Federal Court Cour fédérale

Date: 20250210

Docket: T-1919-23

Citation: 2025 FC 264

Ottawa, Ontario, February 10, 2025

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

BAYER INC. AND
REGENERON PHARMACEUTICALS, INC.

Plaintiffs

and

AMGEN CANADA INC.

Defendant

PUBLIC JUDGMENT AND REASONS
(Confidential Judgment and Reasons issued February 10, 2025)

I. Introduction

[1] The Plaintiffs, Bayer Inc. and Regeneron Pharmaceuticals, Inc., appeal the order of Associate Judge Duchesne (as he then was) (the "Hearing Judge") dated September 17, 2024 (the "Order") pursuant to Rule 51 of the *Federal Courts Rules*, SOR/98-106 (the "*Rules*"). The Order

denied the Plaintiffs' request for an order compelling the Defendant, Amgen Canada Inc. ("Amgen"), for the production of samples pursuant to Rule 249 of the *Rules.*

[2] For the reasons that follow, I dismiss the appeal.

II. Background

A. *The Underlying Action*

[3] The Plaintiffs commenced this action against Amgen pursuant to subsection 8.2 of the *Patented Medicines (Notice of Compliance Regulations)*, SOR/93-122 (the "*PMNOC Regulations*"). The patent at issue is Canadian Patent No. 2,906,768 ("768 Patent"). The 768 Patent describes and claims a cell culture medium comprising certain amino acid ingredients – putrescine and ornithine – and methods of cultivating cells in a cell culture medium to produce a protein of interest (e.g. aflibercept).

[4] The Plaintiffs allege that the cell culture process used to make Amgen's biosimilar ("ABP 938") would directly or indirectly infringe the asserted claims of the 768 Patent. [redacted] the presence of ornithine is disputed.

[5] Amgen denies that any element of the asserted claims is infringed by its manufacturing process for ABP 938. Amgen has also commenced a counterclaim, alleging, in part, that each of the claims of the 768 Patent is invalid, void and of no force and effect.

B. *The Motion for Samples*

[6] Prior to the hearing of the underlying motion, the parties had negotiated a partial outcome of the motion. Amgen agreed to produce samples of its cell culture medium, both in the form of the powders used to make the medium and the formulated liquid medium. Amgen has also provided the Plaintiffs with disclosure and documents regarding Amgen's cell culture process, including the growth conditions of the cell culture medium used in the manufacturing of ABP 938, which show that ornithine is not used in the media. The Plaintiffs do not dispute this.

[7] The remaining issue before the Hearing Judge was whether Amgen should be compelled to produce samples of the cell culture at the end of each in-process steps from N-9 to N [redacted] and any excess cell culture is discarded.

[8] In support of their motion, the Plaintiffs adduced an affidavit from a law clerk at the office of Plaintiffs' counsel, which among other items, attached two scientific publications from 1965 and 1994 describing the conversion of arginine to ornithine under described conditions (the "Arginine Articles"). The Hearing Judge noted that the Plaintiffs had not led expert evidence to explain how this literature is to be understood and applied in the specific context of this motion and proceeding.

[9] Amgen adduced affidavit evidence from Dr. Natalia Gomez, Senior Director of Cell Line Development at Amgen and an expert, Dr. Jeffry Chalmers, Professor of Chemical and Biomolecular Engineering at the Ohio State University. Dr. Gomez provided evidence on the cell line development and culture process for making ABP 938 and the potential harm and disruption caused by the requested sampling. Dr. Chalmers' evidence was that arginine present in Amgen's cell culture medium during Amgen's manufacturing process could not convert to ornithine in accordance with the literature the Plaintiffs rely upon. The pH and temperature conditions described in the Arginine Articles far exceed the tolerable ranges disclosed with respect to the manufacture of ABP 938.

[10] The Hearing Judge noted that Dr. Chalmers agreed on cross-examination that there are test methods available that could test for the presence and concentration of ornithine in Amgen's cell culture media for ABP 938, but that he was not aware of which test could be used, or whether all of the conditions that would be required to preserve the integrity of the samples throughout the testing process could be respected by such testing.

C. *The Order Subject to Appeal*

[11] In his reasons, the Hearing Judge sets out the applicable law governing motions pursuant to Rule 249 (Appendix A of this Judgment), including the principles established by the leading authority, *Apotex Inc v Eli Lilly Canada Inc*, 2013 FCA 45 [*Eli Lilly*] and as applied in *Gilead Sciences Inc v Apotex Inc*, 2022 FC 1460 [*Gilead]*. The key principles relevant on this appeal are:

1. To be successful on a motion pursuant to Rule 249, there must be 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)" (*Eli Lilly* at para 8; *Gilead* at para 23). In assessing whether the moving party has demonstrated "a reasonable possibility that the proposed test will reveal something useful," courts have considered whether there is "a sufficient nexus between testing of [the samples] that may be conducted and the unadmitted allegations in the pleadings" (*Gilead* at para 47); and

2. A motion under Rule 249 requires the Court "to 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." (*Eli Lilly* at para 10; *Gilead* at para 24).

[12] The Hearing Judge held that in order to be successful on the motion, "the Plaintiffs must meet their onus of establishing that a test has been designed and exists, or can be designed and conducted, that has a reasonable possibility to show that a cell culture media comprising 0.6 ± 0.09 mM ornithine and 0.714 ± 0.11 mM putrescine is used in the ABP 938 manufacturing process" (citing to *Sherman v Pfizer Canada Inc*, 2021 FC 554 at paras 13-14 and 24-28 [*Sherman]*).

[13] The Hearing Judge found that there was a lack of evidentiary support for the conversion of arginine into ornithine during the cell culture process and there was no evidence of a test that could identify the presence and concentration of ornithine in ABP 938's cell culture media. As such, there was no basis to conclude that there is a nexus between the notional test and the ornithine issue framed by the pleadings.

[14] As to the balancing of interests, the Hearing Judge acknowledged that producing a sample of cell culture that is otherwise discarded would likely not be any more intrusive than the production of documents Amgen produced to date; however, producing a sample that would otherwise not be discarded would affect its manufacturing process. The balancing of interests did not favour granting the motion, as the Hearing Judge ultimately concluded that the notional existence of a potential test that does not have a reasonable possibility of revealing ornithine in cell culture media does not establish that the production of the samples sought would assist the Plaintiffs or the trier of fact.

III. Issues

[15] The Plaintiffs submit that the Hearing Judge erred in:

1) finding that the Plaintiffs were required under Rule 249 to do more than demonstrate that a test exists that could help the trier of fact (i.e., a test to detect the presence and concentration of ornithine in the samples);

2) finding that the Plaintiffs failed to identify the nature of the test that could be conducted; and

3) concluding that the interest did not favor sample production to the Plaintiffs.

IV. Analysis

A. *The Standard of Review*

[16] The standard of review on an appeal pursuant to Rule 51 of the *Rules* is correctness on a pure or extricable question of law, and palpable and overriding error on a question of fact or a question of mixed fact and law (*Hospira Healthcare Corporation v Kennedy Institute of Rheumatology*, 2016 FCA 215 at para 79, citing *Housen v Nikolaisen*, 2002 SCC 33 at paras 8, 10, 36).

[17] The parties agree that the standard applicable to the second issue is palpable and overriding error, but disagree on the standard applicable to the first and third issues.

[18] The Plaintiffs argue that issues one and three are subject to review on the correctness standard as they relate to extricable questions of law from mixed questions of fact and law. For the reasons explained below, I disagree that the Hearing Judge deviated from *Eli Lilly* in the ways suggested by the Plaintiffs. Having concluded that the Hearing Judge made no error of law, I have considered whether the Hearing Judge made errors of fact or mixed fact and law, which are subject to a standard of review of palpable and overriding error.

B. *Did the Hearing Judge err in requiring the Plaintiffs to do more than demonstrate that a test exists that could help the trier of fact?*

[19] The Plaintiffs argue that the standard of review with respect to the first issue is correctness, characterizing the extricable question of law as whether a moving party under Rule 249 is required to (a) establish that a test exists that has a reasonable possibility of assisting the trier of fact; or (b) describe the parameters of the test that will or can be conducted. The Plaintiffs submit that the Hearing Judge erred in law in following the latter.

[20] The Plaintiffs point to paragraphs 30 and 36 of the Order, asserting that the two paragraphs contradict each other. They say that while the Hearing Judge correctly stated the law in paragraph 30, he deviated from the proper test in paragraph 36. The paragraphs are as follows:

> [30] The moving party is not required to lead evidence that its proposed tests are the only means to establish their case, is not required to disclose the nature of the tests it intends to carry out, or whether it will in fact carry them out (*Gilead*, at para 36).
>
> […]
>
> [36] Reliance on the existence of a notional test without more does not meet the threshold required by Rule 249 and the jurisprudence because a notional, undescribed or theoretical test that could be run does not establish that there is a reasonable possibility that testing can be conducted that may or could reveal something that may be useful for the trial of fact (*Gilead* at para 50; *Sherman* at paras 24 to 29). There is no basis before the Court to conclude that there is a nexus between the notional test and the ornithine issue framed by the pleadings.
>
> [Emphasis added]

[21] These paragraphs neither contradict one another, nor the Rule 249 jurisprudence. The Hearing Judge was not requiring the Plaintiffs to disclose the nature of the tests it *intends* to carry out and he was not asking the Plaintiffs to commit to carrying out any specific test. He was requiring the Plaintiffs to demonstrate that there was a reasonable possibility that the provision of the requested samples would reveal useful information to the trier of fact. The nature of the testing being proposed can be a relevant factor in assessing whether the testing being proposed is capable of revealing something useful for the trier of fact in determining an issue in the proceeding (see e.g. *Sherman* at paras 24-26).

[22] The Hearing Judge considered the *Eli Lily* test in a manner consistent with *Gilead* and the case of *Bayer Inc v Pharmascience Inc*, T-270-20, unreported decision of Associate Judge Tabib dated July 27, 2020 at page 8 [*Bayer]*), cited in *Gilead* at paragraph 36. In both those cases, there was evidence before the Court of the types of tests that could be undertaken to provide the useful information. While the Court did not require the moving parties to undertake to carry out the suggested tests, the nature of the tests was a relevant factor in meeting the burden of demonstrating that the provision of samples would allow it to carry out tests that are likely to reveal useful information. This is the lens through which the Hearing Judge considered the entirety of the evidence before him in making his conclusions on the motion.

[23] While the Hearing Judge may have been clearer in his application of the *Eli Lilly* test, he was consistent with it. As indicated by the "without more" in paragraph 36, the lack of a particularized test was not the only relevant factor that led to the finding that there was not a reasonable possibility that the proposed testing would reveal something useful to the trier of fact with respect to an issue in these proceedings. Two important findings factored into his analysis. First, and importantly, Amgen agreed to provide its liquid and powder cell culture media used in the manufacturing of ABP 938. These samples are the substance of the claims in issue. The Plaintiffs failed to establish that the cell culture media from steps N-9 to N had a reasonable possibility of providing something different from the cell culture media Amgen will provide. Second, the evidence before the Hearing Judge was that it was unknown which test could be used and whether all the conditions related to that proposed testing would preserve the integrity of the samples such that the testing results would reveal something useful to the trier of fact.

[24] The Hearing Judge did not deviate from the *Eli Lilly* test and made no error in law in applying the test to the evidence and argument before him. Whether the evidence meets this threshold is a question of mixed fact and law, reviewable on a standard of palpable and overriding error.

C. *Did the Hearing Judge err in finding that the Plaintiffs failed to identify the nature of the test that could be conducted?*

[25] In the alternative, the Plaintiffs argue that the Hearing Judge made a palpable and overriding error in failing to acknowledge that tests were identified. They assert that they identified Liquid Chromatography Mass Spectrometry ("LC-MS") and ion exchange chromatography as methods that could be used to identify the presence of ornithine in Amgen's cell culture samples.

[26] While the Order makes no mention of LC-MS or ion exchange chromatography, I do not consider these omissions fatal to the Order. As noted by Amgen, on an appeal from a Prothonotary's decision, a lack of detailed reasons, in itself, will not justify a *de novo* or correctness review or invite the Court to deviate from the principle of deference owed to the Prothonotary's findings (*Maximova v Canada (Attorney General)*, 2017 FCA 230 at para 11; *Apotex Inc v Canada (Health)*, 2016 FC 776 paras 81-84; *Apotex Inc v Merck & Co Inc*, 2007 FC 250 at para 13).

[27] Review of the transcript from the hearing shows that the Hearing Judge was aware of and considered the relevance of these testing methods. With respect to LC-MS, counsel for Amgen referred to their expert evidence which attests to the difficulties of testing cell culture compared to

a solution, like media or a finished drug product, and noted that the only evidence of what is done at the various stages of cell culture is to count cells. There is no evidence that LC-MS testing of the cell culture samples, which have a dynamic environment unlike a finished drug product, would provide useful results. With respect to ion exchange chromatography, the Hearing Judge found that the pH levels used in the papers was inapplicable to the cell culture samples, accepting Amgen's expert evidence that the pH would destroy the output manufacturing process.

[28] I agree with Amgen that "a test" does not equate to a "useful test" and that even if testing exists to measure ornithine in a solution, this does not equate to measuring ornithine in cell culture media throughout the cell culture process of the claimed 768 invention. A useful test would need to accurately detect the presence and the concentration of ornithine during the manufacturing process (and not sometime after where further cellular processes have occurred). The Plaintiffs provided no evidence that the proposed test could be conducted to do so. For clarity, this does not mean the Plaintiffs are required to provide the particular parameters that would be used, as noted by the Hearing Judge, but the evidence must show a reasonable possibility of revealing something useful to the trier of fact. The Hearing Judge reasonably and correctly found the evidence fell short of this.

[29] The Plaintiffs adduced no expert evidence of the information the proposed testing could actually provide with respect to the requested samples. The Plaintiffs did not identify these "exemplary" tests in evidence, nor in their written representations; they only pointed to them in oral argument. In doing so, they deprived Amgen's expert of commenting on them, and deprived the Hearing Judge of some clarity as to whether these tests could yield useful results in the context

of this case. This left the Court to speculate whether the proposed tests could provide something useful for the trier of fact in assessing an issue in the proceeding. As the Hearing Judge correctly decided, mere speculative testing does not support a reasonable possibility.

[30] As stated above, while the nature of the type of tests that could be done can be a relevant factor in the *Eli Lilly* test, it is not determinative. The Hearing Judge did not treat it as such. Consequently, even if this Court was to agree that the Hearing Judge made a palpable error in failing to acknowledge the identified tests, it was not overriding. The Plaintiffs failed to meet their burden on this motion because they failed to establish a nexus between the proposed test and the ornithine issue as framed in the pleadings and in the 768 Patent claims.

[31] The Hearing Judge made no palpable and overriding error in finding that that the Plaintiffs failed to meet their burden of showing that these "exemplary" tests could be useful and applicable to the issues for the trier of fact in this matter.

D. *Did the Hearing Judge err in concluding that the interest did not favor sample production to the Plaintiffs?*

[32] The Plaintiffs argue that the Hearing Judge erred in law in balancing the Plaintiffs', Amgen's and the Court's interests by setting the test for samples as requiring a reasonable possibility of showing infringement, as opposed to assisting the trier of fact. The Plaintiffs assert that the legal test is "whether there is a reasonable possibility of assisting the trier of fact in determining an issue in the proceeding, which in this case may support either infringement **or non-infringement**" [emphasis in original]. They submit that this error led to the discounting of the Plaintiffs' and trier of fact's interests in the production of the samples.

[33] To reiterate, the Hearing Judge applied the proper legal test and made no legal error in doing so. The test for Rule 249 describes "something useful for the trier of fact" as "something that will assist the trier of fact in determining an issue in the proceeding" [my emphasis]. The issue that these samples relate to is infringement, which includes determining whether the ornithine is present in the cell culture media. The Hearing Judge was not setting the test as requiring a reasonable possibility of showing infringement; he was requiring the Plaintiffs to prove that the requested samples could be useful to the trier of fact in assessing infringement.

[34] As explained above, the Hearing Judge assessed the usefulness of the samples in light of the evidence before him. This included the fact that Amgen agreed to provide samples of its cell culture media. The Hearing Judge found the Plaintiffs had not demonstrated how the samples requested would be useful in assessing the presence of ornithine in the cell culture media with these samples in hand.

[35] The Hearing Judge found there was no reasonable possibility of ornithine appearing in the cell culture medium during the cell culture process if it was not in the cell culture to begin with. Contrary to the Plaintiffs' submission that the Hearing Judge "assumed that there was no ornithine in the samples," this was a finding of fact based on the evidence, or lack thereof, before him. Given that the Plaintiffs bear the burden on this motion, it is insufficient to rely on what the Defendant's evidence does not say to fill in the gaps of the evidence they should have adduced.

[36] Amgen produced documentary evidence demonstrating the absence of ornithine and agreed to produce samples of its cell culture medium to confirm the absence of ornithine. The Plaintiffs have not established why this is insufficient.

[37] The Plaintiffs chose not to adduce any expert evidence; instead, they rely on two articles, which by attaching to a law clerk's affidavit, deprived the Hearing Judge of scientific clarity with respect to the translation of the non-cellular experiments described within to a cellular context. While expert evidence is not required on a Rule 249 motion, the Plaintiffs still bear the burden of meeting the threshold on this motion (*Gilead* at para 41). Where an issue requires the Court to consider scientific propositions, as often the case in patent cases, expert evidence may be helpful to the Court in assessing that burden. As noted by Amgen, academic articles attached to a law clerk affidavit have been found inadmissible for the truth of their contents (*O'Brien v Bard Canada Inc*, 2015 ONSC 2470 at paras 102-107).

[38] Regardless, I do not find that the Hearing Judge necessarily rejected the Plaintiffs' general assertions for which they rely on the articles for, namely, that arginine is a precursor to ornithine and in some circumstances converts to ornithine. The Hearing Judge found that the evidence did not establish that it was a reasonable possibility that arginine in the cell culture media converts to ornithine, and therefore the Plaintiffs did not meet their burden. The Hearing Judge was entitled to draw factual findings based on the Plaintiff's paucity of evidence. I do not find the Hearing Judge made a palpable and overriding error.

[39] Lastly, I am not persuaded by the Plaintiffs' assertion that unless the samples are produced, the trier of fact has no direct evidence on infringement and will be left with the parties' expert evidence and scientific publications for assessing infringement. I reiterate Justice Southcott's comment that on a Rule 51 motion, this Court's analysis must be guided by the standard of review, applied to the Hearing Judge's decision in the context of the record before him (*Sherman* at para 47). Given that I have found no palpable and overriding error in the Hearing Judge's findings, the Plaintiffs have not demonstrated that the testing is necessary or expedient for the trier of fact. In any event, I am not convinced the lack of these samples produced will prevent the trial judge from assessing infringement based on expert evidence, scientific publications, and the available documentary and testing evidence.

[40] The Hearing Judge did not make a legal or palpable and overriding error in balancing the interests.

V. Conclusion

[41] The appeal is dismissed.

[42] At the hearing, parties indicated that they agreed on costs in the amount of $3,000, not payable forthwith. As Amgen was the successful party, costs are awarded to Amgen in the amount of $3,000.

JUDGMENT in T-1919-23

THIS COURT'S JUDGMENT is that:

1. The Plaintiffs' motion to appeal the Order of Associate Judge Duchesne dated September 17, 2024, is dismissed.
2. The Plaintiffs are ordered to pay costs to the Defendant in the amount of $3,000.

"Michael D. Manson"
Judge

Appendix A

Rules 51 and 249 of the *Federal Courts Rules*, SOR/98-106:

Appeal	**Appel**
51 (1) An order of a prothonotary may be appealed by a motion to a judge of the Federal Court.	**51 (1)** L'ordonnance du protonotaire peut être portée en appel par voie de requête présentée à un juge de la Cour fédérale.
Service of appeal	**Signification de l'appel**
(2) Notice of the motion shall be served and filed within 10 days after the day on which the order under appeal was made and at least four days before the day fixed for the hearing of the motion.	**(2)** L'avis de la requête est signifié et déposé dans les 10 jours suivant la date de l'ordonnance frappée d'appel et au moins quatre jours avant la date prévue pour l'audition de la requête.
Order for inspection	**Ordonnance d'examen**
249 (1) On motion, where the Court is satisfied that it is necessary or expedient for the purpose of obtaining information or evidence in full, the Court may order, in respect of any property that is the subject-matter of an action or as to which a question may arise therein, that	**249 (1)** La Cour peut, sur requête, si elle l'estime nécessaire ou opportun pour obtenir des renseignements complets ou une preuve complète, ordonner à l'égard des biens qui font l'objet de l'action ou au sujet desquels une question peut y être soulevée :
(a) a sample be taken of the property;	**a)** que des échantillons de ces biens soient prélevés;
	b) que l'examen de ces biens soit effectué;

(b) an inspection be made of the property; or

(c) an experiment be tried on or with the property.

Entry on land or building

(2) An order made under subsection (1) may authorize a person to enter any land or building where the property is located for the purpose of enabling the order to be carried out.

Personal service on non-party

(3) Where a motion is brought under subsection (1) for an order in respect of property that is in the possession of a person who is not a party to the action, that person shall be personally served with notice of the motion.

c) que des expériences soient effectuées sur ces biens ou à l'aide de ceux-ci.

Autorisation d'entrée

(2) Dans l'ordonnance rendue en vertu du paragraphe (1), la Cour peut, pour en permettre l'exécution, autoriser une personne à entrer sur le terrain ou dans le bâtiment où se trouvent les biens.

Signification à personne

(3) Lorsqu'une requête présentée en vue de l'obtention d'une ordonnance aux termes du paragraphe (1) vise des biens qui sont en la possession d'une personne qui n'est pas une partie à l'action, l'avis de requête est signifié à personne à cette dernière.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1919-23
STYLE OF CAUSE:	BAYER INC. AND REGENERON PHARMACEUTICALS, INC. v AMGEN CANADA INC.
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DATED:	FEBRUARY 10, 2025

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