Federal Court  Cour fédérale

Date: 20230825

Docket: T-1831-22
T-1842-22

Citation: 2023 FC 1149

Ottawa, Ontario, August 25, 2022

PRESENT: The Honourable Mr. Justice Southcott

Docket: T-1831-22

BETWEEN:

BOEHRINGER INGELHEIM (CANADA) LTD.
AND BOEHRINGER INGELHEIM
INTERNATIONAL GMBH

Plaintiffs /
Defendants by Counterclaim

and

SANDOZ CANADA INC.

Defendant /
Plaintiff by Counterclaim

Docket: T-1842-22

AND BETWEEN:

BOEHRINGER INGELHEIM (CANADA) LTD.
AND BOEHRINGER INGELHEIM
INTERNATIONAL GMBH

Plaintiffs /
Defendants by Counterclaim

and

SUN PHARMA CANADA INC.

Defendant /
Plaintiff by Counterclaim

ORDER AND REASONS

I. Overview

[1] This decision addresses motions brought in two actions under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-113 [Regulations]. In each action, the Plaintiffs, Boehringer Ingelheim (Canada) Ltd. and Boehringer Ingelheim International GMBH, allege that the Defendants (Sandoz Canada Inc. in Court File T-1831-22, and Sun Pharma Canada Inc. in Court File T-1842-22) would infringe or induce the infringement of the asserted claims of six patents by the making, constructing, using, and/or selling of their orally administered empagliflozin tablets.

[2] In each of these actions, the Defendant moves for an Order requiring the Plaintiffs to serve fact evidence pertaining to the invention story of their patents, including any inventor evidence, prior to the date by which the Defendant's in-chief expert reports on invalidity are to be served.

[3] As explained in greater detail below, these motions are dismissed, because the Defendants have not made a compelling case for the Court to vary the usual order for the introduction of evidence.

II. Background

[4] The Plaintiffs market and sell the anti-diabetic drug empagliflozin as JARDIANCE and listed six patents on the Patent Register in respect of JARDIANCE.

[5] Each of the Defendants seeks to market a generic empagliflozin product and accordingly served Notices of Allegation [NOAs] on the Plaintiffs. In those NOAs, the Defendants alleged common invalidity arguments against all six patents, including allegations of obviousness, lack of utility, and overbreadth. In these allegations, the Defendants implicated the inventors' courses of conduct and what the inventors knew and when.

[6] In response to the NOAs, the Plaintiffs issued Statements of Claim against the Defendants, asserting infringement of over 100 claims across the six patents in issue. In turn, in their Statements of Defence and Counterclaims, the Defendants again asserted invalidity as well as grounds of non-infringement. In their Replies and Defences to Counterclaims, the Plaintiffs denied the Defendants' characterizations and put the Defendants to the strict proof of their pleas, including on invalidity issues.

[7] These actions are being case managed, initially by Associate Judge Horne and currently by Associate Judge Duchesne. Pursuant to a Scheduling Order dated January 24, 2023 [Scheduling Order], issued through the case management process, the parties were required to exchange affidavits of documents and schedule 1 productions by February 10, 2023, and complete examinations for discovery by June 9, 2023. The Scheduling Order also prescribes

deadlines for steps leading to motions related to the examinations for discovery, to be heard on August 11, 2023. Any answers ordered on those motions are to be delivered by August 30, 2023. The parties may then seek leave for a second round of discoveries and, if leave is granted, are required to complete those discoveries by September 29, 2023.

[8] The Scheduling Order also prescribes deadlines for the filing of expert reports. The Plaintiffs' expert reports on infringement and the Defendants' expert reports on validity are to be served by December 8, 2023. The Plaintiffs' responding expert reports on validity and the Defendants' responding expert reports on infringement are to be served by April 5, 2024. Any proposed reply expert reports are to be delivered, and any associated motions for leave to file reply expert evidence are to be served and filed, by April 19, 2024.

[9] These actions are scheduled for consecutive trials, before me as trial judge, commencing on May 27, 2024.

[10] The Defendants have a number of concerns about the level of disclosure they have received through the Plaintiffs' documentary productions and other events leading up to the discovery examinations. Some of these concerns resulted in what the Defendants describe as "omnibus motions", heard by Associate Judge Duchesne on April 6 and 24, 2023. The decisions from those motions remained under reserve at the time of my hearing of the present motions on July 27, 2023. The first round of discovery examinations has been completed, and the Defendants have also brought motions seeking to compel answers that were refused during those

discoveries, to be heard by Associate Judge Duchesne on August 18, 2023, and possibly August 21, 2023.

[11] The Defendants also brought motions for letters of request for eight inventors who are not employees of the Plaintiffs. The Plaintiffs did not oppose that motion. On June 8, 2023, the Court issued these letters of request, which the Defendants were acting upon at the time of the hearing of the present motions.

[12] The present motions do not seek adjudication of the sufficiency of the Plaintiffs' efforts to meet their production or discovery obligations. Rather, the Defendants describe the concerns referenced above as fuelling pre-existing concerns that the Plaintiffs will disclose either more facts or a newly curated factual invention story after in-chief expert reports are filed and shortly before trial. On this basis, the Defendants seek in the present motions an Order requiring that the Plaintiffs serve fact evidence pertaining to the invention story of their patents (including any inventor evidence) by November 8, 2023, which is one month prior to the December 8, 2023 deadline for serving in-chief expert reports (including the Defendants' expert reports on validity).

III. Issue

[13] The sole issue in these motions is whether the Court should exercise its discretion to order that the Plaintiffs serve fact evidence pertaining to the invention story of their patents one month prior to the date by which the Defendants' in-chief expert reports on validity are to be served.

IV. Analysis

A. *The Court's Discretion to Grant the Requested Relief*

[14] As a starting point in analysing the issue raised by these motions, I note that the parties agree that the Court has the authority, in the exercise of its discretion, to grant the requested relief. They do not agree on the principles that should govern that exercise of discretion.

[15] In support of the Court's authority to grant these motions, the Defendants rely on provisions of the *Federal Courts Rules*, SOR-98/106 [Rules] and the *Case and Trial Management Guidelines for Complex Proceedings and Proceedings under the PM(NOC) Regulations*, October 16, 2020 as amended [Guidelines]. Among other provisions of the Rules, the Defendants reference provisions guiding the Court in the exercise of its case and trial management functions and the management of evidence at trial, including Rule 285 (which permits the Court at any time to order that any fact be proven by affidavit) and Rule 286 (which permits the Court to order, before trial, that evidence of any fact be given at the trial in such a manner as may be specified in the order). Similarly, paragraph 41 of the Guidelines provides that the parties will ordinarily be expected to adduce evidence-in-chief by way of affidavit, with the Court to fix a schedule for service and filing of such affidavit evidence.

[16] The Defendants also reference Rule 3 and section 6.09 of the Regulations as informing the Court's exercise of its discretion under the powers identified above. Rule 3 provides that the Rules are to be interpreted and applied so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits. Section 6.09 of the Regulations

requires every first person, second person and owner of a patent to act diligently in carrying out their obligations under the Regulations and to reasonably cooperate in expediting any action under subsection 6(1) or counterclaim under subsection 6(3) to which they are a party.

[17] Finally, the Defendants refer the Court to jurisprudence that developed under the Regulations as they existed prior to the 2017 amendments [Pre-2017 Regulations], in which the Court considered and sometimes granted requests to change the usual order and/or timing for the introduction of evidence (see, e.g., *Purdue Pharma v Pharmascience Inc*, 2007 FC 1196 at paras 3-8; *Eli Lilly v Novopharm*, 2008 FC 875 at para 16; *Lundbeck Canada Inc v Ratiopharm Inc*, 2008 FC 579; *Biovail Corp v Canada (Health)*, 2008 FC 1162; *Merck-Frosst v Canada (Health)*, 2009 FC 914; *Janssen-Ortho Inc v Apotex Inc*, 2010 FC 81; *Astrazeneca Canada Inc v Ranbaxy Pharmaceuticals Canada Inc*, 2013 FC 232; *Fournier Pharma Inc v Canada (Health)*, 2012 FC 740; *Pfizer Canada v Apotex Inc*, 2013 FC 1036 [*Pfizer*]).

[18] The Plaintiffs accept that the Court has the authority to grant the requested relief. While they note that Rule 274(1) prescribes the usual sequence of evidence at trial, including requiring a plaintiff to adduce its evidence before that of the defendant, this Rule expressly notes that this sequence is subject to the Court directing otherwise.

[19] Like the Defendants, the Plaintiffs refer the Court to decisions under the Pre-2017 Regulations. The Plaintiffs argue that in the exercise of its discretion, the Court should be guided by principles expressed in such decisions to the effect that any reversal of the sequence of

evidence should be granted only in special or exceptional circumstances (see, e.g., *Pfizer* at para 1; *Abbott v Canada (Health)*, 2007 FC 1291 at para 17).

[20] In the absence of a dispute as to the existence of the authority upon which these motions rely, I need not analyse that point further. However, in considering principles that should inform my exercise of that discretionary authority, I am reluctant to place any significant reliance on decisions made under the Pre-2017 Regulations. As will be further referenced later in these Reasons, the litigation process created by the Pre-2017 Regulations varied significantly from the process that exists under the current Regulations, and I read the jurisprudence that developed under the Pre-2017 Regulations as responding to the peculiarities of the earlier process. I therefore decline to adopt the Plaintiffs' proposition that the Court should vary the usual sequence or timing of trial evidence only in special or exceptional circumstances.

[21] Rather, I agree with the Defendants that my exercise of discretion should be informed by the principles found in Rule 3 and section 6.09 of the Regulations, as set out earlier in these Reasons. Consistent therewith, my analysis will consider the parties' arguments that, broadly speaking, focus on whether the interests of securing a just and efficient determination of this proceeding favour granting or denying the requested relief.

B. *Relevance of Evidence of Inventors' Course of Conduct*

[22] Before turning to those arguments, I will address briefly the relevance of the evidence to which these motions relate. The factual evidence that the Defendants seek to have served by the Plaintiffs, prior to the deadline for the Defendants' service of their expert reports on validity,

relates to the inventors' course of conduct and/or work undertaken by them. The Defendants argue that such evidence is clearly relevant to the issues of obviousness, utility including lack of a sound prediction of utility, and overbreadth, which issues they raise by counterclaim in the actions in challenging the validity of the patents.

[23] Other than in relation to obviousness, I do not understand the Plaintiffs to take issue with the Defendants' position that such evidence is relevant to the invalidity issues.

[24] In relation to obviousness, the Defendants rely on authorities including *Apotex v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*] at paragraphs 69 to 71, for the proposition that the inventors' actual course of conduct is relevant to the obviousness analysis. The Plaintiffs respond that *Sanofi* supports a conclusion only that the inventors' course of conduct may factor into the obviousness analysis. Based on *Sanofi*, the Plaintiffs submit that the inventors' course of conduct is not a mandatory factor in the obviousness analysis and that its relevance is contingent on the establishment of various foundational aspects.

[25] To the extent the Plaintiffs seek to oppose these motions in part through questioning the relevance of the invention story evidence, I find no merit to that position. It is undisputed that such evidence is relevant to some of the invalidity issues, as well as potentially being relevant to the issue of obviousness.

C. *Securing a Just and Efficient Determination of this Proceeding*

[26] I therefore turn to the parties' arguments on whether the interests of securing a just and efficient determination of this proceeding favour granting or denying the requested relief.

[27] In relation to considerations of justice or fairness, the Defendants argue that they would be prejudiced by the conventional order of evidence. As previously noted, Rule 274(1) provides that, unless the Court otherwise directs, a plaintiff must adduce its evidence before that of the defendant. It is common ground between the parties that the patent validity issues arise from the Defendants' counterclaim such that, absent intervention by the Court, the Defendants (as plaintiffs by counterclaim) will be required to adduce their evidence on these issues before the Plaintiffs (see also *Western Oilfield Equipment Rentals Ltd v M-I LLC*, 2021 FCA 24 at para 152). The Defendants argue that, as they are strangers to the invention story, it is an incredibly difficult or impossible task to expect them to adduce this aspect of the factual evidence.

[28] Before turning to my analysis of the Defendants' argument, I note their explanation at the hearing of these motions that it is only service (not filing) of the Plaintiffs' factual invention story evidence that the Defendants wish to position in advance of service of the Defendants' in-chief validity reports. In my view, in the circumstances under consideration in these motions, the distinction between service and filing is not particularly significant. As observed earlier in these Reasons, paragraph 41 of the Guidelines provides that the parties will ordinarily be expected to adduce evidence-in-chief by way of affidavit. As such, the relief the Defendants seek in these motions would require the Plaintiffs to generate their factual evidence, in the form in which it will ultimately be filed with the Court, by the deadline the Defendants seek. While that evidence

would not yet have been filed with the Court, it would effectively be fixed (subject to any leave the Court may subsequently grant to file reply evidence) by the time of the service deadline.

[29] Turning to the Defendants' argument, I appreciate that the facts surrounding the invention are best known to the Plaintiffs (or the individual inventors) rather than the Defendants. However, as the Plaintiffs submit, such circumstances are typical in patent litigation and indeed are not unique to patent law, as litigation will often involve facts known best or only to a defendant, notwithstanding that it is the plaintiff which must first advance its case at trial.

[30] The Plaintiffs refer the Court to Sankoff, *Law of Witnesses and Evidence in Canada*, (Thomson Reuters, 2023), at s 4.1, which observes that burdens of proof have evidentiary and procedural ramifications that favour the party that is not fixed with the burden. I agree with the Plaintiffs that these ramifications are inherent in the trial process and do not constitute injustice, unfairness or prejudice to a litigant that may bear the burden of proof without being directly privy to the facts necessary to discharge that burden. As the Plaintiffs submit and the Defendants acknowledge, the parties are not aware of any patent validity action where the Court has concluded that the usual trial process would cause prejudice and has therefore ordered the patent owner to adduce its fact witness affidavit evidence in advance of the expert reports of the party seeking to impeach the patent.

[31] I also agree with the Plaintiffs that in large measure the answer to the Defendants' fairness concern, about being required to adduce evidence of facts to which they are strangers, lies in the documentary production and discovery processes provided by the Rules. The role of

these processes is to allow a party to gather facts and inform itself of the positions of the other side so as to define the issues and avoid surprise at trial (see, e.g., *Canada v Lehigh Cement Limited*, 2011 FCA 120 at para 30; *Bauer Hockey Ltd v Sport Maska Inc*, 2020 FC 212 at para 4).

[32] The current patent litigation process prescribed by the Regulations takes place by action. This is one of the aspects of the current process that differs significantly from the process under the Pre-2017 Regulations, which required litigation by application. In contrast to the application process, the current process benefits from the production and discovery mechanisms that the Rules make available to parties to an action. Indeed, as the Plaintiffs emphasize, a party challenging the validity of a patent benefits from an additional discovery mechanism that is not necessarily available in all actions. Rule 237(4) provides that, where an assignee is a party to an action, the assignor may also be examined for discovery. As a result of this provision, litigants such as the Defendants may discover inventors, in addition to conducting discovery of the corporate representative selected by the opposing party as contemplated by Rule 237(1).

[33] As identified in the Background section of these Reasons, the Defendants have had the benefit of multiple production and discovery processes provided by the Rules, as well as recourse to the Court to raise concerns about the Plaintiffs' compliance with their obligations under those processes. I appreciate that the Defendants express multiple concerns about the Plaintiffs' compliance. However, as the Defendants acknowledged in their submissions, the motions presently before the Court do not seek adjudication of the sufficiency of such compliance.

[34] I have also considered the Defendants' argument that the need for their requested relief arises from the Plaintiffs having maintained an avowed intention to change its invention story in response to the Defendants' expert reports in-chief. The Defendants' argument relies on a February 20, 2023 email from the Plaintiffs' counsel to the Defendants' counsel, which identified the Plaintiffs' position on a number of procedural issues that had arisen through the case management process and communications between counsel. That email included the following paragraph, related to the identification of a deadline in the pretrial schedule beyond which no further answers or documents could be provided:

> While we are further considering your other positions, I note that we do not agree with your position regarding the document and answer date. Your request is not contemplated by the Court's timetable, **and our proposal of a deadline commensurate with responding expert reports ensures that both parties have the ability to respond to the other side's case**. The extreme breadth of Sun and Sandoz's alleged prior art relied on makes anticipating your clients' invalidity positions virtually impossible. If, following the exchange of first round expert reports, a new document or answer is provided that could not have been anticipated, then there may be a case for reply evidence.
>
> [Defendants' emphasis]

[35] The Defendants take the position that the language highlighted in the above paragraph represents an expressed intention on the part of the Plaintiffs to change or inappropriately curate their factual evidence related to the invention story in response to the Defendants' in-chief expert reports on validity. I agree with the Plaintiffs that this language does not read as the Defendants suggest. There is a difference between a party changing its position (or, to the extent this is what the Defendants are suggesting, altering its evidence) and a party identifying the evidence that it requires to respond to the particular evidence advanced by its opponent.

[36] Each party invokes the frequently cited metaphor of identifying "where the shoe pinches", i.e., determining with precision the particular issues between the parties, as supporting its position that the other should lead its evidence first. However, I agree with the Plaintiffs that, before the Defendants serve their validity reports, it is difficult to see how the Plaintiffs can know the substance of the Defendants' invalidity case and therefore know what factual evidence surrounding the invention story they may wish to adduce in response to that case.

[37] The Defendants refer the Court to the specifics of their invalidity pleadings, and the Plaintiffs argue the allegations therein are not specific enough for them to know how to respond. While some of the invalidity allegations in the Defendants' pleadings are expressed with more precision than others, I do not accept the Defendants' assertion that the Plaintiffs have expressed an intention to engage in an inappropriate litigation tactic by wanting to understand the actual evidence advanced by the Defendants in support of their invalidity case before providing their own factual evidence in response.

[38] I have also considered the Defendants' submission that the litigation resulting in Justice Furlanetto's recent trial decision in *Merck Sharp & Dohme Corp v Pharmascience Inc*, 2022 FC 417 [*Sitagliptin*] demonstrates the sort of prejudice that can result when the evidence of a patent owner's invention story is served only after expert invalidity reports have been exchanged. I do not read *Sitagliptin* as supporting the Defendants' position. I accept that, in that case, the party challenging the validity of the relevant patents (Pharmascience) raised various objections to inventor evidence adduced by the patent owner (Merck) at trial. However, as the Plaintiffs

submit, Justice Furlanetto ruled on those objections in *Sitagliptin* and rejected most of them (at paras 43 to 63).

[39] Indeed, the Court in *Sitagliptin* concluded that the impugned evidence was relevant to the obvious-to-try analysis and the inventor's course of conduct and that, while all the details of the invention story were not specifically pleaded in Merck's reply, the inventor's evidence was clearly responsive to the issues in the proceeding and to Pharmascience's evidence on the invalidity issues (at para 57). If anything, this reasoning favours affording the Plaintiffs in the case at hand the opportunity to adduce invention story evidence in response to the Defendants' invalidity evidence.

[40] Finally, before leaving the subject of justice/fairness, I note the Plaintiffs' submission that the Defendants have not adduced any evidence in these motions in support of their argument that, in the absence of the requested relief, it would be very difficult or impossible for them to discharge their burden of proof on the invalidity issues. The Defendants similarly argue that the Plaintiffs' submissions focus on issues of efficiency and waste and that the Plaintiffs have not adduced evidence, or indeed argued, that they would suffer injustice if the Court were to grant the requested relief. However, as the Plaintiffs submit, it is the Defendants that bear the burden on these motions.

[41] In summary, considerations of justice, fairness or prejudice do not favour granting the Defendants' motions.

[42] Turning to efficiency, the Defendants submit that the relief sought in these motions would facilitate a more efficient and less expensive outcome for the parties. The Defendants argue that they would then know the objective facts pertaining to key issues in advance of providing their in-chief validity evidence. Citing again their interest in knowing "where the shoe pinches", the Defendants submit that their experts would be better able to focus their opinions on obviousness, inutility, sound prediction and overbreadth, and that the Defendants would be able to make better informed choices in the pursuit of further avenues to obtain missing facts through adjudication of objections, second round discovery, notices to admit, and letters of request. They also argue that the Court would benefit from a more coherent, less fractious factual story, based on which both parties can develop their expert evidence.

[43] In response, the Plaintiffs argue that the Defendants' proposal is wasteful, because the Plaintiffs would be guessing as to the substance of the invalidity case that the Defendants will actually advance. This will necessitate the Plaintiffs wastefully introducing unnecessary evidence in order to address every contingency of which they might be able to conceive based on the Defendants' pleadings.

[44] The Plaintiffs also point out that accelerating the introduction of their inventor and invention story affidavits to so far in advance of trial would bring that evidence out of step with other pretrial evidentiary steps. They note that evidence as to the invention story is not limited to affidavits but can arrive through other means such as responding read-ins, documents introduced as business records, joint statements of facts, and requests to admit. Assuming that deadlines for these steps will be set in the usual manner for dates shortly before the commencement of trial,

proximate to when fact witness will-say statements or affidavits are traditionally served, the Plaintiffs argue that it would not be logical or efficient to accelerate the dates for affidavit evidence.

[45] The parties' arguments on efficiency are similar to those canvassed above in relation to prejudice. Again, for substantially the same reasons as explained in my prejudice analysis, I find the Plaintiffs' arguments the more compelling. I am not convinced that the interests of efficiency favour requiring the Plaintiffs to serve factual evidence relevant to patent validity before they have the benefit of the Defendants' expert reports through which the Plaintiffs can develop an understanding of the Defendants' case on invalidity. As for the Defendants' argument as to the advantage of both parties being able to develop their expert evidence with the benefit of the same invention story, it is the production and discovery mechanisms that the Rules afford to the Defendants that are intended to achieve this result.

[46] For the reasons canvassed in the above analysis, my Order will dismiss the Defendants' motions.

V. Costs

[47] Each of the parties requests that, in the event of its success in these motions, the Court order the opposing party to pay a lump sum costs award of $7500.00. The only difference in the parties' costs positions is that the Plaintiffs argue that such costs should be made payable forthwith. In support of this position, the Plaintiffs argue that the within motions should never have been brought. They submit that the motions are speculative and baseless and that, if they

were to be pursued, they should have been presented by the Defendants nine months ago when the Defendants first raised their concerns about the sequence of evidence, rather than waiting until the middle of discovery examinations.

[48] I find no basis to order the costs payable forthwith. This Court has ordered costs payable forthwith in circumstances where a litigant's behaviour in interlocutory motions has been frustrating to the efficient advancement of a proceeding (see, e.g. *Triteq Lock & Security, LLC v Minus Forty Technologies Corp.*, 2023 FC 819; *Yelda Haber Ve Görsel Yayincilik AS v GLWiZ Inc*, 2023 FC 778). I do not consider the Defendants' motions to be of this nature. As for the Plaintiffs' argument that the Defendants delayed in bringing these motions, I note the Defendants' submission that the dates for the hearing of these motions and the service and filing of motion materials was set by the Court in its January 24, 2023 Scheduling Order. I find no merit to the Plaintiffs' delay argument.

[49] However, I accept that $7500.00 is an appropriate costs award, which shall be paid by the Defendants to the Plaintiffs. My Order will so provide.

ORDER IN T-1831-22 and T-1842-22

THIS COURT ORDERS that:

1. The Defendants' motions are dismissed.

2. The Defendants shall pay the Plaintiffs costs of these motions in the lump sum amount of $7500.00.

"Richard F. Southcott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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