Federal Court Cour fédérale

Date: 20240529

Docket: T-48-24

Citation: 2024 FC 816

Ottawa, Ontario, May 29, 2024

PRESENT: Associate Judge Trent Horne

BETWEEN:

JANSSEN INC., AND
MITSUBISHI TANABE PHARMA CORPORATION

Plaintiffs

and

JAMP PHARMA CORPORATION

Defendant

PUBLIC ORDER AND REASONS

(Confidential Order and Reasons issued May 29, 2024)

I. Background

[1] This is a motion for samples in an action under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133.

[2] In their statement of claim, the plaintiffs ("Janssen") request, among other things, a declaration that claims 2, 3, and 5-8 of Canadian patent 2,671,357 (the "357 Patent") will be

infringed by or as a result of JAMP Pharma Corporation (“JAMP”) making, constructing, using, importing, or selling a product containing the medicinal ingredient canagliflozin in accordance with abbreviated new drug submission number 267929.

[3] Janssen pleads that the asserted claims claim a crystalline hemihydrate form of the compound canagliflozin. Claim 2 of the 357 Patent claims a crystalline hemihydrate of canagliflozin having a distinct X-ray diffraction pattern, whereas claim 3 claims a crystalline hemihydrate of canagliflozin having a distinct infrared spectrum. Claims 5 to 8 depend on claims 2 and 3.

[4] The action is in its early stages. Documents have been exchanged; examinations for discovery have not taken place.

[5] Janssen asserts that JAMP’s productions are insufficient for it to fully assess whether the claimed polymorph is present in the JAMP active pharmaceutical ingredient (“API”), the JAMP product, or any intermediate canagliflozin solid created in the synthesis and crystallization of the JAMP API.

[6] Janssen wrote to JAMP on February 21, 2024 with a request for production of samples. In particular, Janssen asked for production of canagliflozin API, finished tablets, and excipients used in the production of certain batch numbers. JAMP responded on March 1, 2024, advising that it was considering the request, and sent another email on April 1, 2024 advising that JAMP was not in possession of any unexpired or expired samples of API, tablets or excipients related to

the ANDS. JAMP further advised that it asked its supplier for samples of API and tablets, and was told that tablets existed, but were expired.

[7] Janssen filed its motion for production of samples on April 5, 2024. The production request in the notice of motion is considerably broader than what was in the February 21, 2024 correspondence, and sets out a cascading series of requests. It begins with a request for production of API from certain batches; intermediate canagliflozin solids; tablets; and excipients. In the event those samples are expired according to manufacturer's standards, Janssen requests production of non-expired API, tablets, intermediates and excipients for products made by JAMP's manufacturer according to the same or an equivalent process used in the manufacture of JAMP products, to the extent such material exists. In the event the samples in the first request are expired, and the second set of materials does not exist, Janssen requests production of samples when they become available on an ongoing basis up until the end of trial. Also in the event the samples in the first request are expired, and the second set of materials does not exist, JAMP requests an order requiring JAMP's manufacturer to manufacture and produce samples of the product that would be representative of JAMP's product to be sold in Canada. In the event the samples in the first request are expired, Janssen further requests production of the expired samples plus information relating to the date of designated expiry and storage conditions.

[8] At the time Janssen's motion was filed, the identity of JAMP's manufacturer was unknown. Janssen was unable to move for examination of a non-party under Rule 238 of the *Federal Courts Rules*, SOR/98-106 ("Rules").

[9] After service of Janssen's motion record, JAMP advised in an email dated April 16, 2024 that it was not in possession of any unexpired or expired samples of API, tablets or excipients related to the ANDS. JAMP advised that manufacture of API was expected in [redacted], and that it was willing to produce 20 grams of canagliflozin API, but that, at the request of its supplier, such disclosure would be restricted to certain lawyers.

[10] JAMP submits that this motion is wholly unnecessary because it offered to produce API samples in [redacted], has no unexpired tablets to produce, and that Janssen can make its own canagliflozin tablets if it wants to do so for the purposes of testing.

II. Rule 249

[11] There was no debate as to the applicable Rule or test.

[12] As I said in *Gilead Sciences, Inc v Apotex Inc*, 2022 FC 1460 ("*Gilead*"):

> [21] The parties agree that a request for samples is properly brought as a motion pursuant to Rule 249 of the *Federal Courts Rules*, SOR/98-106, and that the leading authority is *Apotex Inc v Eli Lilly Canada Inc*, 2013 FCA 45 ("*Eli Lilly*").
>
> [22] Rule 249 states that samples may be ordered where it is "necessary or expedient for the purpose of obtaining information or evidence in full."
>
> [23] In *Eli Lilly* (para 8), the Court of Appeal interpreted "necessary" to mean that there is "a reasonable possibility that the proposed test will reveal something useful for the trier of fact (that is something which will assist the trier of fact in determining an issue in the proceeding)." The Court of Appeal further determined (para 10) that the use of the words "necessary or expedient" was intended to give a broad discretion to the Court.
>
> [24] In determining a motion for production of samples, the Court must balance any number of factors relevant to the three main

> interests at play: those of the party requesting the inspection or samples; those of the party in possession of the property concerned; and those of the trier of fact. It is because of this need to balance all the relevant factors that a party must move to get an order under Rule 249, contrary to other discovery Rules (*Eli Lilly* at para 10).
>
> [25] To obtain an order for the production of samples, the moving party is not required to lead evidence that that the proposed tests are the only means to establish their case, or at least that the facts present an exceptional case where such testing is a solution of last resort (*Eli Lilly* at para 11).
>
> [26] Each case turns on its own facts. Here, Apotex makes a number of arguments as to why production should be refused.

[13] The jurisprudence does not generally or presumptively require expert evidence on a Rule 249 motion, and supports a permissive approach to the Rule (*Gilead* at paras 41-44).

III. The Evidence

[14] Janssen's motion is supported by an affidavit of a law clerk that attaches documents and correspondence, and an affidavit from an expert, Dr Adam Matzger.

[15] JAMP filed two affidavits on the motion. The first is an affidavit from a law clerk that attaches documents and correspondence. The second was affirmed by Gerald Soucy, JAMP's vice-president, supply chain. The Soucy affidavit attaches an email exchange between Mr Soucy and JAMP's supplier.

[16] In broad terms, Mr Soucy sent an email to JAMP's supplier asking whether it had any of the samples requested by Janssen in the notice of motion. A response was received within about a day advising what the manufacturer had and what it did not. Janssen complains that the

questions put to the supplier in the email do not completely reproduce or include what is set out in the notice of motion.

[17] Janssen's broader complaint is that the evidence from the supplier is hearsay, and in some instances double hearsay.

[18] The Soucy affidavit is silent as to whether the employee of the supplier was unable or unwilling to provide an affidavit for this motion. The Soucy affidavit does, however, state a belief that the answers found in the email from the supplier are true and accurate because the author of the email has oversight of the relationship between the supplier and JAMP, and is responsible for the JAMP Canada canagliflozin project. Mr Soucy states that the author can provide information regarding the supply of canagliflozin API and canagliflozin tablets to JAMP, as well as the excipients used in the canagliflozin tablets.

[19] None of the affiants were cross-examined.

[20] Rule 81 states:

Content of affidavits	Contenu
81 (1) Affidavits shall be confined to facts within the deponent's personal knowledge except on motions, other than motions for summary judgment or summary trial, in which statements as to the deponent's belief, with the grounds for it, may be included.	81 (1) Les affidavits se limitent aux faits dont le déclarant a une connaissance personnelle, sauf s'ils sont présentés à l'appui d'une requête – autre qu'une requête en jugement sommaire ou en procès sommaire – auquel cas ils peuvent contenir des déclarations fondées sur ce que

	le déclarant croit être les faits, avec motifs à l'appui.
Affidavits on belief	Poids de l'affidavit
(2) Where an affidavit is made on belief, an adverse inference may be drawn from the failure of a party to provide evidence of persons having personal knowledge of material facts.	(2) Lorsqu'un affidavit contient des déclarations fondées sur ce que croit le déclarant, le fait de ne pas offrir le témoignage de personnes ayant une connaissance personnelle des faits substantiels peut donner lieu à des conclusions défavorables.

[21] Since this is not a motion for summary judgment or summary trial, the hearsay evidence in the Soucy affidavit is not presumptively inadmissible. I can, and Janssen urges me to, draw an adverse inference. Janssen urges me to conclude that, in most respects, there is no evidence from JAMP.

[22] As discussed below, I am not satisfied that JAMP has possession of the samples that Janssen is asking for. In the event the motion is granted in whole or in part, all I can order is that JAMP make reasonable inquiries of its supplier to disclose information and materials.

[23] If I were to order that JAMP make a request of its supplier for some or all of the information and material requested in the notice of motion, the request from JAMP would be generally in the form of the email Mr Soucy sent to the supplier on April 16, 2024. In the ordinary course, the supplier would send correspondence in reply, which would be disclosed to Janssen. I cannot oblige a foreign third party to provide a response by way of affidavit, or attend

for cross-examination. The form of response from the supplier included in JAMP's motion record is the same as if an order had been made.

[24] On the face of the email attached to his affidavit, Mr Soucy asked the supplier "[p]lease answer the questions set out below and provide a response by tomorrow. These are needed urgently for the litigation in Canada." Mr Soucy was not cross-examined. I have no basis to assume or believe that there was a further or collateral communication between Mr Soucy and the supplier in respect of whether the requested samples exist. I have no basis to assume or believe that there was a JAMP employee who had better information than Mr Soucy, and was shielded from cross-examination. I am therefore not satisfied that I have a basis to infer that the answers provided by the supplier are incomplete, inaccurate, misleading, or false, or that I should disregard the communication from the supplier.

IV. JAMP Does Not Have Samples to Provide

[25] The motion materials include two emails from counsel for JAMP to counsel for Janssen (April 1 and 16, 2024). Each of these emails advises that JAMP is not in possession of any unexpired or expired samples of API; tablets; or excipients related to the ANDS.

[26] Mr Soucy was not cross-examined. Mr Soucy could have been asked what, if any, canagliflozin API, tablets or excipients JAMP has on hand. Based on the emails in the motion record, and the absence of any contradictory evidence from Mr Soucy, I cannot conclude that JAMP has any canagliflozin API; tablets; or excipients used in the manufacture of those tablets in its possession. Any production must come by way of request to JAMP's supplier.

V. Expired Tablets

[27] The email from JAMP's supplier states that it has 2 bottles of 100 mg canagliflozin, each containing 90 tablets, and 2 bottles of 300 mg canagliflozin, each containing 90 tablets. It appears these tablets expired in November 2023.

[28] A central point of disagreement is whether I should compel JAMP to request production of expired tablets.

[29] Janssen's request in this respect is supported by the Matzger affidavit, which states:

> 37. Additionally, testing of the JAMP API (as well as intermediate canagliflozin solids) and JAMP Product to determine the presence of solid form(s) in the sample, including the 357 Polymorph, can still be conducted even if the samples are "expired" according to JAMP's manufacturing standards and may generate data that is useful to determining whether the 357 Polymorph was present in the sample prior to expiry. Provided that the JAMP API or JAMP Product (in their unexpired state) contain the 357 Polymorph, testing of expired samples may still be capable of detecting the presence of the 357 Polymorph depending on factors including: (i) the amount of time that has passed beyond the expiration date; and (ii) the storage conditions of the sample. It should be noted, however, that the length of time of storage and/or storage conditions of the sample could affect the sample such that testing of the expired sample might not accurately represent the presence of the 357 Polymorph in the sample prior to expiry. An assessment of the extent to which such testing would be useful would depend on the details of the length of time of storage and the storage conditions of the sample.

[30] JAMP argues that the evidence on expired samples is mere speculation and has no probative value; the Matzger affidavit has nothing specific on the physical or chemical properties of canagliflozin; and nothing specific on JAMP's product or manufacturing process.

[31] I am not aware of a decision that considers production of samples that are considered to be expired. *Gilead* did not address this point; as I said at para 29, the notice of motion in that matter expressly requested unexpired samples of the finished product, API and excipients.

[32] Janssen has the burden to show that there is a reasonable possibility that the proposed testing, specifically of expired samples, will reveal something useful for the trier of fact (that is, something which will assist the trier of fact in determining an issue in the proceeding).

[33] JAMP fairly points out that the evidence in the Matzger affidavit is qualified by stating that the testing of expired samples *may* still be capable of detecting the presence of the claimed polymorph. The Matzger affidavit does not discuss how canagliflozin polymorphs deteriorate over time. That said, JAMP did not cross-examine, and did not file contradictory evidence. It is not self-evident that the expired samples, as JAMP submits, have no probative value.

[34] The expired samples may be the best evidence available. While JAMP expects to have canagliflozin API manufactured in [redacted], it is not apparent whether JAMP's supplier will agree to make this API available to Janssen for testing, or whether Janssen will bring a motion for production from a non-party. The offer in the email from JAMP's counsel dated April 16, 2024 to produce 20 mg of canagliflozin API shortly after its manufacture was expressly qualified with a condition that it not be accessible to anyone except a list of lawyers. It is not at all clear how an offer to provide samples to lawyers, but not experts for testing, would assist in assessing the X-ray diffraction pattern and infrared spectrum of the canagliflozin API manufactured for JAMP.

[35] On the motion, JAMP submitted that it was prepared to make inquiries with its supplier to make the API available to experts, but that inquiry was not made before the hearing, and the supplier's position in this respect is unknown.

[36] There is nothing in the Soucy affidavit, or the emails attached to it, that confirms when the canagliflozin API will be ready, or any willingness of the supplier to provide it to Janssen under different conditions, particularly for purposes of testing. In the absence of any assurance that API will be made available to Janssen, or on what terms, I will order production of expired tablets.

[37] In making this order, I note two things. First, I acknowledge that production of expired samples may increase the issues that will be addressed in the expert reports. If the experts disagree on whether the expired tablets are suitable for the purposes of assessing infringement, or whether data derived from expired tablets is reliable, that will add time and expense to the proceeding. To the extent it is ultimately determined that expired tablets have no probative value in the infringement analysis, or served to unnecessarily complicate the proceedings, that can be addressed in costs.

[38] Second, this outcome does not invite or expect duelling expert evidence on Rule 249 motions. As I said in *Gilead* at para 45:

> [45] Proceedings under the Regulations run on a compressed schedule because of the 24-month statutory stay. In light of a permissive approach to Rule 249, and the nature of proceedings under the Regulations, it should not be generally expected that motions for production of samples will include expert evidence, or invite competing expert evidence in reply. This is particularly the case when

> the Court's Timetable Checklist for proceedings under *the Patented Medicines (Notice of Compliance) Regulations* generally expects motion for production of generic samples at an early stage, even before an oral discovery plan is finalized. I cannot accept that a motion for samples, particularly when there are live issues of infringement of claims including DSC and XRPD values, should routinely invite competing expert evidence at an early stage.

VI. Further Tablets

[39] JAMP's supplier was asked if it had any unexpired canagliflozin tablets from the batches not referenced in JAMP's regulatory submission, but made by the same process. The answer was no.

[40] Janssen submits that that the question put to JAMP's supplier was not the same as what is set out in the notice of motion.

[41] The relief sought in the notice of motion includes a request for tablets "manufactured by JAMP's manufacturer according to the same or an equivalent process used in the manufacture of the JAMP Product, to the extent such material exists." The question JAMP asked of its supplier was "[d]o you have any unexpired canagliflozin tablets from the batches not referenced in JAMP's regulatory submission but made by the same process"? The answer was "no we do not."

[42] In argument, Janssen emphasized that it was seeking production of tablets manufactured by the supplier for third parties by the same or equivalent process as used for JAMP.

[43] I am not satisfied that the supplier has non-expired canagliflozin tablets that were manufactured for JAMP.

[44] Janssen relies on an unreported decision in *Eli Lilly and Company v Apotex Inc*, a January 21, 2000 decision of Justice Hugessen in Court file T-1321-97, then sitting as a judge of the Federal Court of Canada. In considering production of documents from Apotex's offshore suppliers, he determined, at para 5, that "[i]t seems to me that where one may reasonably expect, because of a relationship existing between a party and some third-party, that a request for information will be honored. It is proper to require that party to make such a request."

[45] The notice of motion asks for tablets made by the "same or an equivalent" process. What Janssen means by an "equivalent process" is not exactly clear, and could be the subject of debate. I have no expectation that JAMP's supplier would readily provide details as to who its other customers are, or what any equivalent process is, since that would most likely constitute third party confidential information. I am therefore not satisfied that any such request by JAMP to it supplier would be honoured. No order in this respect will be made.

VII. API

[46] In an email from counsel to counsel dated April 16, 2024, counsel for JAMP advised that canagliflozin API was expected to be manufactured in [redacted].

[47] JAMP submitted that it was prepared to make inquiries of its supplier to produce a sample of canagliflozin API for the purposes of testing by experts. I will so order.

VIII. Intermediates

[48] The email from the manufacturer advises that there is [redacted] of the canagliflozin solid before the final API is made.

[49] Janssen submits that, particularly in the absence of an affidavit from the supplier which would provide an opportunity to cross-examine, there is no way to decipher what "[redacted]" means. Based on the information in the motion materials, I am not satisfied that there is an intermediate to produce, or that if JAMP was ordered to make an inquiry that the answer from the supplier would be any different from the one already received.

[50] Examinations for discovery have yet to be conducted. Doubtless the details of the manufacturing process will be explored. If there is evidence that intermediates are in fact kept by the supplier, the issue may be revisited. In the absence of such evidence now, no order will be made in respect of intermediates.

IX. Excipients

[51] The email attached to the Soucy affidavit advises that the manufacturer does not have any of the solid or liquid excipients that were used in the making of the specific batches for the JAMP submission. I am unwilling to draw an adverse inference and conclude that samples of excipients used in batches that were likely made more than two years ago are currently in the hands of JAMP's supplier.

[52] The email attached to the Soucy affidavit advises that the excipients (which are listed in detail) can be purchased from excipient manufacturers.

[53] If Janssen is of the view that it needs certain excipients for the purposes of tablet manufacture and/or testing, there is no indication that Janssen is unable to acquire the excipients and make its own tablets.

[54] I am not satisfied that any excipients sourced from JAMP's supplier would be any better or different from what Janssen can obtain on its own. No order in this respect will be made.

X. Rolling Production

[55] Janssen clarified in argument that it is not seeking rolling production from every batch of API, intermediates, or tablets that may be manufactured, rather it seeks an order that ensures that it receives one sample from each category.

[56] An order will be made in respect of the API that is expected to be made [redacted], so no further order for API is necessary.

[57] As set out above, I am not satisfied on the evidence presently available that intermediates are separately maintained by the manufacturer, so no order in this respect will be made.

[58] As for tablets, there is no evidence from Mr Soucy, by cross-examination or otherwise, that provides a basis to assume or conclude that JAMP's will have canagliflozin tablets

manufactured, particularly before expert reports are exchanged. I have a particular concern as to making an order, as Janssen requests, for production “up until the end of trial”, specifically compelling production after the exchange of expert evidence.

[59] To the extent Janssen learns on discovery that canagliflozin tablets are, or will be, manufactured within a period whereby testing could be conducted for trial, the issue may be revisited. But without such an indication, and without support in the jurisprudence under Rule 249 for a rolling order, no such order will be made now, but without prejudice to exploring manufacture on discovery and making a further request in the event it is established that tablets do, or will, exist.

XI. Manufacture

[60] One of Janssen’s alternative requests in the notice of motion is to compel the manufacturer of the JAMP product to manufacture certain samples.

[61] I find no support in the Rules or the jurisprudence for this request.

[62] Rule 249 is directed to inspection of property, *ie* something that exists. On its face, the Rule does not contemplate compelling a party to make something. I am not aware of any authority that would support Janssen’s request in this respect, and it will be dismissed.

XII. Costs

[63] The Court has full discretionary power over the amount and allocation of costs (subrule 400(1)).

[64] At the conclusion of the hearing, Janssen submitted that costs should be fixed at $2,720.00 (the amount fixed in *Gilead*), payable forthwith. JAMP agrees with the amount of costs, but submits that they should be payable in the cause.

[65] Costs of a motion are awarded forthwith when it should not have been brought or opposed (Rule 401). Success on the motion was divided. While some of the relief sought by Janssen was granted, other elements of the motion were over-reaching, particularly in respect of the request that JAMP's manufacturer to make tablets for Jansen.

[66] There will be no order as to costs.

XIII. Postscript

[67] A confidential version of this order and reasons was sent to the parties on May 17, 2024 so that submissions on any proposed redactions could be made.

[68] The parties sent an email to the Court on May 24, 2024 attaching a copy of the draft order with proposed redactions to 23 paragraphs. The proposed redactions were substantial. No submissions were provided. I issued a direction the same day stating that it was not self-evident that the highlighted portions of the order and reasons should be redacted, and that submissions,

particularly to address the test in *Sherman Estate v Donovan*, 2021 SCC 25 ("*Sherman Estate*"), would be required.

[69] 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* at para 38; *Pharmascience Inc v Janssen Inc*, 2024 FC 335 at para 105).

[70] It is important that redactions to orders do not impede public understanding of the case (*Concord Premium Meats Ltd v Canada (Food Inspection Agency)*, 2020 FC 1166 at para 128), the intelligibility of the decision (*Apotex Inc v Janssen Inc*, 2022 FC 1476 at para 3), and the ability to know the facts of the case (*Corus Entertainment Inc v Canada (Attorney General)*, 2020 FC 1064 at para 71).

[71] JAMP served and filed submissions on May 28, 2024. The request for redactions was substantially narrower than what was initially proposed. JAMP submits that the precise timing of manufacture of canagliflozin API (month, year) should be redacted on the basis that it relates to JAMPS's pre-launch product planning, and that a technical detail from the manufacturing process should be redacted on the basis that the process constitutes confidential information of JAMP's supplier.

[72] Unlike the circumstances in *7299362 Canada Inc (Alexa Translations) v Amazon.com Inc*, 2024 FC 69, Janssen did not oppose the request to redact this information.

[73] Having reviewed JAMP's submissions, I am satisfied that these narrow and limited redactions satisfy the test in *Sherman Estate*, and would not impede public understanding of the case, the intelligibility of the decision, or the ability to know the facts of the case.

ORDER in T-48-24

THIS COURT ORDERS that:

1. The defendant shall make reasonable efforts to obtain from its supplier and produce to the plaintiffs 90 (ninety) 100 mg canagliflozin tablets, and 90 (ninety) 300 mg canagliflozin tablets manufactured for the defendant for the purposes of testing by the plaintiffs' expert(s).

2. For the tablets described in paragraph 1 of this order, the defendant shall make reasonable efforts to obtain from its supplier information detailing (i) the designated expiration date of each sample; and (ii) the storage conditions of each sample, including but not limited to location, temperature, humidity, and type of container the sample has been stored in.

3. The defendant shall make reasonable efforts to obtain from its supplier and produce to the plaintiffs 20 mg of canagliflozin active pharmaceutical ingredient manufactured for the defendant for the purposes of testing by the plaintiffs' expert(s).

4. The plaintiffs shall bear all costs associated with shipping and handling of the samples.

5. The plaintiffs' motion is otherwise dismissed.

6. There is no order as to costs.

"Trent Horne"
Associate Judge

FEDERAL COURT

SOLICITORS OF RECORD

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