Federal Court Cour fédérale

Date: 20180315

Docket: T-1921-17

Citation: 2018 FC 303

Ottawa, Ontario, March 15, 2018

PRESENT: Case Management Judge Mandy Aylen

BETWEEN:

GENENTECH, INC. AND HOFFMANN-LA ROCHE LIMITED

Plaintiffs

and

AMGEN CANADA INC.

Defendant

ORDER AND REASONS

[1] This action is the first proceeding commenced under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* [*Regulations*] that came into force on September 21, 2017. Within approximately a week of issuance of the Statement of Claim, Amgen Canada Inc. [Amgen] advised the Plaintiffs of its intention to bring a motion pursuant to section 6.08 of the *Regulations* to dismiss the action in respect of Canadian Patent Nos. 2,376,596 [596 Patent] and 2,407,556 [556 Patent] on the basis that it is redundant, scandalous, frivolous or vexatious or

is otherwise an abuse of process. On February 5, 2018, Amgen served the Plaintiffs with its notice of motion.

[2] The Plaintiffs have brought the motion currently before the Court (which they describe as a "meta-motion") seeking the following relief:

A. An order dismissing or adjourning *sine die* Amgen's section 6.08 motion;

B. In the alternative, if this Court determines that the section 6.08 motion is the most appropriate way to proceed, directions that the section 6.08 motion proceed on the basis of the statement of claim alone, with no right to submit evidence; or

C. In the further alternative, if this Court determines that the section 6.08 motion is the most appropriate way to proceed, and that this motion should include the right to rely upon evidence, directions that:

    i. The section 6.08 motion proceed after completion of any oral discovery, including the receipt of answers to undertakings and questions ordered answered;

    ii. The section 6.08 motion be heard by the Trial Judge in this action; and

    iii. The 24-month stay be extended by three months to accommodate Amgen's desire to pursue the motion pursuant to sections 6.09 and 7(8) of the *Regulations*;

D. Costs of the motion; and

E. Such further or other relief as counsel may advise and as this Honourable Court may deem just.

[3] The issues for determination on this motion are as follows:

A. Should Amgen's section 6.08 motion be dismissed or adjourned *sine die*?

B. If Amgen's section 6.08 motion is not dismissed or adjourned *sine die*, what procedure should be followed for the determination of the motion?

C. Should an award of costs be made on this motion?

[4] For the reasons that follow, I find that Amgen's section 6.08 motion shall proceed and shall be determined as proposed by Amgen following documentary discovery and prior to the completion of the examinations for discovery. The Plaintiffs' motion is accordingly dismissed, with cost payable to Amgen.

Analysis

Issue #1 - Should Amgen's section 6.08 motion be dismissed or adjourned sine die?

[5] Section 6.08 of the *Regulations* provides:

An action brought under subsection 6(1) may, on the motion of a second person, be dismissed, in whole or in part, on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents or certificates of supplementary protection.	Toute action intentée en vertu du paragraphe 6(1) peut, sur requête de la seconde personne, être rejetée en tout ou en partie au motif qu'elle est inutile, scandaleuse, frivole ou vexatoire ou qu'elle constitue par ailleurs un abus de procédure à l'égard d'un ou de plusieurs brevets ou certificats de protection supplémentaire.

[6] Section 6.08 is not a new provision introduced with the coming into force of the amended *Regulations* in September 2017. Rather, an earlier embodiment of section 6.08 was found in

section 6(5)(b) of the previous version of the *Regulations* and the language of section 6(5)(b) was almost identical to the current language of section 6.08. Moreover, the language of section 6.08 tracks the language of Rule 221(1)(c) and (f) of the *Federal Courts Rules*.

[7] As with all litigation, it is essential that a mechanism exist that permits a defendant to move to dismiss a claim or a portion thereof at a preliminary stage of a proceeding where the claim is clearly without merit. It is for this reason that the *Federal Courts Rules* include Rule 221 and that the *Regulations* include section 6.08. In the case of the *Regulations*, the need for this mechanism is heightened as the regulatory regime works in such a way that as soon as a first person commences an action under section 6, an automatic stay of the regulatory approval process is engaged and the second person is prevented from obtaining a notice of compliance for its new drug product for 24 months, without any assessment of the merits of the first person's claim of patent infringement. Without the ability of the second person to move pursuant to section 6.08 to dismiss redundant, scandalous, frivolous, vexatious or abusive claims, the regulatory regime could be subject to abuse by first persons to delay new drug products from coming to market.

[8] Moreover, given that actions commenced under section 6 of the *Regulations* must be heard and determined within 24 months, it is all the more important that the issues raised in such actions are streamlined so as to ensure that claims that are clearly without merit do not consume the limited pre-trial and trial time of the parties.

[9] In this proceeding, Amgen has brought a motion to dismiss the action in relation to the 596 and 556 Patents on the basis that the claims related to those patents constitute an abuse of process as they are entirely unrelated to how Amgen intends to market its new drug product.

Amgen asserts that the Plaintiffs lack any evidentiary foundation for their claim that Amgen will infringe or induce infringement of these patents and as such, the claims are doomed to fail and warrant being dismissed.

[10] As a preliminary matter, it is important to note that Amgen is entitled to bring a motion under section 6.08 of the *Regulations* as of right. The *Regulations* do not require that Amgen obtain leave of the Court to bring a section 6.08 motion, nor do the *Regulations* prescribe at what stage of an action a section 6.08 motion may be brought. Accordingly, there is nothing precluding Amgen from filing its section 6.08 motion (with proper notice given to the Case Management Judge) and seeking to have it heard at an early stage of the proceeding.

[11] The issue for determination is whether Amgen's right to bring its section 6.08 motion and have it heard prior to the completion of the examinations for discovery should be denied, either by way of a dismissal or stay of the motion. The burden clearly rests on the Plaintiffs to satisfy the Court that its requested dismissal or stay is warranted.

[12] The Plaintiffs assert that Amgen's section 6.08 motion constitutes an improper use of section 6.08, as Amgen is attempting to obtain early summary judgment on the merits of complex infringement claims in relation to the 596 and 556 Patents prior to the completion of examinations for discovery. The Plaintiffs assert that the determination of Amgen's motion would involve disputed issues of fact and law, claims construction and the need for expert evidence, which is improper on a section 6.08 motion, particularly at this stage of the proceeding. The Plaintiffs rely on a series of cases addressing summary judgment motions, where this Court and other courts have refused to permit such motions to proceed based on the consideration of a number of factors [see, for example, *George Weston Limited v Domtar Inc,*

2012 ONSC 5001; *Wenzel Downhole Tools Ltd v National-Oilwell Canada Ltd*, 2010 FC 966 at para 31].

[13] I reject the Plaintiffs' assertion that Amgen's motion constitutes an improper use of section 6.08. Motions under section 6.08 are not limited to attacking statements of claim for technical irregularities. As was the case with section 6(5)(b) motions, a section 6.08 motion may be used by a second person to seek the dismissal of claims of infringement and/or infringement by inducement where the claims, on their merits, are bereft of any possibility of success [see, for example, *Valeant Canada LP v Apotex Inc*, 2016 FC 1359].

[14] Moreover, Amgen is not seeking to bring a summary judgment motion. This Court has clearly held that the former section 6(5)(b) motions were not summary judgment motions and I find that for the same reasons, section 6.08 motions are also not summary judgment motions [see, for example, *Valeant Canada LP v Apotex Inc*, *supra*; *Nycomed Canada Inc et al v Minister of Health et al*, 2008 FC 541 at para 49]. Had Parliament intended section 6.08 motions to be summary judgment motions and attract the same burden of proof as applicable on a summary judgment motion, Parliament could certainly have described them as such. To the contrary, the Regulatory Impact Analysis Statement [RIAS] clearly analogizes section 6.08 motions to motions to strike under Rule 221 of the *Federal Courts Rules*, stating that section 6.08 supplements Rule 221. As section 6.08 motions are not summary judgment motions, the case law relied upon by the Plaintiffs to support their request that Amgen's motion be dismissed or stayed is not applicable.

[15] The Plaintiffs assert that to permit the section 6.08 motion to proceed will result in a duplication of resources and procedural unfairness to the Plaintiffs as they will have to divert

resources to address the section 6.08 motion while already working under the tight time constraints of the accelerated timetable applicable to this action. I reject this assertion. First, the timetable for this action is not accelerated. The timetable is in keeping with the general timing of steps that will need to be taken in all actions brought under the new *Regulations*. Second, Parliament preserved the right of second persons to bring section 6.08 motions notwithstanding that actions are to be heard and determined within 24 months. The fact that the Plaintiffs will have to respond to the section 6.08 motion while at the same time move forward with the remaining procedural steps in the action does not amount to procedural unfairness. Third, any efforts made by the Plaintiffs to respond to the section 6.08 motion will replace at least a portion of the efforts that the Plaintiffs would have made in prosecuting their claims in the main action. As such, the efforts are not entirely duplicative.

[16] The Plaintiffs note that this Court has held that where moving parties establish clearly and without doubt that there could be no patent infringement, relief under section 6(5)(b) could be granted, but that such circumstances are exceptional [see *Nycomed GMBH v Canada (Minister of Health)*, 2008 FC 541]. The Plaintiffs argue that if such motions were discouraged under the old regime, there should be a heightened level of discouragement under the new *Regulations*, such that the Court should consider pre-emptively dismissing or staying a section 6.08 motion *sine die*. I reject this argument. While the Court may impose a high burden on a moving party on a section 6.08 motion and grant relief only in exceptional circumstances, that does not mean that a second person should be deprived of the right to attempt to obtain the relief.

[17] The Plaintiffs take issue with the fact that Amgen asserts that the section 6.08 motion will not require expert evidence or claim construction, stating that the Court will most definitely need

to engage in claim construction and that absent expert evidence, Amgen's motion is doomed to fail. The Plaintiffs therefore assert that it will be a waste of their resources to be forced to respond thereto, as well as a waste of judicial resources. Whether Amgen's section 6.08 motion is doomed to fail as asserted by the Plaintiffs remains to be seen and it is not the role of the Court to pre-judge the motion. That said, having considered the submissions made by the parties to date, I am not satisfied that on its face Amgen's motion is bereft of any prospect of success. If it is ultimately determined by the Court that Amgen's motion should not have been brought, the Plaintiffs' concerns can be addressed through a heightened award of costs. However, I will not deprive Amgen of its right to bring its section 6.08 motion on the basis of the Plaintiffs' objections.

[18] I am also not satisfied that the Plaintiffs will suffer irreparable harm if Amgen is permitted to have its section 6.08 motion heard at this stage of the proceeding. To the contrary, all parties stand to benefit from efficiencies that could be gained if the section 6.08 motion is granted, as there would be no need to litigate infringement or invalidity in relation to both the 556 and 596 Patents. This would result in an early streamlining of the issues that would enable the parties to use their resources and time more efficiently.

[19] Accordingly, I find that the Plaintiffs have failed to establish that a dismissal or stay of Amgen's section 6.08 motion is warranted.

Issue #2 - If Amgen's section 6.08 motion is not dismissed or adjourned *sine die*, what procedure should be followed for the determination of the motion?

[20] In their notice of motion, the Plaintiffs assert that if Amgen's motion is permitted to proceed, the Court should direct that it proceed on the basis of the Statement of Claim alone,

with no right to file evidence. At the hearing of the motion, the Plaintiffs abandoned this relief. At the hearing of the motion, the Plaintiffs also advised that they have no strong position as to whether the section 6.08 motion is heard by the Trial Judge or the Case Management Judge. Accordingly, I need not make a determination on this issue.

[21] The first remaining sub-issue for determination is whether Amgen's section 6.08 motion should proceed before or after completion of the examinations for discovery and any motions related thereto. The Plaintiffs assert that the majority of the information and evidence relevant to the section 6.08 motion is in Amgen's possession (as particularized in paragraph 56 of the Plaintiffs' written representations) and that Amgen improperly seeks to curtail the Plaintiffs from receiving it by proceeding on the section 6.08 motion before completing discovery in the action. The Plaintiffs assert that they require discovery from Amgen (both documentary and oral discovery) before they can proceed to the hearing of the issues raised on the motion.

[22] The Plaintiffs assert that to permit Amgen's motion to proceed prior to the completion of the examinations for discovery (and all motions related thereto) will have the effect of undoing all of the benefits of the procedural reforms promised to parties under the Comprehensive Economic and Trade Agreement and force the now final adjudication of these two patents as if the action were brought under the old regime. In this regard, the Plaintiffs note that Parliament confirmed in the RIAS that "the switch to full actions will further the interests of justice by providing means for the parties and the Court to access the best available evidence". The Plaintiffs assert that it would be contrary to the regulatory reforms to permit Amgen's section 6.08 motion to proceed prior to the Plaintiffs being given access to the best available evidence through the examination for discovery process.

[23] I reject the Plaintiffs' assertions. The timetable proposed by Amgen for the hearing of its motion would ensure that the Plaintiffs have the benefit of complete documentary discovery prior to filing their responding motion materials. Documentary discovery would include most, if not all, of the relevant information and documents cited at paragraph 56 of the Plaintiffs' written representations. Moreover, Amgen has confirmed that it intends to file an affidavit from the head of Amgen's Canadian marketing operations in support of the motion. The Plaintiffs will therefore have an opportunity to cross-examine the affiant on the documentation and issues relevant to the section 6.08 motion. Should any issues arise as to the appropriate scope of the cross-examination, such issues can be dealt with promptly through case management so as to ensure that the Plaintiffs are able to properly respond to Amgen's section 6.08 motion.

[24] Moreover, proceeding to the merits of the section 6.08 motion prior to the completion of examinations for discovery will not have the effect of reverting back to the old regime. The Plaintiffs will have the benefit of documentary discovery, which they would not have had under the old regime. This is a critical difference, which the Plaintiffs fail to acknowledge. The statements in the RIAS that the new regime will provide means to the parties and the Court to access the "best available evidence" cannot be taken to mean that the Court is prevented from hearing a section 6.08 motion until the examination for discovery process is complete. Had Parliament intended to place a temporal restriction on when section 6.08 motions could be heard, it would have done so. Moreover, as noted above, section 6.08 motions are intended to dismiss claims that are clearly without merit at a preliminary stage in the proceeding. It would make little sense to require such claims to proceed all the way through to the completion of discoveries before a second person could move to have the claims dismissed.

[25] Moreover, even if the Court were to accept the Plaintiffs' assertion that Amgen's section 6.08 motion is in effect a summary judgment motion, the *Federal Courts Rules* do not preclude the hearing of a summary judgment motion before the completion of examinations for discovery (see *Collins v Canada*, 2015 FCA 281 at paras 42-47).

[26] It must also be kept in mind that an action cannot be brought on speculation in the hope that sufficient facts may be gleaned on discovery that will support the allegations made in the pleading [see *AstraZeneca Canada Inc v Novopharm Limited*, 2009 FC 1209 at para 17]. Such conduct amounts to a fishing expedition and constitutes an abuse of process. There is no merit to an assertion that a first person needs to exhaust the examination for discovery process prior to responding to a section 6.08 motion. The first person has commenced the action and in doing so, it must already, outside of the discovery process, have a sufficient factual basis to support its allegations. It cannot be that a first person can commence an action to gain the benefit of a 24-month stay and say to the Court and the second person that it should not have the merits of its patent infringement claims examined at a threshold level until after it has exhausted the examination for discovery process.

[27] Accordingly, I find that Amgen's section 6.08 motion may proceed and need not await the completion of the examination for discovery process.

[28] The second remaining sub-issue for determination is whether the Court should exercise its discretion pursuant to sections 6.09 and 7(8) of the *Regulations* to extend the 24-month statutory stay as a result of Amgen's section 6.08 motion. Section 7(8) of the *Regulations* provides as follows:

As long as the Federal Court has not made a declaration referred to in subsection 6(1), it may shorten or extend the 24-month period referred to in paragraph (1)(d) if it finds that a party has not acted diligently in carrying out their obligations under these Regulations or has not reasonably cooperated in expediting the action.	Lorsque la Cour fédérale n'a pas encore fait la déclaration visée au paragraphe 6(1), elle peut abréger ou prolonger la période de vingt-quatre mois visée à l'alinéa (1)d) si elle conclut qu'une partie n'a pas agi avec diligence en remplissant les obligations qui lui incombent au titre du présent règlement ou qu'elle n'a pas collaboré de façon raisonnable au règlement expéditif de l'action.

[29] I find that there is absolutely no basis upon which to find that Amgen has failed to act diligently in carrying out its obligations under the *Regulations* or has failed to reasonably cooperate in expediting the action. Amgen has brought its section 6.08 motion in a diligent manner and has not delayed the proceeding in any way. Amgen's attempt to have its motion determined prior to the completion of examinations for discovery is entirely appropriate and certainly does not amount to the misconduct of the nature contemplated by section 7(8) of the *Regulations*. Accordingly, the Plaintiffs' request that the 24-month stay be extended is denied.

Issue #3 – Should an award of cost be made on this motion?

[30] I find that the circumstances of this motion warrant an award of costs in favour of Amgen, who was entirely successful in resisting the Plaintiffs' motion. The issues raised by the Plaintiffs could properly have been addressed and discussed at a case management conference and did not warrant the bringing of a "meta-motion". Amgen has sought costs in the amount of $10,000.00 (inclusive of taxes and disbursements), which amount I find to be reasonable.

THIS COURT ORDERS that:

1. The Plaintiffs' motion is dismissed.

2. The Defendant's section 6.08 motion shall proceed in accordance with the following timetable:

   (a) The Defendant shall serve its supporting affidavit evidence by March 21, 2018.

   (b) The Plaintiffs shall serve their responding affidavit evidence by April 20, 2018.

   (c) All cross-examinations shall be completed by May 4, 2018.

   (d) The Defendant shall serve and file its complete motion record by May 18, 2018.

   (e) The Plaintiffs shall serve and file their complete motion record by June 6, 2018.

   (f) The motion shall be heard on a date to be set by the Court. The parties shall, by no later than March 21, 2018, provide their availability for the hearing of the motion during the weeks of June 11th, 18th and 25th, 2018.

3. The parties may, on consent, amend the timetable in paragraph 2 provided that notice is given to the Court of any amendment in advance of the expiry of the deadline sought to be amended.

4. The Plaintiffs shall pay to the Defendant its costs of the motion fixed in the amount of $10,000.00 (inclusive of taxes and disbursements).

"Mandy Aylen"
Case Management Judge

Federal Court  Cour fédérale

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1921-17
STYLE OF CAUSE:	GENENTECH, INC. AND HOFFMANN-LA ROCHE LIMITED v AMGEN CANADA INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	MARCH 8, 2018
REASONS FOR ORDER AND ORDER:	AYLEN P.
DATED:	MARCH 15, 2018

APPEARANCES:

KRISTEN WALL JORDANA SANFT CHELSEA NIMMO	FOR THE PLAINTIFFS GENENTECH, INC. AND HOFFMANN-LA ROCHE LIMITED
ANDREW SHAUGHNESSY YAEL BIENENSTOCK	FOR THE DEFENDANT AMGEN CANADA INC.

SOLICITORS OF RECORD:

NORTON ROSE FULBRIGHT LLP Barristers and Solicitors Toronto, Ontario	FOR THE PLAINTIFFS KRISTEN WALL JORDANA SANFT CHELSEA NIMMO
TORYS LLP Barristers and Solicitors Toronto, Ontario	FOR THE DEFENDANT ANDREW SHAUGHNESSY YAEL BIENENSTOCK