Federal Court  Cour fédérale

**Date: 20210111**

**Docket: T-671-20**

**Citation: 2021 FC 37**

**Toronto, Ontario, January 11, 2021**

**PRESENT: Case Management Judge Angela Furlanetto**

**BETWEEN:**

**SUNOVION PHARMACEUTICALS CANADA INC. AND SUMITOMO DAINIPPON PHARMA CO., LTD.**

**Plaintiffs**

**and**

**TARO PHARMACEUTICALS INC.**

**Defendant**

# ORDER AND REASONS

## I. Background

[1] This is an action under section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* (*"PMNOC Regulations"*) involving three patents listed for the medicinal ingredient lurasidone hydrochloride: Canadian Patent Nos. 2,538,265, 2,696,510 and 2,814,828 ("828 Patent").

[2] This order relates to a motion brought by the Defendant, Taro Pharmaceuticals, Inc. ("Taro"), to amend its Statement of Defence to include allegations not found in its Notice of Allegation ("NOA"), but raised in the Statement of Defence filed in another section 6(1) action for lurasidone hydrochloride, involving the third party generic, Pharmascience Inc. ("Pharmascience").

[3] The proposed amendments seek to add: a) additional prior art references, identified in Schedules A, B and C, to support the allegations of obviousness in respect of the asserted patents; and b) additional grounds of invalidity in respect of the 828 Patent based on anticipation, inutility, overbreadth, ambiguity and insufficiency.

[4] It is not disputed that the specific allegations made under the additional grounds of invalidity and the additional references are the same as those that appear in the Pharmascience Statement of Defence and are in play in that proceeding as against the Plaintiffs.

[5] The Pharmascience action was commenced on February 28, 2020, nearly four months before the within action, which was filed on June 24, 2020. The Statement of Defence in Pharmascience was filed on June 8, 2020, with Taro's Statement of Defence filed on July 27, 2020.

[6] Taro first raised its proposed amendments to the Plaintiffs in correspondence dated October 14, 2020. After unsuccessful efforts to obtain consent to the amendments proposed, this motion was brought on November 10, 2020 and ultimately heard by videoconference on

December 3, 2020. The motion has been brought before any oral examinations for discovery have taken place.

[7] The trial of this action is scheduled to commence on April 25, 2022. The Pharmascience trial will commence on November 1, 2021.

[8] The sole issue before the Court on this motion is whether the proposed amendments should be allowed.

[9] The Plaintiffs argue that it would be abusive to allow the amendments proposed as to do so would be contrary to the requirements set out in the *PMNOC Regulations*. The Plaintiffs assert that the scheme of the *PMNOC Regulations* restricts the allegations of invalidity raised in defence to an action for infringement under section 6(1) of the *PMNOC Regulations* to those that have a detailed statement of fact and law in the generic's NOA. To do otherwise would incentivize generics to hide invalidity allegations until after an action is brought, hindering the innovator's ability to properly evaluate whether to initiate a proceeding and to take on the risks and exposure associated with it. The Plaintiffs contend that the amendments proposed are extensive and that Taro was obligated, but did not diligently disclose what it now seeks to argue; they assert that it would be prejudicial to allow the amendments now without any prior notice in Taro's NOA.

[10] The Defendant argues that the amendments to the *PMNOC Regulations* no longer limit a generic to the issues raised in their NOA; instead, the action is governed by the pleadings and is

intended to parallel a regular patent infringement action. They assert that there would be no prejudice to the Plaintiffs if the amendments were allowed in view of the timing involved and the fact that the amendments are already in play in the Pharmascience proceeding. As such, the Defendant contends that the amendments do not raise any new issues for the Plaintiffs.

[11] For the reasons set out herein, I find that the amendments proposed should be allowed. In my view, the amendments should not be refused outright on the basis that the arguments and prior art sought to be raised were not in Taro's NOA; rather, the amendments must be considered under the principles relating to pleading amendments and with respect to their impact in the present proceedings. From this perspective, I find it appropriate to exercise my discretion to allow the amendments. The amendments are already in play in the Pharmascience action, without objection, and as such are not bereft of a reasonable prospect of success. Further, in view of the stage of the proceeding and the nature of what is proposed, there would be limited prejudice to the Plaintiffs in allowing the amendments into the proceeding now, to parallel the additional invalidity arguments with those in the Pharmascience action.

## II. Are the Amendments Proposed Restricted Outright by the *PMNOC Regulations*?

[12] On September 21, 2017 significant amendments were made to the *PMNOC Regulations (Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017,* SOR/2017-166), most notably converting the right of an innovator under section 6(1) of the *PMNOC Regulations* to bring an application to prohibit the Minister from issuing a notice of compliance ("NOC") to a generic into a right to bring an action for patent infringement as

against the generic. This had the effect of removing the potential for dual track litigation. Under the old regime, an application under section 6(1) of the *PMNOC Regulations* was limited to determining whether allegations of non-infringement and invalidity were justified for the purposes of issuing an NOC and could be followed by a separate action to finally determine issues of patent infringement and validity. Under the new regime parties are granted the right to proceed in a single action, on a full record, to obtain a final decision on infringement and validity, with an effective right of appeal: *Amgen Inc*. v. *Pfizer Canada Inc*., 2018 FC 1078 at para 27, aff'd 2019 FCA 249 at paras 8, 65; *Janssen Inc*. v. *Teva Canada Ltd*., 2020 FC 593 at para 257; *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017*, SOR/2017-166, Regulatory Impact Assessment Statement ("RIAS"), see for example, page 34.

[13] Prior to the amendments to the *PMNOC Regulations*, the NOA defined the issues that could be raised in a section 6(1) proceeding. This was both a factor of the nature of the proceeding itself, which was set out to determine whether the allegations in the NOA were justified so that an NOC could be issued, and of the application process, where there was no pleading from the generic and the notice of application and innovator's evidence were based on a response to the allegations made in the NOA. The NOA was required to be comprehensive and to raise all facts and legal arguments upon which the generic intended to rely in support of its allegations: *Teva Canada Innovation* v. *Apotex Inc*., 2014 FC 1070 at paras 59-66; *AB Hassle* v. *Canada (Minister of National Health & Welfare)* (2000), 7 C.P.R. (4th) 272 (FCA) at para 21-24; *Bayer Inc*. v. *Cobalt Pharmaceuticals Co*., 2013 FC 1061 at para 34-37.

[14] Consistent with the former regime, the triggering event for an action under section 6(1) of the amended *PMNOC Regulations* is the receipt by the innovator of an NOA, which initiates the 45-day period from which the innovator is to determine whether an action for infringement should be brought. However, the context for the NOA has changed.

[15] Instead of the NOA being a precursor to an application to determine whether the allegations made in the NOA are justified, the proceeding that may be instituted is an action, intended to determine patent infringement and validity and for which a Statement of Defence will be filed, and Counterclaim may be provided. As set out in sections 6(1) and 6(3):

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| 6(1) The first person or an owner of a patent who received a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the date on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice. | 6 (1) La première personne ou le propriétaire d'un brevet qui reçoit un avis d'allégation en application de l'alinéa 5(3)a) peut, au plus tard quarante-cinq jours après la date à laquelle la première personne a reçu signification de l'avis, intenter une action contre la seconde personne devant la Cour fédérale afin d'obtenir une déclaration portant que la fabrication, la construction, l'exploitation ou la vente d'une drogue, conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou (2), contreferait tout brevet ou tout certificat de protection supplémentaire visé par une allégation faite dans cet avis. |
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| (3) The second person may bring a counterclaim for a declaration | (3) La seconde personne peut faire une demande reconventionnelle afin d'obtenir une déclaration : |
| (a) under subsection 60(1) or (2) of the *Patent Act* in respect of any patent claim asserted in the action brought under subsection (1) ... | a) soit au titre des paragraphes 60(1) ou (2) de la *Loi sur les brevets* à l'égard de toute revendication se rapportant à un brevet faite dans le cadre de l'action intentée en vertu du paragraphe (1) ... |

[16] The generic is required to provide information that will allow the innovator to assess infringement of the subject patent as well as details of any allegation that the patent is invalid. As stated in the amended subsection 5(3) of the *PMNOC Regulations*:

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| (3) A second person who makes an allegation referred to in paragraph (2.1)(c) shall | (3) La seconde personne qui inclut une allégation visée à l'alinéa (2.1)c) est tenue de prendre les mesures suivantes : |
| (a) serve on the first person a notice of allegation relating to the submission or supplement filed under subsection (1) or (2) on or after its date of filing; | a) signifier à la première personne un avis de l'allégation à l'égard de la présentation ou du supplément déposé en vertu des paragraphes (1) ou (2), à la date de son dépôt ou à toute date postérieure; |
| (b) include in the notice of allegation | b) insérer dans l'avis de l'allégation : |
| (i) a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the | (i) une description de l'ingrédient médicinal, de la forme posologique, de la concentration, de la voie d'administration et de |

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| submission or supplement has been filed, and | l'utilisation de la drogue visée par la présentation ou le supplément, |
| (ii) a statement of the legal and factual basis for the allegation, which statement must be detailed in the case of an allegation that the patent or certificate of supplementary protection is invalid or void; | (ii) un énoncé du fondement juridique et factuel de l'allégation, lequel énoncé est détaillé dans le cas d'une allégation portant que le brevet ou le certificat de protection supplémentaire est invalide ou nul. |
| (c) serve the following documents with the notice: | c) signifier, avec l'avis, les documents suivants : |
| ... | ... |
| (iii) a searchable electronic copy of the portions of the submission or supplement that are under the control of the second person and relevant to determine if any patent or certificate of supplementary protection referred to in the allegation would be infringed, and | (iii) une copie électronique — pouvant faire l'objet de recherches — de toute partie de la présentation ou du supplément qui est sous le contrôle de la seconde personne et qui est pertinente pour établir si un brevet ou un certificat de protection supplémentaire visé par l'allégation serait contrefait, |
| (iv) if the second person is alleging that the patent or certificate of supplementary protection is invalid or void, an electronic copy of any document – along with an electronic dopy of it in English or French if available – on which the person is relying in support of the allegation; | (iv) si la seconde personne allègue que le brevet ou le certificat de protection supplémentaire est invalide ou nul, une copie électronique — ainsi qu'une copie électronique en français ou en anglais si une telle copie est disponible — de tout document à l'appui de son allégation; |

[17] The right to bring an action is intended to be final. As set out at section 6.01 of the *PMNOC Regulations*, the innovator may not bring a subsequent action for infringement in respect of patents that are the subject of the NOA unless the innovator can establish that it was not provided with a reasonable basis to determine that an action should be brought:

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| 6.01 No action, other than one brought under subsection 6(1), may be brought against the second person for infringement of a patent or a certificate of supplementary protection that is the subject of a notice of allegation served under paragraph 5(3)(1) in relation to the making, construction, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) unless the first person or the owner of the patent did not, within the 45-day period referred to in subsection 6(1), have a reasonable basis for bringing an action under that subsection. | 6.01 Aucune autre action qu'une action intentée en vertu du paragraphe 6(1) ne peut être intentée contre la seconde personne pour la contrefaçon d'un brevet ou d'un certificat de protection supplémentaire visé par un avis d'allégation signifié en application de l'alinéa 5(3)a) relativement à la fabrication, à la construction, à l'exploitation ou à la vente d'une drogue conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou (2), sauf si la première personne ou le propriétaire du brevet n'avait pas, dans la période de quarante-cinq jours prévue au paragraphe 6(1), de motifs raisonnables pour intenter une action en vertu de ce paragraphe. |

[18] As with the old regime, a generic is entitled to claim damages under section 8 of the *PMNOC Regulations* for losses suffered during the period that the generic was kept off the market because of an unsuccessful or discontinued proceeding having been brought. The scope of damages is expanded to allow for a claim for any loss suffered as a result of the delayed market entry, without limiting the liability to a specified end date and allows for discretion to

specify a more relevant start date, other than the later of the date of service of the NOA, and the date when the NOC would have issued in the absence of the *PMNOC Regulations*.

[19] The Plaintiffs assert that the purpose of the NOA as it relates to an invalidity allegation has not changed under the new regime. They assert that both the prohibition on bringing subsequent actions for infringement in respect of patents listed in an NOA (section 6.01 of the *PMNOC Regulations*) and the enhanced exposure under section 8 puts even greater emphasis on the importance of providing a detailed statement of all of the invalidity issues that *will be* raised in the proceeding so that the innovator can make an informed choice as to whether a proceeding should be brought in view of the risks and exposure associated with that decision.

[20] However, a view that the NOA restricts the issues in the proceeding such that a Statement of Defence can never be amended to add new arguments is contrary to the express language of the RIAS and is inconsistent with the overall scheme of the *PMNOC Regulations*.

[21] As noted by Taro, the Court may look to the RIAS to help interpret the *PMNOC Regulations* as the Federal Court of Appeal recently did in *Apotex Inc*. v. *Bayer Inc*., 2020 FCA 86 at para 53.

[22] While there is a requirement to provide a detailed statement relating to the legal and factual basis for any allegation of invalidity, as stated at page 40 of the RIAS, the delivery of an NOA is intended to facilitate early consideration of issues *likely* to be raised in the litigation and

is not to circumscribe or limit the issues and arguments that may be raised in the proceeding, which are to be defined, unlike the former regime, by the pleadings themselves:

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| The NOA must provide a legal and factual basis for any allegation made in the submission or supplement. This will facilitate early consideration of issues likely to be raised in litigation. This requirement does not circumscribe or otherwise limit the issues and arguments that may be raised in a proceeding brought under the Regulations. The scope of proceedings will be defined by the pleadings in accordance with prevailing rules and practices. This will further align litigation under the Regulations with litigation under the Act. | L'AA doit énoncer le fondement juridique et factuel des allégations formulées dans la présentation ou le supplément, ce qui faciliterait l'examen à une étape précoce des questions susceptibles d'être soulevées dans la procédure. Cette exigence ne limite aucunement les questions ou arguments qui peuvent être soulevés dans une procédure en vertu du règlement proposé. La portée de l'instance serait définie par les actes de procédure conformément aux règles et pratiques applicables, ce qui harmoniserait les procédures introduites en vertu du Règlement avec celles engagées en vertu de la Loi. |

[23] The documents that a generic must now produce with its NOA from its drug submission allow the innovator to assess whether the relevant patents will be infringed. As with a normal patent infringement action, the material facts relating to an allegation of invalidity are set out in the Statement of Defence and may be set out in a Counterclaim. The NOA and early production obligations relating to invalidity are intended to provide details of the invalidity allegation and to facilitate early review of documents to help accelerate the proceedings and the possibility of settlement. It can be understood from this objective that the issues and arguments raised for invalidity in a Statement of Defence will be premised on those in the NOA, although when read

in connection with the earlier RIAS statement, are not intended to be so limited. As stated at pages 40-41 of the RIAS:

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| Invalidity allegations | Allégations d'invalidité |
| The NOA must provide a detailed legal and factual basis for any allegation of invalidity. The second person must also include electronic copies of any document relied upon in support of the allegation. The requirement to provide detailed invalidity allegations and supporting documents is intended to allow first persons and patent owners who choose to bring a proceeding under the Regulations to begin reviewing and assessing these documents without having to await service of the second person's pleadings. This will help expedite proceedings and facilitate resolution within 24 months. It is expected that case management judges will assess whether early consideration of validity issues was possible and undertaken when scheduling proceedings and making other case management decisions. | L'AA doit fournir un fondement détaillé et factuel à l'appui de toute allégation d'invalidité. La seconde personne doit aussi fournir une copie électronique de tout document à l'appui de son allégation. L'exigence de fournir des allégations d'invalidité détaillées et des documents justificatifs vise à permettre aux premières personnes et aux propriétaires de brevet qui choisissent d'engager une procédure en vertu du Règlement de commencer à examiner et évaluer ces documents sans avoir à attendre la signification des actes de procédure de la seconde personne. Cette façon de faire aidera à accélérer les procédures et à faciliter le règlement des affaires dans le délai de 24 mois. On s'attend à que les juges responsables de la gestion de l'instance cherchent à savoir si un examen précoce des questions de validité était possible ou a été effectué lorsqu'ils fixeront le calendrier des procédures et prendront d'autres décisions concernant la gestion de l'instance. |

...

Non-infringement allegations

Non-infringement allegations need not be as detailed as invalidity allegations; a second person will be free to choose how detailed a non-infringement allegation may be. However, the second person is required to serve, along with its NOA, any portions of its submission or supplement that could be relevant for determining whether a listed patent would be infringed. The second person must comply with this requirement even if it makes no allegation of non-infringement. By reviewing relevant portions of the submission or supplement, first persons and patent owners will be able to assess whether they believe a listed patent will be infringed. By providing first persons and patent owners with needed information and leaving it to them to assess infringement, this approach better reflects the burden of proof applied when patent infringement is litigated under the Act.

Allégations de non-contrefaçon

Les allégations de non-contrefaçon n'ont pas besoin d'être aussi détaillées que les allégations d'invalidité. La seconde personne est libre de choisir jusqu'à quel point elle veut fournir des détails à l'appui de l'allégation de noncontrefaçon. La seconde personne doit toutefois signifier, avec son AA, toute partie de sa présentation ou de son supplément qui peut être pertinente pour déterminer si un brevet inscrit serait contrefait. La seconde personne doit satisfaire à cette exigence même si elle ne formule aucune allégation de non-contrefaçon. En examinant les parties pertinentes de la présentation ou du supplément, les premières personnes et les propriétaires de brevets seront en mesure d'évaluer si elles croient qu'un brevet inscrit sera contrefait. En faisant en sorte que les premières personnes et les propriétaires de brevets disposent des renseignements nécessaires et qu'ils puissent évaluer par eux-mêmes s'il y a contrefaçon, cette approche reflète mieux le fardeau de la preuve appliqué dans les procédures introduites en vertu de la Loi concernant une contrefaçon de brevet.

[24] The objective is that the proceeding be aligned as closely as possible with actions for patent infringement (RIAS, pages 33-34, 36) and that they be governed by the pleadings themselves (RIAS, page 40). This leaves open the possibility that there may be circumstances under which the pleadings may be amended, where the Court is satisfied that it is in the interests of justice to allow the amendments proposed.

[25] Indeed, treating the issues as being defined by the pleadings is not without its own safeguards as the Court maintains discretion, as set out further below, to determine whether a proposed amendment to the Statement of Defence should be allowed pursuant to Rule 75 of the *Federal Courts Rules*.

[26] The Defendant has referred to different examples where a Statement of Defence was amended in a proceeding under section 6(1) of the amended *PMNOC Regulations*: Statements of Defence in T-353-18 and T-1416-18. It asserts that these cases support the proposition that section 6(1) actions are not limited by the party's NOA. In T-353-18, amendments are shown that add prior art references to an existing invalidity ground within the pleading. However, T-1416-18 includes a new head of invalidity that was added by way of amendment. While the amendments in each of these cases were made on consent of the parties, and thus there are limitations as to what can be drawn from them, such examples broadly support the proposition that amendments to a party's defence to add prior art and additional grounds of invalidity are not prohibited outright.

[27] The Plaintiffs argue that the jurisprudence relating to the NOA under the old regime still applies with respect to allegations of invalidity because the choice to initiate a proceeding and an innovator's exposure to damages under section 8 of the *PMNOC Regulations* remains linked to the NOA. However, this argument does not support the distinction asserted between an NOA based on non-infringement and one based on invalidity as an innovator that improperly delays a generic's market entry by failing to establish infringement faces the same section 8 liability as one who is unsuccessful in defending a patent's invalidity. Further, there are additional safeguards under section 8 as any argument that an innovator was improperly influenced to start a proceeding because of an incomplete NOA can be addressed by section 8(6) of the *PMNOC Regulations*, which allows the Court to take into account "all matters that it considers relevant to the assessment of the amount or the apportionment". In this case, a proceeding was already started (Pharmascience action) based on a defence that included the amendments proposed by this motion.

[28] I note that the Plaintiffs have also made an argument that the amendments proposed should not be allowed as they run contrary to section 6.09 of the *PMNOC Regulations*, which requires the parties to act diligently in carrying out their obligations under the *PMNOC Regulations* to move the proceeding forward expeditiously. The Plaintiffs assert that to allow a generic to plead invalidity defences not raised in the NOA would introduce an open season rule on the requirements for NOAs and would incentivize ambush litigation.

[29] While I agree that the Court should not condone efforts intended to mislead a party regarding the issues and arguments that will be raised for invalidity, or to hold back the

substance of those arguments; in my view, the circumstances of the amendments here are not the result of Taro withholding allegations from its NOA only to supplement arguments in its Statement of Defence. Indeed, the Statement of Defence in this case was based on Taro's NOA, which NOA spanned 74 pages. The basis for the amendments is for Taro to have its Statement of Defence raise all possible arguments, including those now known to be raised by Pharmascience in its related proceeding. Section 6.09 of the *PMNOC Regulations* is not triggered in this circumstance.

[30] The Plaintiffs' further argument that Taro should be limited to raising its proposed amendments by counterclaim rather than by amendment to its Statement of Defence is not, in my view, supported by the *PMNOC Regulations*. There is no basis to require Taro to proceed in this manner. Rather, the suggestion that Taro may include a counterclaim with the amendments proposed suggests that there is no prejudice to the addition of the specific allegations.

[31] In my view, the amendments proposed must be considered under the principles set out for pleading amendments in the *Federal Courts Rules*.

## III. Should the Court Exercise its Discretion to Allow the Amendments Proposed

[32] Rule 75 of the *Federal Courts Rules* provides that the Court may at any time, allow a party to amend a document on such terms as will protect the rights of the parties. The general rule on amendment of pleadings is that "an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties,

provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice": *Canderel Ltd*. v. *R*. (1993), [1994] 1 F.C. 3 (FCA) at page 10; *Enercorp. Sand Solutions Inc*. v. *Specialized Desanders Inc*., 2018 FCA 215 at para 19 ("*Enercorp*").

[33] As a threshold issue, a motion to amend a pleading will not be allowed unless the amendment has a reasonable prospect of success when considering the chance of success in the context of the law and the litigation process: *Teva Canada Ltd*. v. *Gilead Sciences Inc*., 2016 FCA 176 at para 29-30. If it is plain and obvious that the amendment would be struck if pleaded, it should not be allowed: *Enercorp supra* at para 22. Only after this initial threshold is met will the Court consider other matters, including whether there is prejudice to the opposing party.

[34] Once it has been established that a proposed amendment has a reasonable prospect of success, consideration will be given to other factors consonant with the interests of justice. Such factors include: the timeliness of the motion to amend; the extent to which the proposed amendments would delay the expeditious trial of the matter; the extent to which a position taken originally by one party has led another party to follow a course of action in the litigation which it would be difficult or impossible to alter; and whether the amendments sought will facilitate the court's consideration of the true substance of the dispute on its merits. Such factors are non-exhaustive and not limiting; a balancing exercise is required with no single factor intended to predominate. Consideration will be given to simple fairness, common sense and the interest that

the courts have that justice be done: *AbbVie Corp*. v. *Janssen Inc*., 2014 FCA 242 at para 3 (*"AbbVie"*); *Continental Bank Leasing Corp*. v. *R.*, [1993] 93 D.T.C. 298 (TCC) at page 302.

[35] In this case, the amendments proposed are already in play in the Pharmascience action, without objection by the Plaintiffs, and as such have a reasonable prospect of success.

[36] I do not agree with the Plaintiffs that the proposed amendments would be vulnerable to being struck as an abuse of process. The Statement of Defence in this case was premised on Taro's NOA, which spanned 74 pages. This is not a case where the documents as initially drafted were intentionally deficient. Further, the argument relies on an interpretation of the *PMNOC Regulations* that limits the scope of the proceedings to only those issues raised in the NOA. For the reasons set out above, it is my view that this interpretation is not supported by the scheme and objectives of the *PMNOC Regulations* as amended.

[37] With respect to the allegation of prejudice, it is noted that even before the proposed amendments to the Statement of Defence were raised, the Plaintiffs had determined that an action should be brought based on the same allegations as raised in the Pharmascience action. There is no credible argument that the amendments raised here would have impacted the Plaintiffs' choice to assert infringement.

[38] Further, as the amendments proposed are already pending in the Pharmascience action, the Defendant is not raising any new arguments that will requirement a new assessment of the validity of the Plaintiffs' patents.

[39] The Defendant has raised these proposed amendments early in the process, before any discovery has taken place. As such, it is difficult to see how there would be any significant prejudice to the Plaintiffs in allowing the amendments into the proceeding, particularly as the allegations are already known from the Pharmascience action.

[40] Balancing the considerations set out in *AbbVie*, and the principles of fairness, common sense and that justice be done, favours allowing the amendments into the proceeding:

- the amendments have been proposed in a timely manner;
- the amendments will not delay the trial of the action;
- the amendments raise allegations that are not new, but are already in play in the Pharmascience action;
- the course of action of the litigation will not be unreasonably altered by allowing the amendments into the proceeding, particularly where the amendments are consistent with those in the earlier proceeding involving Pharmascience and this proceeding is in its early stages;
- the amendments go to the merits of the validity of the patents in issue and will align the arguments in this proceeding with those raised in Pharmascience.

## IV. Costs

[41] Without knowing the outcome of this motion, each of the parties provided oral submissions that an appropriate award of costs for the motion would be, if successful by them, $5,000, payable forthwith. The amount of $5,000 seems appropriate in the circumstances. Thus, such an award will be made to Taro as the party successful on the motion.

[42] However, I do not consider it to be appropriate to require payment of such costs to be made forthwith. As this was the first motion to require an examination of the provisions of the amended *PMNOC Regulations* relating to the NOA, I do not consider this motion to have been entirely without merit. I will accordingly make this award payable in the cause.

**ORDER in T-671-20**

**THIS COURT ORDERS that**:

1. The motion is allowed and Taro is granted leave to serve and file its proposed Amended Statement of Defence, which shall be served and filed within seven (7) days of the date of this Order.

2. Costs are awarded to Taro in an amount fixed at $5,000 in the cause.

"Angela Furlanetto"
Case Management Judge

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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| **DOCKET:** | T-671-20 |
| **STYLE OF CAUSE:** | SUNOVION PHARMACEUTICALS CANADA INC. AND SUMITOMO DAINIPPON PHARMA CO., LTD. v TARO PHARMACEUTICALS INC. |
| **PLACE OF HEARING:** | HELD BY VIDEO CONFERENCE AT TORONTO, ONTARIO |
| **DATE OF HEARING:** | DECEMBER 3, 2020 |
| **ORDER AND REASONS:** | CASE MANAGEMENT JUDGE FURLANETTO |
| **DATED:** | JANUARY 11, 2021 |

**APPEARANCES:**

| | |
|---|---|
| James Holtom | FOR THE PLAINTIFFS |
| Scott Beeser<br>Jon Stainsby | FOR THE DEFENDANT |

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| | |
|---|---|
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| Aitken Klee, LLP<br>Barristers and Solicitors<br>Ottawa, Ontario | FOR THE DEFENDANT |