Federal Court Cour fédérale

Date: 20191223

Docket: T-1315-19

Citation: 2019 FC 1659

Toronto, Ontario, December 23, 2019

PRESENT: Case Management Judge Angela Furlanetto

BETWEEN:

ALLERGAN INC.

Plaintiff

and

APOTEX INC.

Defendant

and

LABORATOIRE HRA-PHARMA

Defendant/Patent Owner

and

THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Defendant/Patent Owner

ORDER AND REASONS

[1] This is a motion brought by the co-owner of the patent, The United States of America ("USA"), for an Order allowing the USA leave to file a responding pleading to Apotex' Statement of Defence. The underlying proceeding is an action brought under s. 6(1) of the *Amended Patented Medicines (Notice of Compliance) Regulations* (*"PM(NOC) Regulations"*) in which Allergan Inc. (acting under the consent of the patent owners) seeks a declaration of infringement in respect of Canadian Patent No. 2,713,254 (the "254 Patent"). In response to the action, Apotex has filed a Statement of Defence asserting that the 254 Patent is invalid on a number of grounds.

[2] The USA was named as a party Defendant to the proceeding pursuant to s. 6(2) of the *PM(NOC) Regulations*. It has not taken any steps of its own to seek a declaration of infringement of the 254 Patent and there are no remedies sought against it in the proceeding. Its interest, as expressed at the motion, is solely to address the validity allegations made in Apotex' Statement of Defence.

[3] Prior to this motion being brought, the USA engaged in correspondence with Allergan and Apotex requesting their consent to serve and file a Reply pleading; while Allergan consented, no agreement could be reached as between the USA and Apotex. As such, a motion was brought by the USA to seek leave to file a responding pleading. The dispute on the motion relates to the entitlement of the USA to file a responding pleading and if so, as to the form such pleading would take. A preliminary issue as to the timing for any responding pleading was also

raised; however, this issue became moot with the USA agreeing that any restrictions as to timing prescribed by the *State Immunity Act* were already met as of the time of hearing.

[4] It is of note that the USA did not include its proposed pleading in its motion materials, but indicated at the hearing of the motion that it had prepared a draft pleading. At the conclusion of the hearing, it was agreed that the draft pleading would be shared with Apotex and Allergan and that the parties would advise the Court whether any joint proposal could be reached as to its form and substance. Despite several weeks of correspondence between the parties, a joint proposal could not be reached on all terms. In a separate case management teleconference, the parties agreed that the Court could consider the further correspondence of the parties and that the disposition on the motion would extend to the issues discussed between the parties, including the form and content of the proposed pleading and the role that the USA would play in the proceeding moving forward, in view of its proposed pleading.

[5] As such, the following issues are before me for determination:

a) Is the USA entitled to file a responding pleading to Apotex' Statement of Defence and if so, what should that pleading be called?

b) Should leave be granted to permit the pleading proposed by the USA and in particular, should paragraph 6 of the proposed pleading be allowed?

c) What role can the USA play in the proceeding during the pre-trial steps and at trial?

Is the USA entitled to file a responding pleading to Apotex' Statement of Defence?

[6] The language of the *PM(NOC) Regulations* makes clear that a patent owner must "be or be made" a party to a proceeding under the *PM(NOC) Regulations* involving its patent.

[7] As set out by sections 6(1) and 6(2) of the *PM(NOC) Regulations,* a patent owner may either initiate a proceeding under the *PM(NOC) Regulations* (section 6(1)) or if the proceeding is brought by a person other than the patent owner, be made a party to the proceeding pursuant to section 6(2):

> 6(1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day 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.
>
> (2) If the person who brings an action under subsection (1) is not the owner of each patent – or of a patent that is set out in each certificate of supplementary protection – that is the subject of the action, the owner of each of those patents shall be or be made a party to the action.

[8] In this case, the USA did not initiate proceedings against Apotex. Instead, it was named as a party Defendant by Allergan in the Statement of Claim, pursuant to s. 6(2) of the *PM(NOC) Regulations*.

[9] At the motion, Apotex argued that the USA should not be entitled to file either a Reply or a Statement of Defence as it is not the proper party for either pleading. As argued by Apotex, only a Plaintiff can reply to a defence to its claim and only a Defendant can defend against allegations made against it in a Statement of Claim. In this case, the USA satisfies neither of these roles.

[10] Following further discussions between the parties, there no longer appears to be a dispute that the USA should be entitled to file some form of responding pleading provided that appropriate safeguards are in place; I agree. It would be inconsistent with section 6(2) of the *PM(NOC) Regulations* which specifically provides that a patent owner must be named as a party to the proceeding to then interpret the same regulations as then saying that a patentee can only play a role in the proceeding if they are a party Plaintiff. This Court has long held that a patent owner should be before the Court when its patent is under consideration (*Pfizer Canada Inc*. v. *Canada (Minister of Health)*, 2007 FC 167 at para 15; aff'd 2008 FCA 15). If the owner is not a Plaintiff it is appropriate to name the patentee as a Defendant.

[11] The USA seeks to call its proposed pleading a "Reply" as it is seeking to respond to the Statement of Defence of Apotex. Apotex objects to this naming. As argued by Apotex, only a Plaintiff may reply to a defence to its claim. As the USA is not a party Plaintiff it cannot stand in the Plaintiff's shoes and reply. However, the USA as a named Defendant is not proposing to defend in the traditional sense either. It is not seeking to respond to the Statement of Claim, but rather to preserve its patent rights and respond to the allegations of invalidity made in the Statement of Defence. The USA does not have any interest in being a Plaintiff in the proceeding

and asserting infringement of the 254 Patent; its only interest is in upholding the validity of the 254 Patent.

[12] This issue was considered by the Federal Court of Appeal under the former *PM(NOC) Regulations.* In *Schering-Plough Canada Inc. v Pharmascience Inc*. 2008 FCA 230, the issue before the Court was how a party who was a named Respondent to an application under the former *PM(NOC) Regulations* was to proceed when they did not oppose the application but nonetheless wished to take part in the proceedings. In that case, the Federal Court of Appeal held that a notice of appearance filed by the patentee Respondent Sepracor should be allowed to stand even though it did not technically comply with Rule 305 of the *Federal Courts Rules* because it indicated that Sepracor intended to "participate" in the application instead of opposing it. The Court held that "a patentee who is named a respondent in an application is entitled to support that application without seeking to be named as an applicant." The Court noted the requirement in the *Rules* that persons with an interest be named as Respondent if they were not an Applicant and recognized that such Respondent would lose their interest in participating in the proceeding if they did not file a notice of appearance.

[13] Similarly, s. 6(2) of the *PM(NOC) Regulations* provides the same type of provision: a patent owner will be or be made a party if they are not a named plaintiff. The *PM(NOC) Regulations* which ensure that a patentee will be named as a party, cannot then be read so restrictively to deprive a Defendant patentee of their right to participate. To advance a position in the action, the Defendant patentee must be able to file some form of pleading, none of which will comply strictly with the framework set out in the *Federal Courts Rules*.

[14] I agree with the USA the objectives set forth in rules 3, 5, 55 and 385 of the *Federal Courts Rules* allows the Case Management Judge to consider the most just, expeditious manner of proceeding and to consider a flexible approach where situations arise that do not fall squarely within the prescribed rules. This is particularly so with proceedings under the *PM(NOC) Regulations,* which are subject to strict time constraints and where common sense approaches are encouraged.

[15] In my view, the USA's pleading should be identified as what it is: a Reply to the Statement of Defence. Safeguards can be put in place to ensure that the patentee does not duplicate the role of Plaintiff and does not abuse the Court's processes. As set out further below, Apotex argues that the USA should not be able to use its Defendant status to seek independent examination of Allergan and to obtain more rights than it would have had as a co-Plaintiff. The correspondence between the parties reinforces that the intended role of the USA is to be responsive to Apotex and not to be adverse to Allergan. In my view naming the pleading a Statement of Defence would cause greater confusion with this intended role. I will accordingly order that the pleading be labelled a "Reply to the Defence of Apotex ("Reply to the Defence of Apotex (Of the Patentee, the United States of America, Added Pursuant to ss. 6(2) of the PM(NOC) Regulations)" as proposed by the USA, but that the role of the USA include certain restrictions as set forth further below.

Should leave be granted to permit the pleading proposed by the USA and in particular, should paragraph 6 of the proposed pleading be allowed?

[16] Counsel for the USA provided the Court with its proposed pleading on December 12, 2019. Allergan consents to it being filed in its current form. Aside from the title of the pleading and its paragraph 6, Apotex does not raise any other specific issues with its content.

[17] Paragraph 6 of the proposed pleading states:

> 6. The Patentee states that the Statement of Defence does not disclose sufficient facts to establish that the decision of the Commissioner of Patents to grant the 254 Patent was improper. Apotex's must establish that the Commissioner of Patents acted unreasonably in granting the 254 Patent.

[18] Apotex argues that paragraph 6 should not be allowed as it raises a new argument beyond what Allergan has asserted in its Reply and it is not sound in law. I do not agree that the paragraph should not be allowed.

[19] With respect to the first point, as noted by the USA, while the USA and Allergan are aligned with respect to their position regarding the validity of the 254 Patent, the USA is a distinct party with distinct interests to those of Allergan. As a patentee and necessary party to the proceedings, the USA is entitled to represent its independent interests in the proceedings, including by way of independent and distinct arguments. As such, it should be permitted to participate separately and raise its own arguments in response (*Schering-Plough Canada Inc. v Pharmascience Inc*. 2008 FCA 230 at para 23, citing *Aventis Pharma Inc*. *v Apotex Inc*. 2004 FC

570). Indeed, there would be no meaningful reason for the USA to participate if its arguments were entirely duplicative of what is already asserted by Allergan in Reply.

[20] Further, paragraph 6 is not connected to a defence to Allergan's claim. Paragraph 6 is an assertion of law regarding the nature of Apotex' onus to establish invalidity of the 254 Patent. It is not in reply to a paragraph that is responsive to Allergan's Statement of Claim.

[21] With respect to the second point, I do not agree that it is clear on its face that the assertion made in paragraph 6 is unmeritorious. It is premature at this stage to conclude that the proposed allegation should not be included in the Reply.

What role can the USA play in the proceeding during the pre-trial stages and at trial?

[22] Apotex argues that the USA cannot have both the rights of a Defendant and a Plaintiff. Apotex argues that under the new regime a party has a choice as to which role it will take. In this case, the USA has chosen not to assert its patent in the proceeding; therefore, it may only participate in a limited capacity.

[23] As I understand the nub of Apotex' concern it is that the patentee should not be entitled to leverage two roles: it should not be entitled to use its Defendant status to obtain more rights than it would have had as a co-Plaintiff. Further, it should not be entitled to receive all of the advantages of a Plaintiff in the proceeding, but not take on the burden of a Plaintiff in terms of accountability and remedies.

[24] It proposes the following restrictions as to the conduct of the USA for the proceeding:

a) Allergan and USA will not conduct examinations for discovery of each other's representatives;

b) Allergan and USA will not conduct examinations of each other's trial witnesses;

c) Allergan and USA together will not lead more than 5 expert witnesses;

d) Trial time will be divided between Apotex (50%) and Allergan/USA (collectively 50%);

e) For both the examination for discovery of Apotex, and for any witness Apotex leads at trial, Allergan and USA will elect which of them will conduct a single examination of the witness on behalf of both Allergan and USA;

f) Allergan and USA will be permitted only one collective set of read-ins from their collective discovery of Apotex;

g) Allergan and US will not file materials in response to each other's motions;

h) Whatever page limits are imposed on the parties for any written arguments or memoranda in any context will apply to Allergan and USA collectively so that Apotex will have the same number of pages for its submission that Allergan and USA will have combined;

i) Whatever time limits for oral arguments are imposed on the parties in any context will apply to Allergan and USA collectively so that Apotex will have the same amount of time for its submissions as will Allergan and USA have combined.

[25] At the hearing of the motion and through the parties' correspondence the USA acknowledged that its interests are aligned with those of Allergan and as such, it is not seeking to examine Allergan's discovery representative or witnesses at trial. With respect to the proposed conditions a, b and g, both the USA and Allergan agreed that as long as their interests remain aligned they would not examine each other's representatives or trial witnesses and would not seek to take an adverse role on motions. This is, in my view, a logical way of proceeding and should be the framework for proceeding. I agree with Apotex, to the extent that down the road the USA or Allergan are of the view that their positions are no longer aligned and that they would need examination of each other; or to the extent that an issue on a motion brought by Allergan requires the USA's response, leave should be sought from the Court to depart from this framework as it would be proposing an alternative role for the USA in the proceeding.

[26] Similarly, I agree with Apotex that to the extent the USA seeks to conduct examination for discovery of Apotex, the discovery should be conducted as a single collective discovery with Allergan and should not be duplicative of the discovery conducted by Allergan.

[27] As the USA's position is adverse to Apotex on the issue of invalidity, Apotex will have the right to documentary discovery from the USA and to *viva voce* examination, including of the inventors from the USA on the issues covered by the Reply.

[28] With respect to the trial-related issues, both the USA and Allergan take the position that these issues are premature in view of the stage of the proceedings. While I agree that the details of the division of time and behaviour of the parties at trial are best left to be discussed at a trial

management conference, in my view the framework should be the same as that for discovery and should be reflective of the limited role that the USA has asserted on this motion. The outcome of this motion is not intended to allow the USA to duplicate the role of Allergan. This framework will be developed further through case management.

Costs

[29] For the reasons set out above, it is my view that the USA's motion should succeed and an Order will issue allowing the USA's Reply to be served and filed; however, I will not make an award as to costs. In my view, the issues on this motion could have been more readily resolved had the USA provided its proposed pleading to Apotex and Allergan in advance of its motion as suggested by the Court during the case management conference on November 8, 2019. Further, as I have adopted a number of the provisions proposed by Apotex which are important to safeguard the role of the USA in the proceeding (all of which were opposed by the USA prior to the motion) it is my view that Apotex has also achieved some success on this motion.

ORDER in T-1315-19

THIS COURT ORDERS that:

1. The USA is granted leave to serve and file its proposed Reply pleading as provided to the Court on December 12, 2019, which shall be formally served and filed by January 7, 2020.

2. The role of the USA in the proceeding shall be limited to participating on the issues arising from the USA's Reply, namely to responding to Apotex' invalidity allegations and seeking to uphold the validity of the 254 Patent; and shall not be duplicative of the role of Allergan. Without leave of the Court, the USA shall not conduct examination for discovery of Allergan's discovery representative, shall not examine Allergan's witnesses at trial, and shall not take positions adverse to Allergan on a motion brought by Allergan.

3. The date for delivery of affidavits of documents set out in the Court's October 7, 2019 Order shall also apply to the USA and the USA shall be subject to examination for discovery, including of its inventors, by Apotex.

4. The parties shall provide further submissions as to the schedule and any procedural issues relating to the role of the USA as part of its January 24, 2020 correspondence to be provided to the Court under the existing October 7, 2019 Scheduling Order.

5. There shall be no award as to costs.

"Angela Furlanetto"

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1315-19
STYLE OF CAUSE:	ALLERGAN INC. v. APOTEX INC. AND LABORATOIRE HRA-PHARMA AND THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES
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