Federal Court Cour fédérale

Date: 20230501

Docket: T-2118-22

Citation: 2023 FC 629

Ottawa, Ontario, May 1, 2023

PRESENT: The Honourable Madam Justice Furlanetto

BETWEEN:

PFIZER CANADA ULC AND PFIZER INC.

Plaintiffs

and

UNIQURE BIOPHARMA B.V.

Defendant

ORDER AND REASONS

[1] This motion, brought by the Defendant, uniQure BioPharma BV [uniQure], seeks to stay the present patent impeachment action [Action] on the basis that uniQure's Canadian Patent No. 2,737,094 [Patent] is being re-examined, at its own request, and in the process that the scope of claims and the issues in the proceeding may be narrowed.

[2] The Patent, entitled "Factor IX Polypeptide Mutant, its Uses and a Method for its Production", relates to a modified Factor IX protein that can be used in gene therapy to treat

hemophilia B. Factor IX [FIX] is a protein (or polypeptide) that is critical to the formation of blood clots, which is deficient in patients with hemophilia B. The Patent purportedly covers uniQure's HEMGENIX® gene therapy product, which has obtained regulatory approval in the United States and conditionally in Europe.

[3] In the underlying action [Action], Pfizer Canada ULC and Pfizer Inc [collectively Pfizer] seek to impeach the Patent, asserting that certain of its claims are anticipated, obvious, lack utility and/or are overly broad and comprise unpatentable subject-matter. They also assert that there has been a material misrepresentation as to inventorship under section 53 of the *Patent Act*, RSC 1985, c P-4 [Patent Act].

[4] For the reasons set out further below, it is my view that upon considering the factual context, including the length and purpose of the requested stay and the potential impact of the re-examination on the Action, along with what would constitute the just, most expeditious, and least expensive determination of the proceeding on its merits, and the issue of prejudice, it is not in the interests of justice to grant the stay requested.

I. Background

[5] The Action was commenced on October 14, 2022 and challenges the validity of claims 1-2 and 4-15 of the Patent [Impugned Claims]. The Impugned claims include claims to *inter alia*, a modified FIX polypeptide for use in a FIX replacement therapy, and a nucleic acid encoding the modified FIX polypeptide for use in gene therapy, along with pharmaceutical compositions comprising them.

[6] The Patent has three independent claims (claims 1, 7 and 16), each of which requires the modified FIX polypeptide to have at least 70% sequence identity with the peptide sequence of SEQ ID NO:1 (the immature unmodified FIX polypeptide sequence) or SEQ ID NO:2 (the mature unmodified FIX polypeptide sequence). Thus, the claims allow for FIX polypeptides with up to a 30% sequence variability with SEQ ID NO:1 or SEQ ID NO:2.

[7] The impugned independent claims also specify that either leucine or aspartic acid is present at amino acid position 338 when compared to SEQ ID NO:2, and require that the FIX polypeptide (or pharmaceutical composition comprising the FIX polypeptide) be used in a FIX replacement therapy at a daily dosage of between 0.1 µg/kg and 400 µg/kg body weight. The Patent explains that the leucine variant at amino acid 338 [R338L] is the variant that has been found in patients.

[8] The statement of claim [SOC] alleges that:

- the Impugned Claims are anticipated in view of a prior art reference referred to as Stafford;
- the Impugned Claims are not inventive as it would have been obvious to try the R338L variant as a FIX replacement therapy;
- the inventor of the Patent did not make or disclose FIX variants across the breadth of the variance permitted by the Impugned Claims, nor was there any demonstration or sound prediction that such variants would work;

- the Impugned Claims claim methods of medical treatment and therefore are not patentable subject-matter; and

- there has been a material misrepresentation that would affect the whole of the patent as to the inventorship of its subject-matter.

[9] The SOC alleges that Pfizer wishes to sell its own gene therapy product in Canada (and elsewhere) for use in treating adults with hemophilia B. The product has undergone a Phase 3 clinical trial; however, there is no evidence that a submission for regulatory approval has been filed in Canada.

[10] Shortly after the SOC was issued, on October 21, 2022, uniQure filed a request to re-examine its Patent, pursuant to section 48.1 of the Patent Act, allegedly in response to new prior art that was brought to uniQure's attention during foreign proceedings involving Pfizer.

[11] In its response at the first stage of the re-examination request [First Stage Determination], the Re-examination Board [Board] accepted that the new prior art raised a substantial new question of patentability [SNQP] with respect to the independent claims of the Patent; and in particular, the utility of the polypeptides covered by those claims. However, it did not find a SNQP with respect to the dependent claims.

[12] As permitted under subsection 48.3(2) of the Patent Act, in its reply to the First Stage Determination, uniQure filed a proposed amended claim set [Proposed Claims]. The Proposed Claims no longer claim a modified FIX polypeptide that has 70% sequence identity with SEQ ID

NO:1 or SEQ ID NO:2, nor do they specify a daily dosage amount. uniQure asserts that its Proposed Claims have been restricted to the modified FIX polypeptide sequence found in patients.

[13] The Board will have until April 14, 2024 (twelve months from the time the reply was filed) to provide its decision in the re-examination. Pursuant to subsection 48.4(1) of the Patent Act, there may be three outcomes of the re-examination process: 1) the Board could maintain existing claims as patentable; 2) the Board could cancel existing claims as unpatentable; and/or 3) the Board could adopt some or all of the Proposed Claims, or any other amended claims proposed that are determined to be patentable.

[14] At the hearing of the motion, uniQure provided the Court with an undertaking that upon receipt of the Board's re-examination decision, it would not defend any extant claims of the Patent, if any remain, provided the Board accepts any of their claim amendments.

[15] The Action is in its initial stages. The pleadings have only recently closed and the parties have not yet begun discovery. In a proposal made to the Court during case management, Pfizer requested a schedule that would have all discovery completed by the middle of April 2024 with expert reports in chief exchanged at the end of June 2024. The Case Management Judge has indicated that a trial would not be scheduled to commence before 2025.

II. Issue

[16] The sole issue on this motion is whether the Action should be stayed until April 14, 2024, or the date that the Board completes re-examination of the Patent.

III. Analysis

[17] Paragraph 50(1)(b) of the *Federal Courts Act*, RSC, 1985, c F-7 provides the Court with discretion to stay a proceeding where it is in the interests of justice to do so.

[18] As explained in *Mylan Pharmaceuticals ULC v AstraZeneca Canada Inc*, 2011 FCA 312 [*Mylan*] at paragraph 5, in determining whether to stay its own proceeding, the Court exercises a jurisdiction that is not unlike scheduling or adjourning a matter, where broad discretionary considerations come to bear. This is distinct from a request for the Court to enjoin another body from exercising their jurisdiction. While there is a public interest consideration to move proceedings forward fairly and with due dispatch, it is qualitatively different from the public interest considerations that apply when the Court forbids another body from doing what Parliament said it can do.

[19] Whether the Court should exercise its discretion to stay its own proceeding depends on the factual circumstances, including the length and purpose of the stay and its impact (*Mylan* at para 5; *ArcelorMittal Exploitation minière Canada SENC v Canada (Attorney General)*, 2021 FC 998 at para 19); and is guided by considerations such as securing the just, most expeditious, and least expensive determination of the proceeding on its merits, and whether the requested stay

would unfairly prejudice one of the parties (*Windsor (City) v Canadian Transit Co*, 2016 SCC 54 at para 124; *Coote v Lawyers' Professional Indemnity Company*, 2013 FCA 143 at paras 12-13).

[20] This includes balancing the responsibility to ensure that proceedings move forward in an expeditious, timely and fair manner (*Clayton v Canada (Attorney General)*, 2018 FCA 1 [*Clayton*] at para 28) with considerations such as whether it would be premature to proceed with the litigation because another body has jurisdiction over an issue whose determination will have a material impact on the merits of the litigation (*Iris Technologies v Canada (Revenue Agency)*, 2023 FC 188 [*Iristel*] at paras 34-35).

[21] uniQure asserts that a stay should be granted in this case because the claims of the Patent are not yet defined. It asserts that the claims are the foundation for the Action and that their scope as determined by the Board will have a material impact on whether the issues of utility/claim breadth and patentable subject-matter remain in issue. It contends that if these issues are no longer in play this will affect the scope of discovery and the expert reports. uniQure asserts that it would be both prejudicial and unjust to proceed with the litigation before the re-examination decision as it will result in uniQure defending and taking positions that are inconsistent with positions being taken before the Board, and will result in a waste of time and resources on claims that will no longer be in dispute.

[22] Pfizer asserts that such a lengthy stay should only be granted in the clearest of cases. It contends that the next stages of the litigation will not be materially altered by the result of the re-examination as the effect on the issues of utility/claim breadth and patentable subject-matter is

speculative and there will be no impact on at least the issues of anticipation, obviousness, and material misrepresentation. Pfizer takes issue with uniQure's undertaking. It asserts that the undertaking is case splitting and does not present a definitive course of action but only a conditional option. It asserts that there is an insufficient nexus between the outcome of the re-examination and the litigation to warrant a stay. Pfizer further contends that uniQure has an evidentiary burden to establish that it would be prejudiced if a stay is not granted (and that Pfizer would not be so prejudiced) and that such burden has not been met.

[23] In my view, a stay pending re-examination will not serve to sufficiently narrow the issues and next steps in the proceeding or prejudice uniQure such that it would be in the interests of justice to grant the stay requested.

[24] First, I do not consider this case analogous to what was before me in *Iristel*, as argued by uniQure. In *Iristel*, the Defendants sought to stay an action against the Canada Revenue Agency [CRA] seeking damages for misrepresentation, misfeasance in public office, abuse of process and negligence. The claim was advanced *because* Iristel believed it had a right to net tax refunds that had been withheld by the CRA. As the entitlement to net tax refunds was within the sole jurisdiction of the Tax Court of Canada, I held that it was premature to proceed with the action in this Court until the entitlement to the net tax refunds was determined. As stated at paragraphs 33-37 of *Iristel*:

> [33] I agree with the Defendants, Iristel would not have brought the present action if the $79 million in net tax refunds had not been withheld. The torts and equitable claims have no independent foundation: they are advanced in this action on the basis that a right to the net tax refund exists: *Hester v Canada*, [2007] GSTC

> 172 (Ont. Sup. Ct.) at paras 53 and 54; leave dismissed [2008] GSTC 55 (Ont. Div. Ct.).
>
> [34] In my view, it is premature to entertain the Claim while a fundamental issue that grounds the Claim − the validity of the Assessments and the entitlement to the net tax refunds − remains outstanding in the Tax Court Appeals, and it is only the TCC that can determine these issues.
>
> [35] Further, it is inevitable that the outcome of the Tax Court Appeals will have an impact on merits of the Claim. The request for a stay is thus also supported by the principles of judicial economy.
>
> [36] As set out earlier, the present action is grounded on an assumption that Iristel is entitled to the net tax refunds withheld. If the TCC finds that the Assessments are valid, it is difficult to see how Iristel could maintain its claim for damages suffered from an allegedly improper and unlawful Assessment in the present claim. Indeed, even Iristel conceded at the oral hearing that such a finding could be used as a defence in the action.
>
> [37] Similarly, if Iristel were successful in the Tax Court Appeals, this finding would assist in the present action as it would remove the need to litigate around the lawfulness of the Assessments. The evidence would be reduced to conduct and state of mind.

[25] In this case, while the Board has sole jurisdiction to amend the claims, any amendment of the claims will not be dispositive of the Action. Indeed, uniQure admits that the crux of the purported invention of the Patent is the R338L variant and its use in gene therapy, which remain the focus of the Proposed Claims. While a SNQP has been raised with respect to the utility and breadth of the independent claims of the Patent, any amendments to the claims will not remove the allegations of anticipation and obviousness of the R338L variant, or the section 53 allegation. The patentability of the R338L variant will remain in dispute whether or not the amendments put forward on the re-examination are accepted. Thus, there can be no argument that the outcome of

the re-examination will dispose of the litigation. Nor is there a risk of inconsistent findings; uniQure is not seeking to have its Patent invalidated through re-examination.

[26] Further, while uniQure is seeking to narrow its claim set and remove the dosage limitations in the claims, arguably affecting the allegation that the claims are directed to a method of medical treatment, the First Stage Determination suggests that the Board may not accept such omissions. In the First Stage Determination, the Board reminded uniQure that any claim amendments made to the Patent could not broaden the scope of the monopoly (subsection 48.3(2) of the Patent Act). The Board noted that the absence of a dosage limitation in proposed claims reciting a use in FIX replacement therapy would potentially enlarge the scope of the claims. Although uniQure is no longer proposing to directly claim the modified FIX polypeptide for use in a FIX replacement therapy, it is unclear whether the Board will accept the amendments and deletions proposed.

[27] It is also unclear to what extent the dependent claims may be affected by the re-examination, if at all. The SNQP is defined in respect of the independent claims only. In my view, the undertaking given by uniQure, while permissible, does not fully address this issue as it remains both conditional and uncertain as to effect. The undertaking is premised on acceptance of at least some of uniQure's claim amendments. However, if such claim amendments are not accepted, the undertaking leaves open the ability of uniQure to defend the extant claims, which rely on the same 70% sequence identity language sought to be removed from the independent claims.

[28] uniQure argues that without the issue of utility and claim breadth, documentary discovery would be significantly narrowed as there would no longer be a need to produce documents relating to the development and sound prediction of the invention. However, this does not overcome the obligation to produce documents relating to the inventor's course of conduct or to address the issue of inventorship under section 53.

[29] As stated in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*] at paragraph 71, the inventor's course of conduct is relevant to the obviousness analysis:

> [71] For example, if the inventor and his or her team reached the invention quickly, easily, directly and relatively inexpensively, in light of the prior art and common general knowledge, that may be evidence supporting a finding of obviousness, unless the level at which they worked and their knowledge base was above what should be attributed to the skilled person. Their course of conduct would suggest that a skilled person, using his/her common general knowledge and the prior art, would have acted similarly and come up with the same result. ...

[30] Pfizer alleges in the SOC that "[b]y the Relevant Date (or by the priority date, if any), it was obvious to try the FIX R338L variant as a FIX replacement therapy, both as a polypeptide therapy and in gene therapy. ... It was more-or-less self-evident that the R338L variant would be hyperactive and there was motivation among skilled persons to use the R338L variant as a FIX replacement therapy."

[31] In its statement of defence, uniQure asserts that "the ordinary person skilled in the art would not have been aware of the unexpected benefits of the invention, nor motivated to find the particular solutions of the 094 Patent in view of the state of the art and common general

knowledge. It would have been counterintuitive, and furthermore necessary, for the skilled person to conduct prolonged and arduous experimentation."

[32] The inventor's course of conduct has been put into play by the pleadings. I agree with Pfizer, there is nothing in *Sanofi* supporting the proposition that a patentee may elect not to permit discovery on the inventor's course of conduct, or that arguments relating to the inventor's course of conduct can only be used as a shield, and not as a sword. Indeed, counsel for uniQure could not direct the Court to any jurisprudence establishing this premise.

[33] Further, from a procedural stand-point, a document is relevant for purposes of discovery where it is reasonable to suppose that it contains information that could, either directly or indirectly, enable a party to advance its own case or that of its opponent, or would fairly lead to a train of inquiry that may have either of those two consequences: *Eli Lily Canada Inc v Novopharm Ltd*, 2008 FCA 287; *Apotex Inc v Canada*, 2005 FCA 217.

[34] While the outcome of the re-examination could narrow some of the issues, I agree with Pfizer it will not materially affect the discovery steps that would take place while the re-examination decision is pending. Even if there are no longer issues of utility and claim breadth in the proceeding, it will not avoid the necessity of producing documents relevant to the inventor's course of conduct in arriving at the R338L variant and its use in a gene therapy, which is at the core of the purported invention.

[35] Similarly, I am not satisfied that uniQure will be unfairly prejudiced if a stay is not granted. While I do not consider it fatal to the motion that there was no direct evidence from uniQure of prejudice, as the facts that were relevant to uniQure's arguments arise from the record, I am nonetheless not persuaded by the prejudice claimed.

[36] uniQure argues that it will be required to defend positions in the Action that it has already decided not to pursue in re-examination. It similarly argues that it will be required to unfold a different litigation strategy and take positions in the Action that it otherwise may not have taken if re-examination were completed first. However, it has already argued the former to the Case Management Judge and was ordered to file a statement of defence despite the present motion. It cannot now make a collateral attack on that prior ruling. As the pleadings have now closed, any pleading amendments that might be required because of the outcome of the re-examination would still be necessary even if a stay were granted.

[37] The statement of defence makes reference to the re-examination, as does Pfizer's reply. The Action is not proceeding without acknowledgement of the re-examination process. I do not consider this situation parallel to that in *Skehar v Bonavista Energy Corporation*, 2022 ABQB 136.

[38] Additionally, uniQure was and has always been free to choose its own litigation strategy. It was uniQure's choice to wait to seek re-examination in Canada despite narrowing its claims elsewhere well in advance of the initiation of the Action. It cannot now claim prejudice from circumstances created in part by its own doing. There is also nothing preventing uniQure from

making formal admissions in the Action to limit what it perceives as unnecessary areas of inquiry for discovery in view of positions it has taken in the re-examination.

[39] uniQure asserts that if the action were to proceed in parallel with the re-examination, Pfizer could use litigation tactics to circumvent uniQure's statutory right to re-examination by seeking a summary trial that could be completed before any re-examination decision. However, counsel for Pfizer provided confirmation during its oral submissions at the motion that this was not its goal. Rather, counsel represented to the Court that it was not seeking to proceed by summary trial, but instead to obtain a trial date at the earliest opportunity. On the basis of this representation to the Court and in view of the Court's order indicating that a trial date would not be assigned before 2025, I am satisfied that proceeding in parallel will not remove uniQure's right to re-examination of its Patent.

[40] For the reasons already stated, I am also not persuaded that uniQure will be unfairly prejudiced because of wasted resources. Pfizer's challenge to the patentability of the R388L variant and its use as a gene therapy will remain in issue as will the attacks on at least the basis of anticipation, obviousness and misrepresentation under section 53. The impact of the re-examination on the next steps of the litigation are uncertain and could be addressed in parallel through other procedural tools such as formal admissions by uniQure relating to those aspects of the current claims it seeks to remove.

[41] In this case, the Board maintains the right to take up to twelve months to issue its decision (subsection 48.3(3) of the Patent Act). While it could issue its decision sooner, it is

speculative to suggest that it will do so. In the context of the overall schedule proposed which would have the Action proceeding to trial in under three years, I do not view twelve months as a short timeframe. Where there is a request for such a long wait, the impact of the re-examination should not be tenuous: *Mylan* at para 19.

[42] As noted by Pfizer, contrary to the provisions in the Patent Act relating to reissuance (section 47) and disclaimer (section 48), the Patent Act does not state that a patent cannot be impeached while it is under re-examination. The scheme of the Patent Act suggests that re-examination and impeachment are separate and distinct paths that can proceed in parallel.

[43] uniQure argues that there is no urgency to this Action as this is not a proceeding under the *Patented Medicines (Notice of Compliance) Regulations* and Pfizer has not yet filed its regulatory submission. However, there is no argument before me on this motion that Pfizer is not an interested party. Indeed, uniQure asserts that it is not seeking to interfere with Pfizer's ability to seek impeachment. As established in the context of this motion, having completed Phase 3 clinical trials, Pfizer has a commercial interest in proceeding with the litigation. As set out in *Clayton*, the responsibility to proceed with the action in an expeditious, timely and fair manner remains as a critical factor.

[44] When this responsibility is balanced against the factual context, including the uncertain and limiting impact the re-examination might have on the Action, it is my view that this does not favour granting a stay.

[45] In my view, the interests of justice will not be served by granting a stay in this Action and as such, the motion shall be dismissed.

[46] Each of the parties provided submissions as to costs. While the parties agreed that the quantum of costs should be fixed in an amount of $5,000, they did not agree as to the conditions of the award, with counsel for uniQure arguing that costs should awarded in the cause, and counsel for Pfizer requesting costs payable forthwith.

[47] As set out in rule 401(2) of the *Federal Courts Rules*, the Court may order costs payable forthwith where it is satisfied that a motion should not have been brought or opposed. Although I did not find in uniQure's favour on this motion, I do not consider the present motion to fall into this category.

[48] Considering the Court's discretion and the rule 400 factors, in my view it is appropriate to award $5,000 to Pfizer in any event of the cause.

ORDER IN T-2118-22

THIS COURT ORDERS that:

1. The motion is dismissed.

2. Costs are awarded to Pfizer in an amount fixed at $5,000, in any event of the cause.

"Angela Furlanetto"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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