Federal Court Cour fédérale

Date: 20210505

Docket: T-380-21

Citation: 2021 FC 402

Ottawa, Ontario, May 5, 2021

PRESENT: Case Management Judge Mandy Aylen

BETWEEN:

BIOMARIN PHARMACEUTICAL INC.

Plaintiff

and

DR. REDDY'S LABORATORIES LTD.

Defendant

ORDER AND REASONS

[1] The underlying proceeding is an action commenced pursuant to section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* [*PMNOC Regulations*] in relation to an innovative biopharmaceutical called KUVAN®.

[2] As pleaded in the Statement of Claim, KUVAN® is a prescription medicine comprising the active ingredient sapropterin dihydrochloride. KUVAN® is sold in Canada by the Plaintiff, *inter alia*, as powder for oral solution at a strength of 100 mg. The Plaintiff holds approval from Health Canada with respect to KUVAN®. KUVAN® is approved in Canada to reduce blood phenylalanine [Phe] levels in patients with hyperphenylalaninemia [HPA] due to tetrahydrobiopterin-(BH4-) responsive Phenylketonuria [PKU] and it is indicated to be used in conjunction with a Phe-restricted diet.

[3] The Plaintiff has listed the following patents against KUVAN® on the Patent Register – Canadian Patent No. 2,545,584 [584 Patent], Canadian Patent No. 2,682,598 [598 Patent] and Canadian Patent No. 2,545,968 [968 Patent].

[4] The evidence before the Court is that on January 13, 2021, the Defendant served the Plaintiff's counsel (who is their address for service on the Patent Register) with three Notices of Allegation [NOAs], one in respect of each patent listed against KUVAN® on the Patent Register, together with three USB sticks containing documents relevant to the Abbreviated New Drug Submission [ANDS]. The NOAs indicate that the Defendant seeks approval to sell a generic version of KUVAN®, that the Defendant had filed an ANDS with the Minister of Health seeking a Notice of Compliance [NOC] for the generic product and that the Defendant's ANDS compares the generic product to KUVAN® 100 mg powder for oral solution.

[5] However, counsel for the Plaintiff was under the mistaken belief that they had been served with three copies of the NOA for the 598 Patent (as opposed to three distinct NOAs – one for each

of the 598, 584 and 968 Patents), such that the 584 and 968 Patents were not at issue between the parties.

[6] On February 26, 2021, the Plaintiff commenced this action alleging that, *inter alia*, the Defendant's proposed product would infringe only the 598 Patent. In relation to the 584 and 968 Patents, the Plaintiff pleaded that as the Defendant had not addressed them in the NOA, the Minister of Health was precluded from issuing an NOC to the Defendant until the expiry of the 584 and 968 Patents or until the applicable requirements under section 7 of the *PMNOC Regulations* are otherwise met.

[7] The Statement of Claim was served on the Defendant on March 1, 2021. Various exchanges occurred between counsel for the parties thereafter, during which counsel for the Plaintiff was not disabused of their mistaken belief. It was only on March 23, 2021 that Plaintiff's counsel learned of their mistaken belief. Inquiries were immediately made and counsel for the Plaintiff confirmed that they were in fact served with three distinct NOAs in respect of KUVAN®, one for each patent.

[8] Counsel for the Plaintiff took immediate steps to attempt to amend the Statement of Claim and alerted the Court to the issue. A case management conference was held two days later, during which the Defendant advised that it would not consent to the proposed amendments on the basis that the amendments were outside the 45-day limitation period. As a consequence, the Plaintiff has filed the motion presently before the Court.

[9] On this motion, the Plaintiff seeks leave to amend its Statement of Claim in the form appended as Schedule "A" to the Notice of Motion. The Plaintiff seek to amend its pleading to:

A. Seek a declaration that the making, constructing, using, selling, offering for sale, importing or exporting of the proposed generic product in accordance with the ANDS would infringe, directly or indirectly, and/or induce infringement of the asserted claims of each of the 968 and 584 Patents.

B. Seek injunctive relief related to the infringement or induced infringement of the asserted claims of each of the 968 and 584 Patents.

C. Add the facts related to the issuance of, title of, application for, inventors of and validity of each of the 968 and 584 Patents.

D. Add the facts regarding the asserted claims of each of the 968 and 584 Patents.

E. Add the facts regarding the NOAs for each of the 968 and 584 Patents.

F. Add the facts regarding the specific acts of infringement and inducing infringement of the asserted claims of each of the 968 and 584 Patents.

[10] The Defendant opposes the amendments on the basis that the proposed amendments are time-barred and statute-barred and do not have a reasonable prospect of success.

[11] For the reasons that follow, I find that the Plaintiff has not demonstrated that the causes of action that they seek to add to their Statement of Claim (infringement of the 584 and 968 Patents)

arise out of substantially the same facts as the cause of action originally pleaded. Accordingly, the motion shall be dismissed.

A. Principles applicable on a motion to amend a pleading

[12] Rules 75, 76, 77, 200 and 201 of the *Federal Courts Rules* address the amendment of pleadings in various circumstances and for various purposes. Rule 75 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.

[13] In *Canderel Ltd v Canada (CA)*, [1994] 1 FC 3, [1993] FCJ No 777 at page 10, the Federal Court of Appeal held that, while it was impossible to set out all the factors that a judge must take into consideration in dealing with an application to amend pleadings, the general rule 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."

[14] However, as a preliminary matter, the proposed amendment must have a reasonable prospect of success. If a proposed amendment does not have a reasonable prospect of success, the Court need not consider any other matter, such as the potential prejudice to the opposing party occasioned by the amendment [see *Teva Canada Limited v Gilead Sciences Inc*, 2016 FCA 176 at paras 29-32]. The burden is on the amending party to demonstrate such a reasonable prospect of success [see *Merck & Co Inc v Apotex*, 2003 FCA 488 at para 46].

[15] In determining whether a proposed amendment has a reasonable prospect of success, its chance of success must be examined in the context of the law and the litigation process and a realistic view must be taken [see *Teva, supra* at para 30].

[16] If it is plain and obvious that a proposed amendment would not withstand a motion to strike, the amendment must be refused [see *Lantech.com, LLC v Wulftec International Inc*, 2018 FC 41; *Enercorp Sand Solutions Inc v Specialized Desanders Inc*, 2018 FCA 215 at para 22; *VISX Inc v Nidek Co,[1996] FCJ No 172, 72 CPR (3d) 19* at para 16]. The Court must assume that the facts pleaded in the proposed amendment are true for the purposes of considering whether or not to grant leave to amend [see *VISX, supra* at para 16]. Therefore, the Court should only deny amendments in plain and obvious cases where the matter is beyond doubt and should not deny amendments when one is dealing with an area of law that cannot be said to be settled with certainty [see *Hoechst Aktiengesellschaft v ADIR*, [1998] FCJ No 1028, 82 CPR (3d) 344 at para 7 (FC)].

[17] Once it has been established that the proposed amendment has a reasonable prospect of success, other factors must be considered, including the timeliness of the motion to amend, the extent to which the proposed amendment 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 the merits. No single factor predominates nor is its presence or absence necessarily determinative. All must be assigned their proper weight in the context of the particular case. Ultimately, it boils down to a consideration of simple fairness, common sense and the interests that the Court has that justice be done [see *Janssen Inc v Abbvie Corporation*, 2014 FCA 242 at para 3].

[18] With respect to causes of action that are time-barred, read together, Rules 76, 77 and 201 allow an amendment adding a new cause of action for which the limitation period has expired provided that the cause of action arises out of substantially the same facts as the cause of action originally pleaded and justice requires that the amendment be made [see *Seanix Technologies Inc v Synnes Information Technologies, Inc*, 2005 FC 243; *Domco Industries Ltd v Mannington Mills Inc* (1990), 29 CPR (3d) 481 (FCA), leave to SCC refused (199), 33 CPR (3d) (note); *Saddle Lake Indian Band v R*, [2000] FCJ No 1997 (FC)].

B. The PMNOC Regulatory Regime

[19] On September 21, 2017, significant amendments were made to the *PMNOC Regulations*, 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 an 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 inherent in the prior regime, in which a section 6 application determined whether allegations of non-infringement and invalidity were justified for the purposes of issuing an NOC and in which final determinations on patent infringement and validity would only be made in a subsequent action. Under the new regime, section 6(1) proceedings focus on determining, with finality, the underlying questions of patent invalidity and infringement [see *Amgen Inc* v *Pfizer Canada Inc*, 2018 FC 1078 at para 27, aff'd 2019 FCA 249 at paras 8, 65; *Sunovion Pharmaceuticals Canada Inc v Taro Pharmaceuticals Inc*, 2021 FC 37 at para 12; *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017*, SOR/2017-166, Regulatory Impact Assessment Statement [RIAS], see for example, page 34].

[20] 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. Section 6(1) provides:

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.

[21] The right to bring an action is intended to be final. As prescribed by 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:

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	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

allegation served under paragraph 5(3)(a) in relation to the making, constructing, 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.	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.

[22] In considering the circumstances in which it may be found, pursuant to section 6.01, that an innovator did not have a reasonable basis for bringing an action within the initial 45-day period, the RIAS provides at page 37:

> Possible situations where the first person or owner of the patent could be found not to have had a reasonable basis for commencing litigation include situations where the information provided by the second person was false, materially misleading, or materially incomplete (including as a result of a subsequent change in the generic product).

[23] The *PMNOC Regulations* are enabled under subsection 55.2(4) of the *Patent Act*. They bridge the *Patent Act* and the patent rights afforded to the patentee of an innovative drug with the issuance of an NOC by Health Canada, under the *Food and Drug Regulations*, to a subsequent entry product, a generic drug. Under the *PMNOC Regulations*, when an NOC submission compares a proposed generic drug to a marketed drug against which patents are listed, those patents must be addressed either by awaiting their expiry, obtaining consent or otherwise in the NOA [see *Viiv Healthcare Company v Sandoz Canada Inc*, 2020 FC 1040 at para 55-56].

[24] The importance of the *PMNOC Regulations* is enshrined in subsection 55.2(5), which considers inconsistency or conflict between the *PMNOC Regulations* and any Act of Parliament. Section 55.2(5) provides:

(5) In the event of any inconsistency or conflict between (a) this section or any regulations made under this section, and (b) any Act of Parliament or any regulations made thereunder, this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.	(5) Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.

[25] The Federal Court of Appeal has confirmed the extraordinary nature of the *PMNOC Regulations*, finding that they "override any other Act or regulations including the Federal Courts Act and the Federal Courts Rules" [see *Merck Frosst Canada Inc v Apotex Inc*, [1997] 2 FC 561 (FCA) at para 9].

C. Position of the Plaintiff

[26] The Plaintiff asserts that the 45-day period prescribed by section 6(1) of the *PMNOC Regulations* acts in the same manner as any other limitation period. While section 6(1) may prevent a new action from being commenced pursuant to the *PMNOC Regulations*, it does not prevent amendments to an existing action. Instead, amendments are addressed under the *Federal Courts Rules*, which allow the inclusion of limitation-barred claims by way of an amendment in certain circumstances.

[27] The Plaintiff asserts that, pursuant to the *Federal Courts Rules*, the test for admitting new causes of action, even where a limitation period has expired, is well-settled. The amendment should be allowed if: (a) the facts underlying the amendments arise out of substantially the same facts as those already at issue in the action; and (b) it is in the interests of justice to allow the amendments to ensure a full decision of all relevant issues.

[28] The Plaintiff asserts that the aforementioned practice in the Federal Court is consistent with that of the Ontario courts, which operate under a rebuttable presumption of prejudice when an amendment is made after the expiry of a limitation period. This presumption is overcome where the moving party establishes the presence of "special circumstances", which takes into consideration the factual underpinning of the amendments and their relationship to the existing action. The Plaintiff asserts that the Ontario Court of Appeal has stressed that there is no exhaustive list of what amounts to "special circumstances" and that there are often procedural or informational mistakes that have neither misled the other party nor caused them to defend the claim in any different manner than would have occurred had the amendments been included from the outset [see *Frohlick v Pinkerton Canada Limited*, 2008 ONCA 3].

[29] In respect of the present motion, the Plaintiff asserts that the proposed amendment is not a new action. Instead, the amendment operates within the existing action and acts to ensure that all relevant issues are clearly before the Court. The Plaintiff commenced this action in respect of the 598 Patent within the 45-day period and now only seeks to amend its pleading in that action. While the Plaintiff acknowledges that it cannot commence new actions under section 6(1) of the *PMNOC Regulations* in relation to the 584 and 968 Patents, the Plaintiff asserts that there is no temporal or

statutory bar that would preclude the Plaintiff from amending them into an existing section 6(1) action.

[30] Further, the Plaintiff asserts that, contrary to the assertion of the Defendant, there is no conflict or inconsistency as between the *Federal Courts Rules* (that would permit amendments to add causes of action for which a limitation period has expired) and the *PMNOC Regulations*. The *PMNOC Regulations* do not address how amendments to pleadings are to be handled and thus the parties must turn to, and apply, the *Federal Courts Rules* to address the proposed amendments.

[31] As stated at paragraph 14 of its reply written representations, the Plaintiff asserts that "the sole question for the Court is whether the proposed amendments arise out of substantially the same facts as the existing cause of action and if the amendments are in the interests of justice. If these requirements are met, the expiry of the limitations period does not act as a bar to the amendments, and they should be permitted".

[32] Turning to that issue, the Plaintiff asserts that the amendments arise out of substantially the same facts as are already at issue in this action – the characteristics of the Defendant's generic product and the actions the Defendant would take in respect of that generic product if permitted to come to market. The Plaintiff asserts that the main issue underlying the action is the Defendant's intention to obtain an NOC. The following facts and issues all relate to the underlying dispute:

A. The Plaintiff holds approval from Health Canada with respect to KUVAN® and had its relevant patents listed on the Patent Register.

B. The Defendant filed an ANDS for its generic product on November 30, 2020.

C. The Defendant's generic product relies upon the safety and efficacy of KUVAN® as a basis for its approval.

D. The Defendant was required to address the patents relevant to KUVAN® that are listed on the Patent Register by way of NOAs.

E. The Plaintiff commenced an action under the *PMNOC Regulations* within the statutory timeframe, asserting that the making, constructing, using, selling, offering for sale, importing or exporting of the Defendant's generic product will infringe the Plaintiff's listed patent rights.

F. By reason of this action, the automatic 24-month statutory stay prohibits the Defendant's generic product from obtaining an NOC until the issues can be decided by the Court.

G. The issue to be decided by the Court is whether the Defendant's generic product will infringe upon the Plaintiff's valid patent rights.

[33] The Plaintiff asserts that each of the aforementioned facts and issues are equally applicable to the amendments. The amendments apply to the same ANDS filing and generic product, the same parties as "first person" and "second person" and the same actions of the Defendant that infringe the Plaintiff's patent rights. Both the original Statement of Claim and the proposed amended Statement of Claim relate to the same question – namely, is the Defendant able to obtain an NOC for its generic product prior to the expiry of the Plaintiff's patent rights in respect of KUVAN®?

[34] The Plaintiff asserts that the only facts required in respect of the amendments are further particulars of the Defendant's generic product, the details and characteristics of which are already at issue on this action. Many of these facts are expected to be identical to those at issue in the existing action. For example, the four ANDS documents produced by the Defendant with the 598 Patent NOA are identical to those provided for the 584 Patent and the six ANDS documents underlying the 968 Patent equally comprise the same four ANDS documents as the 598 and 584 Patents.

[35] The Plaintiff asserts that it must be kept in mind that Rule 201 does not require identical facts, but rather only substantially similar facts. To interpret Rule 201 too strictly would defeat the purpose of Rule 201 and render amendments virtually impossible. The focus must be on the central facts underlying the core dispute between the parties, which the Plaintiff asserts, in this case, are substantially the same.

[36] The Plaintiff further asserts that it is in the interests of justice to allow the amendments and ensure that the Court can address all relevant issues in dispute as part of this action. The Plaintiff has provided the Court with extensive evidence and submissions as to the basis for its counsel's mistaken belief, from the time of service of the NOAs until the request was made to amend its pleading. According to the Plaintiff, allowing the Plaintiff to correct its mistaken belief ensures a full decision on all issues of patent infringement related to KUVAN® and does not prejudice the Defendant or the Court. Moreover, according to the Plaintiff, the schedule for the proceeding will not be impacted by the amendments, nor will the trial date. The Plaintiff asserts that the interests of justice would not be served by deciding the case on technicalities arising out of an inadvertent mistake, when the issue can be readily corrected without any prejudice to the parties or the Court.

[37] The Plaintiff further asserts that, on the same rationale, the amendments would also meet the test if the Court were to apply the "special circumstances" framework set out by the Ontario Court of Appeal.

[38] Having established that the proposed amendments have a reasonable prospect of success, the Plaintiffs assert that the other factors all support permitting the requested amendments, as the motion to amend was brought in a timely manner, the proposed amendments will not delay the expeditious trial of the matter, there is no position taken originally by one party that has led another party to follow a course of action in the litigation which it would be difficult or impossible to alter and the amendments sought will facilitate the Court's consideration of the true substance of the dispute on the merits. Moreover, the Plaintiff asserts that there is no non-compensable prejudice to the Defendant arising from the proposed amendments.

D. Position of the Defendant

[39] The Defendant asserts that the proposed amendments to add causes of action in respect of the 584 and 968 Patents are time-barred and statute-barred and do not have a reasonable prospect of success.

[40] The Defendant asserts that the amendment of a statement of claim to add new causes of action under section 6(1) of the *PMNOC Regulations*, after the expiry of the 45-day period, is contrary to the plain language of section 6(1) and section 6.01. The Defendant relies on the decision in *Pfizer Canada Inc v Canada (Health Minister)*, 2008 FCA 15 at para 8, in which the Federal Court of Appeal confirmed that this Court has no jurisdiction to extend the 45-day time limit, citing with approval the following excerpt from *Pfizer Canada Inc v Canada (Minister of Health)*, 2007 FC 205:

> [18] The fundamental requirement under the Regulations is that an application to the Court must be commenced within 45 days of the notice of allegation. The Court has no jurisdiction to extend the 45 days because the general rule on extensions would be in direct conflict with Regulation s. 6(1). (Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare) (1997), 72 C.P.R. (3d) 453 (F.C.T.D.))
>
> [19] However, once the matter is commenced within the statutory time limits, the Federal Courts Rules, SOR/98-106, apply except where there is a conflict. The Act and Rules apply to a number of matters not specifically addressed in the Regulations including the right to appeal. (Bayer AG v. Canada (Minister of National Health and Welfare) (1993), 51 C.P.R. (3d) 329 (F.C.A.) at 336).

[41] The Defendant asserts that this Court cannot extend the period of time to permit these new causes of action to be pleaded and the failure to read an NOA that has been properly served is not a situation in which it can be found that a first person or patent owner did not have a reasonable basis to commence an action within the 45-day period, as contemplated by section 6.01 of the *PMNOC Regulations* [see *Viiv*, *supra*].

[42] Further, the Defendant asserts that to the extent that the *Federal Courts Rules* would permit the Plaintiff to amend its pleading to add causes of action that are time-barred, the *Federal Courts Rules* are inconsistent or conflict with section 6(1) of the *PMNOC Regulations* and thus cannot be relied upon by the Plaintiff to permit the amendments.

[43] Even if the amendments are not statute-barred and time-barred and the Plaintiff is entitled to rely upon the *Federal Courts Rules* applicable to pleading amendments, the Defendant asserts that the Plaintiff is not seeking to correct the name of a party or to alter the capacity in which a party is bringing a proceeding. As such, Rule 76 does not apply. If Rule 76 does not apply, Rule 77 (which permits amendments notwithstanding the expiration of a limitation period) also cannot

apply because it only applies to amendments permitted by Rule 76. The Defendant asserts that Rule 201 is also of no assistance to the Plaintiff as it only applies in the context of an amendment pursuant to Rule 76. I would note, however, that the Defendant did not pursue this argument at the hearing of the motion. In that regard, the jurisprudence is clear that Rules 76, 77 and 201 have not been construed as proposed by the Defendant. Rule 201 is available to a party to raise a new cause of action if it arose out of substantially the same facts as alleged in the original statement of claim, notwithstanding that the new cause of action is barred by a limitation period [see *Saddle Lake Indian Band v R, supra* at para 38].

[44] The Defendant further asserts that even if Rule 201 applies, the proposed amendments do not arise out of substantially the same facts already pleaded in the Statement of Claim. The Defendants rely on the Federal Court of Appeal's decision in *Domco Industries Ltd v Mannington Mills Inc*, [1990] FCJ No 269, in which the Federal Court of Appeal denied an amendment to a statement of claim on the basis that the original claim alleged the defendant infringed by offering for sale and selling infringing products, whereas the proposed amendment alleged infringement by inducing, procuring or conspiring to have others infringe. The Federal Court of Appeal held that the proposed amendment was a new cause of action "based on a different factual situation" and thus did not come within the requirements of Rule 201.

[45] The Defendant asserts that the focus of a section 6(1) action under the new PMNOC regime is the underlying questions of patent infringement and validity. The basic requirements for pleading a cause of action in patent infringement requires that the statement of claim clearly show: (a) the facts by virtue of which the law recognizes a defined right as belonging to the plaintiff; and (b) the facts that constitute an encroachment by the defendant on that defined right of the plaintiff.

If a statement of claim does not disclose those two elements, it does not disclose a cause of action and may be struck [see *Pharmaceutical Partners of Canada Inc v Faulding (Canada) Inc*, [2002] FCJ No 1305 at para 7 (FCTD), citing *Dow Chemical Co v Kayson Plastics & Chemicals Ltd* (1966), 47 CPR 1 (Ex Ct)].

[46] The Defendant asserts that the proposed amendments assert for the first time the infringement of the 584 and 968 Patents under subsection 6(1) of the *PMNOC Regulations*, which are statutory rights of action that arise from different material facts than are found in the current pleading. This is made clear by the extensive amendments being proposed by the Plaintiff. According to the Defendant, the Plaintiff's current pleading does not come close to meeting the basic requirements for pleading a cause of action in patent infringement with respect to the 584 and 968 Patents.

[47] The Defendant asserts that the Ontario jurisprudence relied upon by the Plaintiff has no application in this Court, as it is premised on different procedural rules. Moreover, even if applicable, the Defendant asserts that the loss of a limitations defense gives rise to a presumption of prejudice to the Defendant and there are no special circumstances in this case that rebut the presumption of prejudice. Three distinct NOAs were properly served on counsel for the Plaintiff. The decision of the Plaintiff's counsel to review only one of the three NOAs does not constitute "special circumstances".

E. Analysis

[48] As a preliminary point, I note that at the hearing of the motion, the Plaintiff attempted to resile from the position that the additional causes of action that it seeks to add by way of amendment were limitations-barred and thus the Plaintiff had to come within the requirements of

201. The Plaintiff stated that it was not arguing that Rule 201 applies on this motion and that, as a result, it must fit within the "substantially similar facts" requirement because the limitation period has not expired. Rather, the Plaintiff stated that Rule 201 was only raised "by analogy".

[49] This assertion, however, is entirely contradicted by the position asserted and arguments put forward by the Plaintiff in its moving and reply written representations. For example, at paragraph 31 of its moving written representations, the Plaintiff states that the issue for the Court's determination on this motion is whether "the amendments should be permitted notwithstanding the expiry of a limitations period, due to the fact they arise out of substantially the same facts as those already at issue in the underlying action and there are special circumstances surrounding the commencement of the underlying action". This framing of the issue was re-iterated in the Plaintiff's reply written representations, where, at para. 14, the Plaintiff asserts that "the sole question for the Court is whether the proposed amendments arise out of substantially the same facts as the existing cause of action and if the amendments are in the interests of justice. If these requirements are met, the expiry of the limitations period does not act as a bar to the amendments, and they should be permitted".

[50] The Plaintiff further confirms its position on the motion in its reply written representations where it states:

> [5] …..At no point in this proceeding has BioMarin disputed that it did not assert the 968 and 584 Patent within the 45-day limitation period. BioMarin equally does not seek an extension of the limitation period in order to commence a new proceeding. Rather, BioMarin seeks to amend this Statement of Claim, which is an action properly brought under section 6(1) of the *Regulations*, pursuant to Rules 75, 76, 77 and 201. BioMarin submits that this amendment is permitted, notwithstanding the expiry of the 45-day limitation period, as the amendments arise out of substantially the

> same facts as are already in dispute, and it is in the interests of justice to have all relevant patent issues surrounding the Reddy Product resolved in this single proceeding. [emphasis added]

[51] The Plaintiff has repeatedly asserted that Rule 201 applies on this motion as the limitation period to assert a claim for patent infringement of the 584 and 968 Patents under section 6(1) of the *PMNOC Regulations* has expired. The Plaintiff cannot now resile from that position. Moreover, and in any event, I am satisfied that Rule 201 applies as it is apparent that the Plaintiff could not now commence a section 6(1) action for patent infringement of the 584 and 968 Patents.

[52] Even if I were to accept the Plaintiff's submission that section 6(1) of the *PMNOC Regulations* is not a bar to the proposed amendments, and even if I were to accept the Plaintiff's submission that there is no inconsistency between the operation of Rule 201 and the *PMNOC Regulations*, I cannot accept the Plaintiff's assertion that the proposed amendments arise out of substantially the same facts as the cause of action originally pleaded.

[53] While I agree with the Plaintiff that Rule 201 does not require that all of the facts be the same, the causes of action that the Plaintiff seeks to add by way of amendment are not grounded in the existing facts as pleaded in the Statement of Claim.

[54] The Plaintiff acknowledged at the hearing of the motion that actions under the *PMNOC Regulations* are treated by the Court in the same manner as patent infringement actions. In order to constitute a properly pleaded action for patent infringement, a statement of claim must clearly show: (a) the facts by virtue of which the law recognizes a defined right as belonging to the plaintiff; and (b) the facts that constitute an encroachment by the defendant on that defined right of the plaintiff [see *Dow Chemical, supra*]. A cause of action for patent infringement is patent specific, such that these material facts related to each patent must be pleaded.

[55] I find that the Statement of Claim does not contain the material facts necessary for an allegation of patent infringement in relation to the 584 and 968 Patents. Specifically:

A. The pleading does not contain the facts that demonstrate the Plaintiff's rights in the 584 or 968 Patent.

B. The pleading does not detail any of the asserted claims of the 584 or 968 Patents.

C. The pleading does not detail the facts regarding the NOAs for each of the 584 and 968 Patents.

D. The pleading does not detail the facts regarding the Defendant's specific acts of infringement and inducing infringement of the various asserted claims of the 584 or 968 Patent.

[56] All of these material facts are sought to be added by way of amendment.

[57] While a number of facts already pleaded are material to the new proposed allegations of patent infringement (such as the parties, the proposed generic product, the Defendant's ANDS and the Defendant's generalized intention to make, construct, use, sell, offer for sale, import and export the proposed generic product), the need for the aforementioned list of significant additional facts is not surprising given that each of the three patents disclose different inventions. The 598 Patent addresses methods for administering tetrahydrobioperin, associated compositions and methods of measuring. The 968 Patent addresses crystalline forms of (6R)-L-erythro-tetrahydrobiopterin Dihydrochloride. The 584 Patent addresses methods and compositions for the treatment of metabolic disorders.

[58] Accordingly, I am not satisfied that the Plaintiff has established that the causes of action it seeks to add by way of amendment arise out of substantially the same facts as the cause of action originally pleaded. On this basis, the motion must be dismissed.

[59] While the Plaintiff has provided the Court with various authorities from the Courts in Ontario, that jurisprudence is based on different procedural requirements from the *Federal Courts Rules* and thus have no application on this motion. While those decisions may have been informative, by analogy, to the issue of whether justice requires that the amendment be made, I need not go on to consider that issue in light of my findings above.

[60] That said, I agree with the Plaintiff that this case involves a unique and unfortunate sequence of events that fully explain why the Plaintiff mistakenly did not assert infringement of the 584 and 968 Patents at the outset of the action. On the evidence before me, I accept that the actions of the Plaintiff arose as a result of a mistaken belief by its counsel and not as a result of a strategic delay tactic.

[61] I have empathy for the circumstances in which the Plaintiff and its counsel find themselves, but the Court must apply the *Federal Courts Rules* as written and in accordance with the requirements of applicable jurisprudence.

F. Costs

[62] At the hearing of the motion, the parties agreed that cost submissions should follow the determination of the merits of the motion. Accordingly, the parties shall attempt to reach an agreement on the costs of the motion. In the event that they are unable to do so, the Plaintiff shall, by no later than May 21, 2021, serve and file brief cost submissions in the form of a letter of no

more than three pages. The Defendant shall, by no later than May 28, 2021, serve and file brief responding cost submissions in the form of a letter of no more than three pages. The Plaintiff may file a brief reply in the form of a letter of no more than two pages by no later than June 2, 2021.

THIS COURT ORDERS that:

1. The Plaintiff's motion is dismissed.

2. The parties shall attempt to reach an agreement on the costs of the motion. In the event that they are unable to do so, the Plaintiff shall, by no later than May 21, 2021, serve and file brief cost submissions in the form of a letter of no more than three pages. The Defendant shall, by no later than May 28, 2021, serve and file brief responding cost submissions in the form of a letter of no more than three pages. The Plaintiff may file a brief reply in the form of a letter of no more than two pages by no later than June 2, 2021.

"Mandy Aylen"
Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-380-21
STYLE OF CAUSE:	BIOMARIN PHARMACEUTICAL INC. v. DR. REDDY'S LABORATORIES LTD.
PLACE OF HEARING:	OTTAWA
DATE OF HEARING:	APRIL 30, 2020
ORDER AND REASONS:	AYLEN, P.
DATED:	MAY 5, 2021

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SOLICITORS OF RECORD:

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