

Federal Court



Cour fédérale

Date: 20240722

**Docket No.: T-1094-23
T-1095-23**

Citation No: 2024 FC 1137

Ottawa, Ontario, July 22, 2024

PRESENT: Case Management Judge Benoit M. Duchesne

BETWEEN:

**ALEXION PHARMACEUTICALS, INC. AND
ALEXION PHARMA INTERNATIONAL OPERATIONS LIMITED**

Plaintiffs

and

AMGEN CANADA INC.

Defendant

ORDER

[1] The Defendant has brought a motion for leave pursuant to Rule 75 of the *Federal Courts Rules* (the “*Rules*”) to amend its Second Amended Statement of Defence in these two proceedings. Both proceedings were commenced pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the “*Regulations*”). The proceedings are identical for the purposes of the Defendant’s motion and the amendments for

which leave is sought are also identical save for differences in paragraph numbering in the proposed Third Amended Statements of Defence. The reasons and order that follow apply equally to the motion for leave brought in the T-1094-23 proceeding as well as in the T-1095-23 proceeding.

[2] The Defendant's proposed amendments are described by the Defendant as:

- a) amendments pertaining to section 53 of the *Patent Act* (the "*Act*"), which serve to further particularize the Defendant's existing material misrepresentation allegation;
- b) an Applicant-derived disclosure amendment, which revises an existing allegation to include allegedly novelty destroying disclosure to Chemical Abstracts Services; and,
- c) prior art amendments, which add two pieces of prior art to the existing list of documents citable for obviousness.

[3] The Plaintiffs contested these proposed amendments on the basis that they do not present a proper pleading, would be incapable of surviving a motion to strike, and will not aid in the Court's adjudication of the true substance of the action on its merits in addition to being untimely. The interests of justice are therefore not served by granting leave for the contested proposed amendments, and leave should be denied.

[4] The resolution of this motion requires the Court to consider section 53 of the *Act*, the rules applicable to pleadings as set out in the *Rules* and more particularly Rule 181(1), as well as Rule 75 and the jurisprudence applicable to a motion for leave to amend.

[5] At the end of the hearing of the Defendant's motion, the Court requested that the parties provide additional submissions as to the interaction between Rule 181 of the *Rules* and section 53 of the *Act*, as well as whether the particulars required in pleading a misrepresentation claim or defence as set out in *Lana International Ltd v Menasco Aerospace Ltd. (1996)*, 1996 CanLII 7974 (ON SC) ("*Lana International*") in the application of Rule 25.08(6) of Ontario's *Rules of Civil Procedure*, RRO 1990, O. Reg 194, and its requirement that "full particulars" be pleaded in connection with allegations of misrepresentation should apply by analogy or otherwise.

[6] The Court thanks the parties for their thoughtful submissions on this issue.

[7] The Defendant rightly notes that Rule 25.08(6) of Ontario's *Rules of Civil Procedure* requires that a party plead "full particulars" of their misrepresentation allegations whereas Rule 181(1)(a) of the *Rules* does not. The Ontario practice as reflected in *Lana International* is based on a pleading requirement that exceeds that which is required by the *Rules*. The Defendant argues that regardless of whether the particulars as outlined in *Lana International* are required in this Court, its proposed amended pleadings meet the more stringent requirement of pleading identified and called for in *Lana International*, if applied.

[8] The Plaintiffs argue that this Court has previously held in *Apotex Inc v Shire LLC*, 2017 FC 831 at para 17, that allegations of misrepresentation pursuant to section 53 of the *Act*, "[...] are essentially allegations of fraud and state of mind, which require, pursuant to Rule 181 of the Federal Courts Rules, full particulars". Prothonotary Tabib, as she then was, wrote as follows in her decision on a plaintiff's motion for leave to amend its Statement of Claim:

[17] As mentioned in my reasons for order dated November 14, 2016 in this same action (reported at 2016 FC 1267), section 53 allegations are essentially allegations of fraud and state of mind, which require, pursuant to Rule 181 of the *Federal Courts Rules*, full particulars. The pleadings now proposed contain no particulars of exactly who made what statements to the patent office, or of any factual basis upon which the Court might be able to conclude that this person or persons knew, at the time, that the statements were false or that these persons intended to mislead the patent office by making the statements. Pleadings of fraud are a serious matter. Parties should not make them recklessly and without sufficient evidence or a reasonable belief as to their truthfulness. Especially after discovery has been had, Apotex should have been able to set out the particular facts upon which a Court might find any particular state of mind or knowledge in any particular persons at any particular time. Apotex's failure to do so, especially in light of the admonishment contained in the order of November 14, 2016, leads me to infer that it has no reasonable basis to advance these allegations, and that it is not in the interest of justice that they be permitted.

[9] This statement followed her reasoning as set out in *Apotex Inc v Shire LLC*, 2016 FC 1267 (CanLII), at para 3, where she wrote as follows in her decision on a motion to strike the plaintiff's Reply:

[3] Section 53 allegations are essentially allegations of fraud and of a state of mind. As per Rule 181 of the *Federal Courts Rules*, such allegations require full particulars. The pleadings fail to identify exactly who made what statements to the Patent Office. They are further bereft of particulars as to the factual basis upon which the Court might be able to conclude that this person or persons knew, at the time, that the statements were false or that these persons intended to mislead the Patent Office by making the statements. The allegations of the Reply amount only to a vague allegation that "Shire" made "assertions" as to the utility of the invention, and that Shire now allegedly denies that these assertions amount to utility. The allegations of the Reply, taken alone or in conjunction with those of the Statement of Claim, are insufficient to be taken as implicitly pleading that the person who made the "assertions" knew them to be false or misleading at the time, especially given that Shire was not the original applicant for the patent at issue. Implicit allegations of fraud are not, of course, proper pleadings. However, where the material facts can be

inferred from the pleadings or the representations of the party on a motion to strike, the defective pleading is amenable to being saved by ordering particulars or granting leave to amend. That is not the case here.

[10] It bears mentioning that the excerpts of *Apotex Inc v Shire LLC*, 2017 FC 831 reproduced above arose from a motion for leave to amend a Statement of Claim in which the plaintiffs sought to recycle factual allegations previously made in their pleading related to inutility and to recast them as the factual basis for their bare and unparticularized pleaded legal conclusion of misrepresentation. The facts differ from the case at bar in that in these proceedings the Defendant has already pleaded its defence of misrepresentation and now seeks to complete its particulars.

[11] The Plaintiffs argue that the particulars required by Rule 181 are full particulars despite the absence of the word “full” before the word “particulars” in the Rule itself. The requirement of full particulars identified by Prothonotary Tabib align generally with the particulars identified in *Lana International* taking into account the subject matter distinctions between tort claims (as was the case in *Lana International*) and section 53 *Patent Act* misrepresentation defences. The Plaintiffs suggest that the required elements of particularized pleading for a section 53 *Patent Act* misrepresentation defence must include full particulars that consist of:

- a) The alleged material misrepresentation itself;
- b) When, where, how, by whom and to whom it was made;
- c) That the statement made was untrue;
- d) That the statement was material to the granting of the patent;
- e) That the statement was made with a wilful intent to mislead; and
- f) That the statement would be likely to mislead the skilled person.

[12] The Plaintiffs argue that the Defendant's pleading does not satisfy these particulars, even as amended as proposed, and that leave should not be granted as a result.

[13] I agree with the Plaintiffs that properly pleading a section 53 *Patent Act* misrepresentation defence requires a defendant to plead particulars that may be described as "full particulars", and that those "full particulars" are similar to the description of the necessary particulars set out in *Lana International* and by Prothonotary Tabib in *Apotex Inc v Shire LLC*, 2016 FC 1267 (CanLII) and in *Apotex Inc v Shire LLC*, 2017 FC 831. These particulars are also required to plead a reasonable cause of action in misrepresentation. I come to this conclusion without reading in the word "full" before the word "particulars" in Rule 181(1)(a). Rather, as is set out below, I so conclude by following the Federal Court of Appeal's instruction as to the degree of particularity required in pleading when Rule 181 is engaged, and that "full" particulars are implied by the jurisprudence applicable to Rule 181(1) for it to achieve the purpose of pleadings in the context of claims or defences where a state of mind or fraud are alleged.

[14] For the reasons that follow, the Defendant's motion for leave to amend is granted in part and dismissed in part.

I. **The Act and the Rules**

[15] An action commenced pursuant to subsection 6(1) of the *Regulations* is governed by the *Regulations* and also by *Rules*. It is an action like any other action that is governed by Part IV of *Rules*, except that some aspects of the litigation procedure applicable to it is contained in the *Regulations*. The *Regulations* do not contain any particular rule or test applicable to a motion for leave to amend a pleading. Rule 75 of the *Rules* applies.

[16] The parties agree upon the test applicable to a motion for leave to amend pursuant to Rule 75.

[17] The applicable rule and the legal principles engaged on this motion were thoroughly canvassed by Justice McHaffie in *GE Renewable Energy Canada Inc v Canmec Industrial Inc.*, 2024 FC 187 (CanLII) (“*GEREC I*”), and again in a summarized manner in *GE Renewable Energy Canada Inc v Canmec Industrial Inc*, 2024 FC 887 (CanLII) (“*GEREC II*”). Justice McHaffie summarized the applicable legal principles in *GEREC II* as follows:

I. Legal principles

[9] The principles on a motion to amend are not in dispute. I summarized them in my decision in *GEREC I*. In the interests of efficiency, I will simply repeat that discussion here.

[10] The general rule is that an amendment pursuant to Rule 75(1) of the *Federal Courts Rules*, SOR/98-106 should be allowed at any stage of an action for the purpose of determining the “real questions in controversy,” provided that allowing the amendments (i) would not result in an injustice to other parties not capable of being compensated by an award of costs; and (ii) would serve the interests of justice: *Enercorp Sand Solutions Inc v Specialized Desanders Inc*, 2018 FCA 215 at para 19, quoting *Canderel Ltd v Canada*, 1993 CanLII 2990 (FCA) at p 10; *McCain Foods Ltd v JR Simplot Company*, 2021 FCA 4 at para 20; *Janssen Inc v Abbvie Corporation*, 2014 FCA 242 at para 9. The onus lies on the amending party to show the amendments should be allowed: *Merck & Co, Inc v Apotex Inc*, 2003 FCA 488 at paras 29, 35–36.

[11] In assessing whether an amendment would serve the interests of justice, the Court may consider factors such as (i) the timeliness of the motion to amend; (ii) whether the proposed amendments would delay trial; (iii) whether the amending party’s prior position has led another party to follow a course of action in the litigation that it would be difficult to alter; and (iv) whether the amendments will facilitate the Court’s consideration of the substance of the dispute on its merits: *Enercorp* at paras 20–21, quoting *Continental Bank Leasing Corp v Canada*, 1993 CanLII 17065 (TCC) at p 2310; *Federal Courts Rules*, Rule 3. These

factors are considered together without any single factor being determinative.

[12] An amendment must also yield a sustainable pleading, and an amendment that is liable to be struck out under Rule 221 should not be permitted: *Enercorp* at para 22; *McCain* at paras 20–22; *Teva Canada Limited v Gilead Sciences Inc*, 2016 FCA 176 at paras 28–32. Thus, where it is plain and obvious that proposed amendments do not disclose a reasonable cause of action, or the amendments represent a “radical departure” from the party’s prior positions, they should not be permitted: Rule 221(1)(a),(e); *Enercorp* at paras 22–28; *McCain* at paras 20–23; *Hospira Healthcare Corporation v The Kenny Trust for Rheumatology Research*, 2020 FCA 191 at para 5, citing *Merck* at para 47; *Atlantic Container Lines AB v Cerescorp Company*, 2017 FC 465 at para 8; *Proslide Technology, Inc v Whitewater West Industries, Ltd*, 2023 FC 1591 at paras 15–16; but see *J2 Global Communications Inc v Protus IP Solutions Inc*, 2009 FCA 41 at paras 8–10. This has been described as a “threshold issue,” to be addressed before turning to other questions of justice and injustice: *Teva* at para 31.

[13] Pleadings that are inadequately particularized to allow the opposing party to plead in response are also subject to being struck under Rule 221 for failure to comply with the requirement in Rule 174 that they contain “a concise statement of the material facts on which the party relies”: *Mancuso v Canada (National Health and Welfare)*, 2015 FCA 227 at paras 16–20; *Fox Restaurant Concepts LLC v 43 North Restaurant Group Inc*, 2022 FC 1149 at paras 4, 20–32. Amendments may similarly be refused on this ground, whether considered as a threshold issue or as a matter of the interests of justice: *McCain* at paras 22–23; *Enercorp* at paras 34–37. However, where appropriate, a lack of particulars in a proposed amendment may be addressed by granting leave to reapply or by imposing an obligation of particulars as a condition of the amendment: *Enercorp* at paras 26–30, 34–38; *Atlantic* at para 15.

[14] I add one further note to the foregoing summary. Where a party seeks to amend a pleading after discovery and seeks to rely on discovery evidence to justify its proposed amendment, it is open to the Court to review and assess that evidence in determining whether, taking a realistic view in the context of the law and the litigation process, the proposed amendment discloses a reasonable cause of action or is “doomed to fail”: *Teva* at paras 27–32, 38–42. In this regard, the Federal Court of Appeal has noted that an allegation made without any evidentiary foundation is an abuse of process, and that an unsupported allegation cannot be sustained

simply in the hope that sufficient facts will be obtained on discovery that will support the allegation: *AstraZeneca Canada Inc v Novopharm Limited*, 2010 FCA 112 at paras 4–5.

[15] In other words, while the general rule is that the factual allegations in a proposed amendment are to be assumed to be true, it is relevant to both the threshold issue and, at the very least, the interests of justice whether a proposed amendment is supported or contradicted by the available discovery evidence. At the same time, a motion to amend is not the occasion to weigh competing evidence where the amending party has established credible evidentiary support for its amendments: *Atlantic* at para 16. As GEREK underscores, a motion to amend is not a motion for summary judgment or summary trial.

[18] The Defendant seeks leave to include additional allegations to its previously pleaded defence that the Plaintiffs made representations that cause its patents to be void pursuant to section 53 of the *Act*. Section 53 of the *Act* reads as follows:

Void in certain cases, or valid only for parts

53 (1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.

Exception

(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is

Nul en certains cas, ou valide en partie seulement

53 (1) Le brevet est nul si la pétition du demandeur, relative à ce brevet, contient quelque allégation importante qui n'est pas conforme à la vérité, ou si le mémoire descriptif et les dessins contiennent plus ou moins qu'il n'est nécessaire pour démontrer ce qu'ils sont censés démontrer, et si l'omission ou l'addition est volontairement faite pour induire en erreur.

Exception

(2) S'il apparaît au tribunal que pareille omission ou addition est le résultat d'une erreur involontaire, et s'il est prouvé que le breveté a droit

proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled.	au reste de son brevet, le tribunal rend jugement selon les faits et statue sur les frais. Le brevet est réputé valide quant à la partie de l'invention décrite à laquelle le breveté <i>est</i> reconnu avoir droit.
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[19] As noted by the Plaintiffs in their submissions, section 53 has been described as the *Act*'s "fraud provision" (*Apotex Inc v Eli Lilly Canada Inc.*, 2021 ONSC 3111 (CanLII), at para 21, *aff'd* 2022 ONCA 587 (CanLII), leave to appeal dismissed, 2023 CanLII 33987 (SCC); *Camsco Inc v Soucy International Inc.*, 2019 FC 255 (CanLII) at para 430).

[20] In *SNF Inc v Ciba Specialty Chemicals Water Treatments Limited*, 2015 FC 997 (CanLII) (*aff'd*, 2017 FCA 225, leave to appeal dismissed, 2018 CanLII 53458 (SCC) ("*SNF*")) at paras 215 to 217, the Court noted that the starting point for an analysis of allegations of false and misleading statements as an issue in a proceeding pursuant to section 53 of the *Act* requires:

- a) the identification of the impugned statements;
- b) the establishment that they were untrue;
- c) the demonstration that they were material;
- d) that they were made in the drafting of the patent with wilful intent to mislead; and,
- e) that the impugned statement would likely mislead the skilled person.

[21] These five elements are the essential elements of the defence of misrepresentation pursuant to section 53 of the *Act*.

[22] These types of allegations are properly characterized as allegations of misrepresentation (*NOV Downhole Eurasia Limited v TLL Oil Field Consulting*, 2014 FC 889 (CanLII), at para 25). As allegations pursuant to section 53 of the *Act* are allegations of misrepresentation, they must also comply with Rule 181(1) of the *Rules*. Rule 181(1) sets out the rules of pleading applicable to a pleading of misrepresentation even if a statutory provision such as section 53 of the *Act* may also apply substantively at trial. Rule 181(1) reads as follows:

Particulars

Précisions

181 (1) A pleading shall contain particulars of every allegation contained therein, including

181 (1) L'acte de procédure contient des précisions sur chaque allégation, notamment:

(a) particulars of any alleged misrepresentation, fraud, breach of trust, wilful default or undue influence; and

a) des précisions sur les fausses déclarations, fraudes, abus de confiance, manquements délibérés ou influences indues reprochés;

(b) particulars of any alleged state of mind of a person, including any alleged mental disorder or disability, malice or fraudulent intention

b) des précisions sur toute allégation portant sur l'état mental d'une personne, tel un déséquilibre mental, une incapacité mentale ou une intention malicieuse ou frauduleuse.

[23] Rule 181 applies to require that a party pleading any act of misrepresentation in its pleadings provide “particulars”. The scope of the particulars of an allegation of misrepresentation is relevant to determining whether the party pleading misrepresentation or seeking to amend its pleading to include allegations of misrepresentation has properly pleaded its claim or defence as required by the *Rules*. If the particulars that are required by Rule 181 in

addition to any statutory or common law essential elements for a claim or defence of misrepresentation are not pleaded in a sufficient manner, then the misrepresentation claim or defence may be struck on the basis that there is a failure to plead a reasonable cause of action or defence. A reasonable cause of action or defence therefore consists of the essential elements of the claim or defence combined with the particulars required by the *Rules*.

[24] Prothonotary Lafrenière, as he then was, held in *Benaissa v Canada (Attorney General)*, 2005 FC 1220 (CanLII), as follows at para 24 when he determined a motion to strike in which he was required to consider the sufficiency of the pleadings and whether reasonable causes of action were pleaded:

[24] The essential elements of the tort of negligence are a duty of care, breach of the duty, causal connection between the breach of duty and the injury, and actual loss. Full particulars of the allegations of negligence should have been provided, such as "what each allegation of such wrongful act is, and the when, what, by whom and to whom of the relevant circumstances": *Lana International Ltd. v. Menasco Aerospace Ltd.* (1996), 1996 CanLII 7974 (ON SC), 28 O.R. (3d) 343 (Gen. Div.).

[25] Prothonotary Lafrenière's statements were subsequently echoed by the Federal Court in several decisions pertaining to the rules of pleading. As stated succinctly by Justice Mactavish in *Leahy v Canada*, 2008 FC 620 (CanLII), at para 13, when a particular cause of action is pleaded, the claim must contain material facts satisfying all the necessary elements of the cause of action. Otherwise, the inevitable conclusion will be that such a claim discloses no reasonable cause of action.

[26] In *Bigeagle v Canada*, 2023 FCA 128 (CanLII), at para 39, citing *Mancuso v Canada (National Health and Welfare)*, 2015 FCA 227, at paras 17, 19 and 27, the Federal Court of Appeal held that pleadings should tell the adverse party the “who, when, where, how and what” that gives rise to liability or, as the case may be, that gives rise to a defence. This is not controversial.

[27] In *Merchant Law Group v Canada Revenue Agency*, 2010 FCA 184 (CanLII) (“Merchant”), at paras 33 and 35, the Federal Court of Appeal held in the context of a pleading concerning the tort of misfeasance in public office that particulars of such an allegation are necessary pursuant to Rule 181 of the *Rules* because the allegation requires the demonstration of a particular state of mind. The degree of particulars required, however, cannot go “[...] beyond the level of particularity necessary to fulfil the purpose of pleadings in civil proceedings”. That purpose was held to be fulfilled when the issues in the action are defined with reasonable precision, the adverse party has sufficient information to investigate the matter, and the pleadings can be adequate in light of the particulars provided (*Merchant*, at para 39).

[28] Negligent misrepresentation as a common law cause of action in civil proceedings requires that the following essential elements be pleaded and be supported by allegations of material fact: (1) there must be a duty of care based on a "special relationship" between the representor and the representee; (2) the representation in question must be untrue, inaccurate, or misleading; (3) the representor must have acted negligently in making said misrepresentation; (4) the representee must have relied, in a reasonable manner, on said negligent misrepresentation; and (5) the reliance must have been detrimental to the representee in the sense that damages resulted (*Queen v Cognos Inc*, 1993 CanLII 146 (SCC), [1993] 1 SCR 87, at page 110). The Ontario Court

of Appeal in *Lysko v Braley*, 2006 CanLII 11846 (ON CA), at para 30, confirmed that a pleading of misrepresentation at common law and in a civil proceeding, even if of innocent misrepresentation, must set out with careful particularity the elements of the misrepresentation alleged and relied upon, that is:

1. the alleged misrepresentation itself,
2. when, where, how, by whom and to whom it was made,
3. its falsity,
4. the inducement,
5. the intention that the plaintiff should rely upon it,
6. the alteration by the plaintiff of his or her position relying on the misrepresentation, and,
7. the resulting loss or damage to the plaintiff.

[29] The particularity required to properly plead misrepresentation in a civil proceeding as set out in *Lysko*, itself following *Lana International* and the description of the particulars required to properly plead misrepresentation in a civil proceeding in Ontario, is a requirement of pleading before most Canadian superior courts either through procedural rules or jurisprudence (British Columbia's *Supreme Court Civil Rules*, BC Reg 168/2009, at Rule 3-7(18) to 3-7(20); (*Provalcid Inc v Graff*, 2015 ABQB 574 (CanLII), *Boyd v Eacom Timber Corporation*, 2012 SKQB 226 (CanLII), *King's Bench Rules*, Sask QB Rules 2013 at Rule 13-9(1); Manitoba's *Court of King's Bench Rules*, Man Reg 553/88, at rule 25.06(11); Ontario's *Rules of Civil Procedure*, RRO 1990, O. Reg. 198 at Rule 25.06(8); New Brunswick's *Rules of Court*, NB Reg 82-73, at Rule 27.06(9); *Civil Procedure Rules*, NS Civ Pro Rules 2009 at Rule 38.03(3); *Rules*

of Civil Procedure, PEI Rules at Rule 25.06(8).; *61050 Newfoundland and Labrador Inc. (Hickman Chrysler) v Royal Garage Limited*, 2012 CanLII 13240 (NL SC).

[30] When pleading misrepresentation, identifying what is a misrepresentation involves specifying what is represented as well as how it is false. This is quite simply identifying what makes a representation a misrepresentation (*Drywall Acoustic Lathing and Insulation, Local 675 Pension Fund v SNC-Lavalin Group Inc.*, 2015 ONSC 256 (CanLII), at para 29; *Lana International; Rahn v McNeill*, 1987 CanLII 2507 (BC SC), [1987] B.C.J. No. 2337, 19 B.C.L.R. (2d) 384 (S.C.), at p. 392 B.C.L.R.). Without such particularity, the purpose of pleadings is left unfulfilled, particularly in light of a pleading where liability arises in connection with an intention to mislead, or, in the case of a misrepresentation plea pursuant to section 53 of the *Act*, where a patent may be voided because of a material misrepresentation that was intended to mislead.

[31] Considering the jurisprudence referred to above, the Federal Court of Appeal's instruction in *Merchant*, and reconciling those elements with the constituent elements of a misrepresentation defence pursuant to section 53 of the *Act* as set out in *SNF*, I conclude that it is implied by the jurisprudence applicable to Rule 181(1) of the *Rules* that a reasonably pleaded misrepresentation defence pursuant to section 53 of the *Act* must contain the essential elements of the defence required by section 53 of the *Act* as well as the particulars, regardless of whether described as "full particulars" or not, that are consistent with the particulars of a misrepresentation claim in a civil proceeding. Those would therefore be as follows:

- A) Essential elements required by section 53 of the *Act*:
 - a) the identification of the impugned statements;

- b) the establishment that they were untrue;
- c) the demonstration that they were material;
- d) that they were made in the drafting of the patent with wilful intent to mislead;
- and,
- e) that the impugned statement would likely mislead the skilled person.

and,

B) Particulars required by Rule 181(1):

- a) the identity of the representor;
- b) the identity of the representee;
- c) when, where and how the representation was made;
- d) the actual words, figures, or information that are alleged to constitute the misrepresentation(s);
- e) how the representation is untrue or false;
- f) that the representor knew that the representation was untrue or false when made to the representee; and,
- g) that the misrepresentation was made with the intention that the representee rely upon it.

[32] Failing the particularized pleading of such essential elements and necessary particulars, the pleading would not constitute a reasonable cause of action within the meaning of Rule 221(1)(a) and could be struck.

II. The Proposed Amendments

[33] The Defendant's contested proposed amendments in the T-1094-23 Second Amended

Statement of Defence read as follows, with the proposed amendments underlined:

47. In March 2018, API represented that "eculizumab and its correct sequence were not made publically available until after the filing date." API made this statement, knowing it to be untrue. In this same Office Action response, API also represented that "the complete structure of eculizumab was not disclosed in the prior art or available to the public prior to the 15 March 2007 effective date of the present application" ["not" emphasized in the original by single-underline], "the prior art fails to teach or suggest the full sequence of eculizumab, and in particular the unique, non-naturally occurring, protein-engineered heavy chain of eculizumab (including the CH1-hinge-CH2-CH3 regions) of SEQ ID NO: 2", "the full structure of eculizumab was not published", and the "unique, non-naturally occurring protein engineered CH1-hinge-CH2-CH3 sequence" of the heavy chain consisting of SEQ ID NO: 2 "confers unexpected advantageous effects on the antibody eculizumab ... including decreased effector function". These statements were also knowingly untrue when API made them.

49. API's statements to CIPO in December 2016 and March 2018 regarding the sequence of eculizumab and the purportedly unexpected decreased effector function not being previously known were knowingly untrue in light of its submissions to the EPO. API's statements were also untrue in light of its prior publications, statements, and uses, e.g., the CAS Listing (hereinafter referring to the listing comprising CAS Registry No. 219685-50-4, including CAS Listing A and CAS Listing B), the 015 Patent (including its listing on the Patent Register and with respect to statements made to the Patented Medicines Pricing Review Board in at least 2017), US 245, US 298, US 972, Thomas 1996, Mueller 1997, and WO 971, and at least the studies disclosed in US 298, Hillmen 2004, Hill I 2005, Hill II 2005, Hill 2004, SHEPHERD 2005, and TRIUMPH 2005. Those statements supported the material and misleading inclusion of "SEQ ID NO: 2" and "SEQ ID NO: 4" in the patent claims instead of "eculizumab", without which (as API knew) the 810 Patent would not have been granted.

69A. In the further alternative, Alexion disclosed, without any obligations of confidence, the subject matter of claims 1 to 2 of the 810 Patent to CAS, Lonza Biologics and/or Dr. Peter Hillmen more than one year before the filing date. Such disclosure was an enabling disclosure, alone or in combination with the common general knowledge.

[34] These same amendments are contained in the proposed Third Amended Statement of Defence in the proceeding bearing file no.: T-1095-23 at paragraphs 50, 52 and 72A.

[35] The objection to the proposed amendment in proposed paragraph 69A (and 72A) is limited only to the inclusion of “CAS” in the first sentence.

[36] Finally, the Defendant proposes to include two documents in its list of disclosed and alleged prior art at Schedule 1 of both pleadings.

III. **Procedural Background**

[37] These proceedings were commenced on May 25, 2023. They are scheduled to be heard at trial commencing on January 20, 2025, almost 7 months from the date upon which this motion was argued.

[38] The parties have completed corporate representative and inventor examinations for discovery. Each party has brought motions to compel after their initial examination for discovery and after follow-up examinations were completed. The parties’ in-chief expert reports are currently scheduled to be served on August 2, 2024, and the responding expert reports are due on November 1, 2024.

[39] The Defendant's original Statement of Defence was delivered in July 2024 and contained the allegation that the Plaintiffs' Canadian Patent No.: 2,645,810 (the "810 Patent") was void due to misrepresentation pursuant to section 53 of the *Act*. The Defendant amended its Statement of Defence twice since, on March 11, 2024, and on April 26, 2024, on consent. Those amendments included amendments to the allegations that the 810 Patent is void due to misrepresentations.

[40] The amendments under consideration on this motion were proposed to the Plaintiffs on March 8, 2024, and are at least in part directed to adding substance to the existing misrepresentation allegations.

[41] The Plaintiffs have not previously argued that the Defendant's misrepresentation, either as drafted or as proposed through a draft proposed amended Statement of Defence, were improper. The Plaintiffs have had the opportunity to examine the Defendant on its allegations of misrepresentation as they read prior to the amendments sought to be permitted through this motion, as well as on the amendments now under consideration. No motion to strike has been brought.

IV. **Parties' Arguments**

[42] The Defendant argues in general that its proposed amendments meet the threshold of Rule 75 and should be allowed. It argues that their proposed amendments are neither new allegations, nor allegations advanced in an untimely manner such that the Plaintiffs will not be in a position to fully and adequately address them before trial. It argues that the interests of justice would be served by granting leave for the proposed amendments to be made.

[43] The Plaintiffs argue that the proposed amendments do not form a proper pleading, and would be struck under Rule 221(a) on a motion to strike on the basis of lacking particularity and sufficiency of pleaded material facts for the constituent elements of the allegations. They also argue, on the basis of expert evidence led on this motion, that the proposed amendments are doomed to fail pursuant Rule 221(c) because the references cited by the Defendant as being allegedly anticipatory and/or demonstrative of material misrepresentation are clearly incapable of establishing those allegations. The Defendant, so argues the Plaintiffs, does not even attempt to show that its proposed amendments have a reasonable chance of success to meet the threshold under Rule 221(a) or that they are not doomed to fail under Rule 221(c). It follows that leave should not be granted.

a) Misrepresentation Amendments

[44] The Defendant argues that the amendments to the proposed Third Amended Statements of Defence provide additional particulars to its section 53 *Patent Act* defence, including those requested by the Plaintiffs on discovery and provided by the Defendant in writing. The proposed amendment, it argues, clearly plead a reasonable defence, i.e., an assertion that the 810 Patent is void under section 53 of the *Act*. It also argues that the proposed amendments point to additional allegedly materially misleading statements found within the Plaintiffs' 2018 correspondence to the Canadian Intellectual Property Office ("CIPO") and identifies with specificity public disclosures the Plaintiffs made that contradict the statements it made to CIPO.

[45] The Defendant argues that its proposed amendments simply make clear in the pleading much of what has already been provided to the Plaintiffs by way of undertaking and/or written answers following the Plaintiffs' motion to compel.

[46] The Plaintiffs counter that the Defendant seeks to expand its material misrepresentation allegation by citing additional statements to CIPO that allegedly also constitute material misrepresentations. The Defendant's proposed amendments also add allegations that the statements are untrue in light of the Plaintiffs' alleged "prior statements, publications, and uses", which the Defendant pleads by referencing various statements, publications or uses, without closing the list of documents they allege as material facts to substantiate their defence.

[47] The proposed amendments, they argue, seek to make new misrepresentation allegations and allege that: (i) four additional statements constitute material misrepresentations; and (ii) that all the statements are untrue in light of the open-ended list of references, without pleading what facts within those references allegedly made the statements to CIPO knowingly untrue. The proposed amendments as to misrepresentation thus seek to expand rather than particularize the defence already pleaded.

[48] The core of the misrepresentation defence pursuant to section 53 of the *Act* is pleaded at paragraphs 44, 45 and 46 of the Second Amended Statement of Defence in the T-1094-23 proceeding pleading. The misrepresentation defence is similarly pleaded in the Second Amended Statement of Defence in the T-1095-23 proceeding.

[49] Reading the Second Amended Statement of Defence holistically, the existing misrepresentation allegation made by the Defendant is that the 810 Patent contains additions from the originally filed patent petition that were wilfully made for the purpose of misleading because the 810 Patent's original application refers to "eculizumab", not sequence listings, and SEQ ID NO: 4 contained 22 additional amino acids on the N-terminus. Additional pleaded allegations pertain to a December 2016 amendment to the description and the sequence listing in

the patent application and that those sequences were first disclosed in the application to CIPO. That the application filed with CIPO was the first disclosure of the amended sequence listing is part of the apparent core of the Defendant's allegation of misrepresentation; the Defendant contends that the first disclosure was made elsewhere prior to the application to CIPO and that the documents it alleges as material facts in its pleading particularize the Plaintiffs' misrepresentation.

[50] The Defendant has already pleaded in the first sentence of paragraph 47 that the Plaintiffs made a representation in March 2018, that "eculizumab and its correct sequence were not made publicly available until after the filing date". The proposed amendment to paragraph 47 attempts to particularize the insufficiently pleaded and generic "representation" of March 2018, by describing the "where" of the representation that had already been somewhat alleged by date – an Office Action response with no precise date, sender or recipient – in which other alleged misrepresentations were made with respect to disclosure prior to March 15, 2007, what the prior art taught or suggested, and other fragments of statements contained in the described Office Action response.

[51] In my view the proposed amendments to paragraph 47 are best characterized as adding material facts to the allegation made at paragraph 44 of the Second Amended Statement of Defence that the patent application that resulted in the 810 Patent being issued contained a "material misrepresentation" in the specification.

[52] As this is not a motion to strike but a motion for leave to amend in which the substance of a motion to strike must be considered to determine whether the amendments sought to be added have a reasonable chance of success, it is not the Court's duty to assess whether the previously

pleaded misrepresentation defence has a reasonable chance of success regardless of whether the proposed amendments are allowed. The Court's function is to determine whether the proposed amendments are doomed to fail, not whether the defence pleaded in a prior iteration of the pleading is doomed to fail. An independent motion to strike separate from a motion for leave to amend would be required for such a determination.

[53] The material facts that are sought to be added by amendment to support the previously advanced defence can neither fail nor succeed; they are material facts rather than claims or defences that may, if established at trial, support a viable claim or defence. I find that the proposed amendments to paragraph 47 are not "doomed to fail".

[54] The proposed paragraph 49 amendments include two facets. The first is the inclusion of a previously unpleaded alleged misrepresentation pertaining to the "purportedly unexpected decreased effector function", and a list of apparent prior publications and uses that are described by reference to publication information without more particularity.

[55] The first paragraph 49 amendment pertaining to the "purportedly unexpected decreased effector function" does not constitute a new defence being asserted for the first time. Rather, as is the case with the proposed paragraph 47 amendments, it is an allegation of material fact to establish its misrepresentation defence. I find that this proposed amendment is not "doomed to fail".

[56] The balance of the paragraph 49 proposed amendments is a list of apparent prior publications and uses that are described by reference to publication information without greater detail. If these publications are being alleged as particulars of the misrepresentation defence

advanced with respect to the content of the Plaintiffs' patent application, then they fall far short of what would be acceptable to complete the allegation of misrepresentation based upon them if considered on a motion to strike. The purpose of pleading particulars of a misrepresentation defence is not met by including a generally defined list of publications without pinpoints that are purported to substantiate that the alleged representation in the patent application was false when made.

[57] The Plaintiffs argue that the particulars sought to be added through the proposed amendments to paragraph 49 are nevertheless doomed to fail because they are frivolous and vexatious in light of the evidence led on this motion that none of the listed publications disclose the full sequence of eculizumab i.e. SEQ ID NOs. 2 and 4 of the 810 Patent.

[58] I agree with the Plaintiffs that there is some frivolity involved with the proposed amendment with respect to the disclosure of the full sequence. Dr. Tessier's evidence is compelling in this regard, and to the point. The evidence before me is that none of the publications listed in the proposed paragraph 49 amendment disclose the full sequence for which the patent was sought. Nevertheless, Dr. Tessier's evidence is silent on the allegation of misrepresentation regarding the effector function.

[59] These proposed amendments are allegations of material fact meant to support the previously pleaded misrepresentation defence. As noted above, material facts are not claims or defences and cannot be independently found to be "doomed to fail." The proposed amendments to paragraph 49 cannot be said to be doomed to fail as appreciated on a motion for leave to amend.

b) Anticipation: The paragraph 69A proposed amendment

[60] The proposed amendment at paragraph 69A is to include a reference to a prior disclosure of claims 1 and 2 of the 810 Patent to CAS. This allegation is in support of an anticipation defence.

[61] The amendment seeks to add allegations of material fact in the further alternative to other pleaded anticipation defences that the Plaintiffs disclosed the subject matter of claims 1 and 2 of the 810 Patent to CAS without specifying when and how the disclosure occurred.

[62] The Plaintiffs rely on Dr. Tessier's evidence to argue that the inclusion of "CAS" in the proposed paragraph 69A is frivolous and doomed to fail because the CAS Listing defined at paragraph 49 of the proposed Third Amended Statement of Defence to mean the listing comprising CAS Registry No. 219685-50-4, including CAS Listing A and CAS Listing B (themselves particularized as items 17 and 73 of Schedule 1 to the proposed Third Amended Statement of Defence) do not contain the full sequence of eculizumab, and therefore cannot establish anticipation through disclosure.

[63] The Court appreciates the Plaintiffs' argument and finds it compelling. However, determining whether the reference to the CAS in the proposed paragraph 69A is doomed to fail requires the Court to interpret that part of the Defendant's pleading that refers to "the subject matter of claims 1 and 2 of the 810 Patent" in the context of the specific paragraph in the pleading and whether that is limited to the full sequence of eculizumab or not. That interpretation and whether its meaning can be made out in the evidence is best left to the trier of fact at trial. The Court cannot say that the proposed amendment is doomed to fail as that test is appreciated

on a motion for leave to amend.

c) Prior Art: New Additions

[64] The Defendant seeks to allege and include two documents alleged to constitute prior art as items 73 and 74 of Schedule 1 to its Second Amended Statement of Defence. The documents at issue are what has been pleaded in the proposed paragraph 47 as the CAS Listing B dated February 14, 1999 as item 73, and a publication described as “Alexion Issued Key C5 Complement Inhibitor Patent for Inflammatory Diseases” dated March 15, 2002, as item 74.

[65] The Plaintiffs argue that CAS Listing B is dated June 11, 2019, and thus cannot constitute prior art because it post-dates the claim date. Upon review of the document, it appears that the date of June 11, 2019, is the copy print date included in the footer of the printed document. It does not appear to be the date upon which the information was registered with CAS under Registry Number 219685-50-4. Reference to the document itself does not lead the Court to conclude that the CAS Listing B document post-dates the claim date.

[66] The proposed item 74 pre-dates the claim date. There is no suggestion that the document would not be helpful in the context of this litigation such that it ought not to be included in the list of prior art pleaded by the Defendant.

[67] The proposed additions to the Defendant’s Schedule 1 to its proposed Third Amended Statement of Defence are not doomed to fail or frivolous as that test is appreciated on a motion for leave to amend.

V. **The interests of justice**

[68] The interests of justice in granting or refusing leave to amend as proposed require that the Court consider such factors such as (i) the timeliness of the motion to amend; (ii) whether the proposed amendments would delay trial; (iii) whether the amending party's prior position has led another party to follow a course of action in the litigation that it would be difficult to alter; and (iv) whether the amendments will facilitate the Court's consideration of the substance of the dispute on its merits without any single one of these factors being determinative.

[69] The Defendant's motion is not untimely considering the litigation timetable, the length of time to trial and the date upon which it proposed its amendments to the Plaintiffs, nearly 10 months before the scheduled first day of trial. Considered in light of the typical targeted 21-month trial commencement timeline in an action pursuant to subsection 6(1) of the *Regulations*, the proposed amendments were disclosed only slightly after the mid-way point in the litigation's timeline. That is not untimely in the circumstances of this case.

[70] There is no suggestion that granting leave for the amendments to be made would delay the trial or that any party's position must be altered as a result of the amendments if leave is granted.

[71] The Court is not persuaded that allowing the proposed amendments will complicate the Court's consideration of the substance of the dispute between the parties with the exception of the list of publications pleaded at the proposed paragraph 49 amendments.

[72] The amendments found at the second sentence of the proposed paragraph 49 consist of an unlimited list of prior publications and uses that are described by reference to publication

information without greater detail. Their open-ended description, opacity and absence of specificity will complicate the Court's adjudication of the misrepresentation defence advanced by the Defendant.

[73] Leave will therefore be granted to the Defendant to amend its pleadings in accordance with the proposed Third Amended Statements of Defence filed for this motion in both the T-1094-23 and T-1095-23 proceedings, save and except for the proposed amendments found in the second sentence of the proposed paragraph 49 of the Third Amended Statement of Defence filed for this motion in the T-1094-23 proceeding, and in the parallel proposed second sentence of paragraph 52 of the Third Amended Statement of Defence filed for this motion in the T-1095-23 proceeding, for which leave is not granted on the basis that their inclusion is not in the interests of justice.

VI. COSTS

[74] The Court strongly encourages the parties to confer and attempt to agree on the costs of this motion prior to August 2, 2024. If the parties agree on costs by then, they may deliver a letter on consent to the case management office in Ottawa to my attention that sets out their agreement as to costs and, if the Court considers such costs appropriate, a subsequent Order as to costs consistent with the agreement as to costs will issue.

[75] In the event that the parties do not agree on the costs of this motion, then the Defendant shall have until August 7, 2024, to serve and file its costs submissions that do not exceed three pages, double-spaced, exclusive of schedules, appendices and authorities. The Plaintiffs will then

have until August 16, 2024, to serve and file its costs submissions, also limited to three pages, double-spaced, exclusive of schedules, appendices, and authorities.

[76] If no agreement as to costs is filed by August 2, 2024, and no costs submissions are served and filed by August 7, 2024, then no costs will be awarded on this motion.

THIS COURT ORDERS that:

1. The Defendant's motion for leave to amend its pleadings in the manner and with the content of its proposed Third Amended Statements of Defence is granted in part and dismissed in part.
2. Leave is hereby granted for the Defendant to amend its pleadings in the manner and with the content of its proposed Third Amended Statement of Defence in the proceedings bearing docket no.: T-1094-23 and T-1095-23, filed in support of this motion save and except for those proposed amendments found:
 - i. in the second sentence of the proposed paragraph 49 of the Third Amended Statement of Defence filed for this motion in the T-1094-23 proceeding; and,
 - ii. in the second sentence of the proposed paragraph 52 of the Third Amended Statement of Defence filed for this motion in the T-1095-23 proceeding;
 - ii. for which leave is denied.

3. Costs are reserved to be adjudicated after receipt of the parties' costs agreement or submissions.

"Benoit M. Duchesne"

Case Management Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1094-23 & T-1095-23

STYLE OF CAUSE: (T-1094-23) ALEXION PHARMACEUTICALS, INC.,
and ALEXION PHARMA INTERNATIONAL
OPERATIONS LIMITED v AMGEN CANADA, INC.;
and (T-1095-23) ALEXION PHARMACEUTICALS,
INC. and ALEXION PHARMA INTERNATIONAL
OPERATIONS LIMITED v AMGEN CANADA INC.

PLACE OF HEARING: OTTAWA, ONTARIO (BY VIDEOCONFERENCE)

DATE OF HEARING: JUNE 13, 2024
JUNE 20, 2024 (SUPPLEMENTAL SUBMISSIONS)

**CONFIDENTIAL JUDGMENT
AND REASONS:** ASSOCIATE JUDGE BENOIT M. DUCHESNE

DATED: JULY 22, 2024

APPEARANCES:

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