] Without the assurance of confidentiality, people cannot be expected to speak honestly and candidly with their lawyers, which compromises the quality of the legal advice they receive. It is therefore in the public interest to protect solicitor-client privilege. For this reason, 'privilege is jealously guarded and should only be set aside in the most unusual circumstances'" (*Alberta (Information and Privacy Commissioner) v University of Calgary*, 2016 SCC 53 at para 34, citations omitted). Litigation privilege serves to facilitate the adversarial process. It "gives rise to a presumption of inadmissibility for a class of communications, namely those whose dominant purpose is preparation for litigation. …[A]ny document that meets the conditions for the application of litigation privilege will be protected by an immunity from disclosure unless the case is one to which one of the exceptions to that

privilege applies" (*Lizotte v Aviva Insurance Company of Canada*, 2016 SCC 52 ("*Lizotte*") at paras 36-37).

[63] With certain exceptions discussed below, PMS does not contest that the information it seeks is privileged, rather asserts that Janssen has waived the privilege. I am not satisfied that Janssen has waived privilege, either expressly or by implication.

[64] As associate judge Tabib found in *Amlodipine* (pages 3-4), as a sophisticated corporation, it is to be expected that Janssen Inc would seek legal advice prior to or as part of the implementation of its strategies. Janssen has not relied on the legal advice it received in the real world as part of its defence. Janssen has advised who would have been involved in the decision-making process in the BFW, but has not relied on legal advice as a justification for what it says would have happened in the BFW. This is very different from situations like *The Corporation of the City of Kawartha Lakes v Gendron*, 2018 ONSC 3498 at para 64 where an affiant voluntary provided detailed evidence of professional and confidential communication relating to ongoing settlement discussions, the reasonableness of conduct, and a settlement strategy. The affiant also referenced legal advice received from external counsel.

[65] A purely narrative reference to the giving of legal advice does not constitute waiver (*PCP Capital Partners LLP & Anor v Barclays Bank Plc*, [2020] EWHC 1393 (Comm) at para 49). Here, I am not satisfied that Janssen is holding out what its lawyers said to justify actions, strategies or conduct.

[66] As I indicated during the hearing, even if I assume that all the questions in this category are relevant, the nature of the information sought (probability of success, likelihood of success in litigation, quantification of what may happen in certain section 8 cases, probability of settlements) are litigation outcomes, and include legal analysis and advice. I am not satisfied that disclosing the names of two lawyers in the answer to undertaking at question 2824 constitutes waiver. Janssen has disclosed who was involved in the decision-making process, but does not rely on what they said. The real world and the BFW are inherently different. The fact that lawyers may have contributed to BFW negotiations does not mean that privilege has been waived.

[67] As I indicated during the hearing, the questions in this category will not be ordered answered.

D. *US Litigation History*

[68] Category F is a series of questions arising from United States press releases, materials filed with the United States Securities and Exchange Commission, and decisions of United States Courts. PMS intends to argue that Janssen fought “tooth and nail” to preserve its US monopoly for abiraterone, and that the business and litigation strategy in the United States is consistent with Janssen’s real world behaviour in Canada, and inconsistent with the narrative Janssen will present for the BFW.

[69] Questions in Category D (Janssen litigation history) were ordered answered during the hearing, but those questions involved Janssen’s activities in Canada. The relevance of activities

in the United States is more limited, particularly because the "Hatch-Waxman" legislation differs in material respects from the Regulations. In particular, there is no apparent equivalent to section 8 damages in the United States.

[70] To the extent PMS' questions request production of press releases directed to abiraterone, it is a reasonable discovery request to obtain copies from Janssen to ensure that there is no issue as to whether the document is complete. Such a request is not burdensome. Item 155 will be ordered answered. Janssen has already admitted that PMS production 391 is a true copy, so item 162 will not be ordered answered. Similarly, Janssen has admitted that PMS productions 420 and 424 are true copies, so items 148 and 169 will not be ordered answered.

[71] Some of the questions in this category seek confirmation of events that happened in United States litigation, such as the outcomes of court proceedings, whether appeals were filed, and whether injunctive relief was sought. PMS production 390 is a decision of the United States Patent Trial and Appeal Board dated January 17, 2018, and was admitted during the discovery to be a copy of that decision. PMS production 424 is a decision of the United States Court of Appeals, Federal Circuit, and PMS has confirmed that it is a true copy. To the extent a court or tribunal communicated its findings in a published decision, that document speaks for itself. In the event questions seek confirmation that a litigation step was taken (or not taken) that is not apparent from a decision or Court record, limited questions in this respect may be appropriate. Items 153, 170, 171, which arise from copies of judicial decisions, will not be ordered answered. Items 164-166 seek confirmation that Janssen sought injunctive relief after a trial decision. Item 167 seeks confirmation of an outcome in the Supreme Court of the United States. While

I have reservations as to the relevance of this line of inquiry, responses would be limited to a "yes" or "no", and I do not see a published decision or similar document in the record that would make the answer self-evident. Items 164, 165, 166, and 167 will be ordered answered.

[72] Some of PMS' questions ask for confirmation that certain statements in press releases are accurate, such as whether Johnson and Johnson strongly disagrees with a ruling and will continue to defend the patent. These kind of questions go beyond what Janssen did or did not do to protect its patent rights in the United States. Questions in Category A going to expectations or belief of patent validity were not ordered answered. I am not satisfied that Janssen's belief as to the validity of its US patent rights constitutes a proper question. Items 154, 156, 157, 158, 159, 163 will not be ordered answered. I have difficulty following item 161. At question 1593, there seemed to be some confusion as to what document was being referred to, and an indication that the issue would be revisited the next day. This item will not be ordered answered.

[73] PMS wants to present an argument that Janssen was an aggressive litigant in the real world in both Canada and the United States. I have hesitation as to the weight that could be afforded to what Janssen did in other countries, however the questions in items 168, 147, 149, 176, 177 and 178 are limited factual questions that could advance this argument and will be ordered answered. Ultimately, whether this evidence is admissible, and what weight (if any) should be afforded to it is up to the trial judge.

[74] Subcategory F3 includes questions directed to when settlement negotiations with Apotex began in the United States, when those settlement negotiations concluded, whether the US

discussions included settlement discussions about Canada, and whether Janssen had a belief that its Canadian patent was valid. I am not satisfied that any of the questions in this sub-category are proper. In response to undertaking item 189, Janssen has already advised PMS when certain Canadian settlement negotiations began. Cross-border settlement discussions may occur, but I am not satisfied that by answering a question about when settlement discussions began in Canada, PMS has opened the door to settlement discussions in other jurisdictions. I have difficulty seeing how Janssen could answer questions about its beliefs on the validity of the 422 Patent without revealing information that is protected by solicitor-client and/or litigation privilege. Items 150, 151, 152, 103, and 104 will not be ordered answered.

E. *License Agreements*

[75] Categories R and BTG E are directed to a license agreement between BTG International Ltd ("BTG") and Cougar Biotechnology, now Janssen Oncology, Inc, involving abiraterone. PMS wants to learn about the royalty rates in the agreement, on the theory that the greater the royalty rates, the greater the motivation for BTG to pursue litigation without entering into settlement agreements. Janssen argues that this seeks irrelevant information, and that PMS has not established a factual foundation for the questions.

[76] I am satisfied that production of the license agreement would not be burdensome, and the document may be relevant. Items 5, 6, 37, and 38 will be ordered answered. The request for records of royalty payments by year and by country is too broad and burdensome. Item 7 will not be ordered answered. Janssen has undertaken to answer item 35. As for item 17, I agree with

Janssen's submissions that this was answered in response to undertaking item 3; it is not clear what additional information is sought by PMS, and this item will not be ordered answered.

III. Adjudication of Questions not Argued

[77] 17 categories in PMS' motion were not spoken to at the hearing. PMS requested that I adjudicate the remaining questions after the hearing on the basis of the written materials. Janssen made the same request for its motion. I cannot conclude that the parties had any realistic expectation that questions not spoken to at the hearing would be deferred, and later considered in writing, and I am unwilling to do so. No order will be made in respect of questions that were not addressed at the hearing, both in this motion and the Janssen motion.

[78] Discussions relating to scheduling the motions to compel began in about November 2023. On November 14, 2023, PMS wrote to the Court and proposed a schedule leading up to a 1.5 day hearing for the motions.

[79] A case management conference was conducted on November 15, 2023. The parties were advised that both motions would be set for one day. I issued a direction on the same day setting a January 22, 2024 hearing date for the motions to compel, and also stating that the motions for both PMS and Janssen would not exceed one day. Limiting motions to compel to a single day is consistent with the Court's practice in proceedings under the Regulations. There have been circumstances where associate judges have scheduled discovery motions for more than a day, but that is typically where there are co-pending actions involving separately represented generics, and the discoveries are proceeding in tandem. That is not the case here. Even if other case

management judges have assigned more than a day for motions to compel, that discretion was not exercised here.

[80] There was no request at the case management conference to effectively bifurcate the motions, and have some matters addressed at the oral hearing, and any remaining questions resolved in writing. This was always an oral motion, and only an oral motion.

[81] Limiting discovery motions to a day is also consistent with section 8 of the Court's Case and Trial Management Guidelines for Complex Proceedings and Proceedings under the *PM(NOC) Regulations*, last amended October 18, 2023 ("Guidelines"), which limit refusal motions to 1 hour per day of discovery of each party's representative.

[82] Before the motions were filed, each side knew that they would have half a day of Court time for their respective motions.

[83] PMS' motion involved 360 disputed questions that were divided into about 30 categories and further sub-categories. In addition to 12 volumes (3899 pages) of supporting documents, PMS filed over 50 pages of written submissions, separate from the chart of questions in issue. When Janssen's responding submissions were added to the chart of disputed questions, it brought the length of that document to 257 pages. For a half-day motion. Janssen's responding submissions advised that about 60 questions would be answered, leaving about 300 to be adjudicated.

[84] Janssen's motion was also voluminous, with about 175 questions in issue, divided into 15 categories and further sub-categories. The chart of disputed questions, including responding submissions, was 230 pages.

[85] Questions on discovery motions are typically decided in the moment. Taking disputed questions under reserve is the exception, not the norm. Further, questions are taken under reserve after oral argument. There is no established practice that any questions that were not the subject of argument will be adjudicated after the fact based only on written submissions. It should have been apparent to both PMS and Janssen, at the time their responding records were exchanged, that it would be exceedingly difficult, if not impossible, to speak to all the disputed questions in the time allotted.

[86] The scheduling directions for these motions required the parties to write to the Court by a fixed date and advise what questions have been settled. This step is deliberately included in scheduling directions to incentivize the parties to reach a compromise, narrow the issues, and make the most efficient use of limited Court time. The parties wrote to the Court on January 18, 2024 as directed, and advised that PMS would not be pursuing six items, and Janssen would not be pursuing six items, a compromise that had no real impact on the time that would be required to speak to the questions that remained.

[87] The hearing began early, at 9:00 am. At the outset, it was indicated that the day would be divided equally.

[88] PMS' began its submissions by speaking to section 8 cases generally, then the settlement agreement, cooperation agreement, and waiver issues discussed above. Argument on these categories lasted about 2.5 hours. Parties on a discovery motion can, of course, allocate their time and prioritize categories as they see fit. The order in which categories and questions will be addressed, and how long to take on the categories, is in the hands of the moving party, not the Court.

[89] More than 3 hours into PMS' motion, I raised the issue of questions that would not be spoken to, and my expectation that matters not spoken to during the hearing would not be adjudicated in writing. PMS submitted that it was not aware of such a rule, that there was no practice direction to this effect, and requested that any questions that were not argued at the hearing be determined based on the written materials. Janssen was content with adjudicating the remainder of the PMS motion in writing, provided its motion was treated the same way.
I reserved my decision on this point, and advised that there would be the same outcome in both the PMS and Janssen motions.

[90] Counsel for PMS also submitted that the responding parties took a disproportionate share of the time on its motion. I cannot agree. While I did not use a chess clock on the motions, responding submissions in both motions did not, in the aggregate, exceed those of the moving party. I did not observe one party "running the clock" to the disadvantage of the other. Where possible, I tried to expedite submissions to maximize the number of questions that would be spoken to.

[91] This is not an instance where a few scattered questions could be addressed on the basis of written submissions after the hearing, even if I was inclined to do so. Over a quarter of PMS' questions had not been argued when its allotted time expired.

[92] Permitting the parties to split their motions into oral and written adjudication would be inconsistent with, and indeed a collateral challenge to, the scheduling direction that limited the Court time assigned to the motions to a single day. It would also be inconsistent with the Court's expressed desire, particularly in the Guidelines, to make the discovery process (including refusal motions) more efficient.

[93] If parties are obliged to argue discovery motions within time limits, but can then obtain adjudication of all further disputed questions in writing, the time limit is meaningless. Permitting this practice would create a disincentive to compromise on questions that are the subject of a motion, particularly when motions from both sides are being heard on the same day. If time limits for hearings are treated as what they are, limitations, then both sides are incentivized to cooperate. If there are no practical time limits, there is little incentive.

[94] Not that long ago, the conduct of discoveries and related motions was largely in the hands of the parties. Discoveries probed the furthest reaches of relevance, and discovery motions could stretch out over multiple days. Parties, lawyers, and the Court alike complained about the inefficiencies, both in terms of time and money. Fortunately for everyone involved, those days are long over.

[95] Generally, the Supreme Court has recognized the need for a culture shift in civil litigation, a shift that entails simplifying pre-trial procedures (*Hryniak v Mauldin*, 2014 SCC 7 at para 2). More specifically, Federal Court jurisprudence rebuked "autopsy" forms of discovery (*AstraZeneca Canada Inc v Apotex Inc*, 2008 FC 1301 at para 19). An overall aim of the Guidelines is efficiency in the discovery process. Supplementing long oral motions with longer written motions would be contrary to all these objectives.

[96] Deferring swaths of disputed questions to adjudication in writing is unfair to the parties. On a motion in writing, everyone is aware that they must include everything they want to say in the written representations; that is all the Court will have. Also, the moving party on a motion in writing has a right of written reply (subrule 369(3)). Shifting a substantial part of an oral motion to a motion in writing deprives the parties of the ability to emphasize certain submissions, and make argument in reply.

[97] Supplementing an oral discovery hearing with adjudication in writing is inefficient. During the oral hearing of a discovery motion, parties routinely alter their positions based on rulings received. Often a ruling on one question can lead to a resolution of others. Sometimes it is apparent that certain questions can be answered in a slightly modified way to the mutual satisfaction of the parties, and an agreement reached. None of this can happen on a motion in writing. If a moving party knows there is effectively no time limit, there is no incentive to limit the size of the motion in the first instance, and little incentive to move through the hearing with dispatch. This would encourage a "kitchen sink" approach to discovery motions, one of the things the Guidelines were developed to avoid.

[98] Placing scores of questions in the hands of the presiding judicial officer for determination in writing after a time-limited hearing is unfair to the Court, and touches on the ability of the Court to control its own process. If a time limit is set on a discovery motion, unless otherwise expressly stated, that cannot be read as providing the parties with unlimited judicial time after the hearing to consider what the parties did not make time to address at the hearing. Further, the Court cannot ask questions that may arise from an initial review of the materials; clarification cannot be sought. It would be much more time consuming to adjudicate a discovery motion in writing, compared to an oral hearing. That is particularly the case where the charts of disputed questions span hundreds of pages. Even if the parties had made such a request in November 2023, I would never have agreed to determine all or part of this motion in writing.

[99] Resources of courts are frequently, and fairly, described as scarce. The Court is busy. All litigants expect timely adjudication of their matters. The parties to this proceeding are certainly entitled to their day in court, but are not entitled to take days of someone else's time as well. Particularly in this instance, PMS only got through about half of its categories of questions during oral argument, and could not have expected that it would effectively get days of court time for its discovery motion when everyone else gets half a day.

[100] Other litigants, particularly in proceedings under the Regulations, have had time limits imposed on their discovery motions, and did not have their unresolved questions later determined in writing. Those parties had to make choices as to what to pursue, what to prioritize, and sometimes what to leave behind. Adjudicating a significant part of these motions based on the

written materials alone would be unfair to others who were held to, and worked within, their time constraints.

[101] For all the above reasons, no order will be made in respect of questions that were not addressed at the hearing.

[102] Some of the questions for which no order will be made include a dispute as to whether an undertaking was answered or not. The Janssen motion included disputed undertakings as well. The Court should not be called upon to adjudicate whether undertakings have been answered. As I stated in *Triteq Lock & Security, LLC v Minus Forty Technologies Corp*, 2023 FC 819, an undertaking is a promise or a pledge to do something. If a party voluntarily promises to do something, that promise must be honoured in full and on time. The fact that no ruling was made on the disputed undertakings does not take away from the parties' obligations to fully and completely provide answers to the undertakings they gave.

IV. Costs

[103] The parties agreed that costs of the motion should be in the cause, and such an order will be made.

V. Postscript

[104] A confidential version of this order and reasons was sent to the parties on February 19, 2024 so that submissions on any proposed redactions could be made. The parties

were unable to agree on proposed redactions, and each filed correspondence on February 26, 2024.

[105] The open court principle is jealously guarded. A person asking a court to exercise discretion in a way that limits the open court presumption must establish that: court openness poses a serious risk to an important public interest; the order sought is necessary to prevent this serious risk to the identified interest because reasonably alternative measures will not prevent this risk; and as a matter of proportionality, the benefits of the order outweigh its negative effects. These principles apply to redactions (*Sherman Estate v Donovan*, 2021 SCC 25 ("*Sherman Estate*") at para 38).

[106] Both sides submit that redactions should be made to paragraph 44; the redactions proposed by PMS are broader than those proposed by Janssen.

[107] Janssen's February 26, 2024 correspondence attaches a version of the order and reasons, with the proposed redactions highlighted. No submissions were made as to why the proposed redactions specifically meet the test in *Sherman Estate*, or generally why the benefits of redacting this information outweigh the negative effects. By contrast, the submissions from PMS detail the harm that could arise if the information was made public. I am satisfied that the redactions proposed by PMS are reasonable, and that the benefits of the proposed redactions outweigh the negative effects.

[108] Janssen submits that the identity of the lawyers in paragraph 61 be redacted. PMS disagrees. It is not self-evident why disclosing the names of these individuals would have a negative consequence to Janssen; no submissions were made in this respect. I also note that Ms. Yee is mentioned in an order on PMS' motion to substitute a discovery witness, and no request was made to redact her name from that order. No redactions will be made to paragraph 61.

ORDER in T-732-22

THIS COURT ORDERS that:

1. With respect to the Janssen Inc and Janssen Oncology, Inc discovery:

    a. the defendants shall answer:

        i. items 106–107 (category C);

        ii. items 181–204, 209–217, 222–228, 233–258, question 1749 (category D);

        iii. items 205–208, 218–221, 229–232, and 259–263 (category E2);

        iv. item 147, 149, 155, 164-168, and 176-178 (category F);

        v. items 82–84 (category H); and

        vi. items 37 and 38 (category R).

    b. the defendants are not required to answer:

        i. items 92, 355, and 135–143 (category A);

        ii. items 1-3, 357, 7, 14-15, 356, and 26-27 (category B);

        iii. items 47, 58–61, 63–68, and 70–75 (categories E1 and E3);

        iv. items 103-104, 148, 150-154, 156-159, 161-163, and 169-171 (category F);

        v. items 4-6, 8-13, 17-25, 28, 32-34, 127, and 133 (category G); and

        vi. items 85–86 (category H).

2. With respect to the BTG International Ltd discovery:

    a. the defendant shall answer:

        i. items 5 and 6 (category BTG E).

b. the defendant is not required to answer:

i. items 102-109 (category BTG A);

ii. items 25, 36, 74-75, and 86-88 (category BTG B);

iii. items 117-118 and 121-122 (category BTG C);

iv. items 119-120 and 123-129 (category BTG D); and

v. items 7 and 17 (category BTG E).

3. Costs in the cause.

"Trent Horne"
Associate Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-732-22
STYLE OF CAUSE:	PHARMASCIENCE INC. v JANSSEN INC. ET AL
PLACE OF HEARING:	HELD BY WAY OF VIDEOCONFERENCE
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APPEARANCES:

Marcus Klee Aleem Abdulla Émilie-Anne Fleury Alyssa Gaffen	FOR THE PLAINTIFF
Stephanie Anderson Heather Lindsay Kelly Zhang	FOR THE DEFENDANTS JANSSEN INC. AND BTG INTERNATIONAL LTD
David Yi William Chalmers Fiona Sarazin	FOR THE DEFENDANTS JANSSEN ONCOLOGY INC.

SOLICITORS OF RECORD:

AITKEN KLEE LLP Barristers and Solicitors Ottawa, Ontario	FOR THE PLAINTIFF
BELMORE NEIDRAUER LLP Barristers and Solicitors Toronto, Ontario	FOR THE DEFENDANTS JANSSEN INC. AND BTG INTERNATIONAL LTD

NORTON ROSE FULBRIGHT CANADA LLP
Barristers and Solicitors
Toronto, Ontario

FOR THE DEFENDANTS JANSSEN ONCOLOGY INC.