Federal Court Cour fédérale

Date: 20180301

Docket: T-317-18

Citation: 2018 FC 233

Ottawa, Ontario, March 1, 2018

PRESENT: Madam Prothonotary Mandy Aylen

BETWEEN:

GENENTECH, INC.

Applicant/Patent Owner

and

HOFFMANN-LA ROCHE LIMITED

Applicant/First Person

and

PFIZER CANADA INC.

Respondent/Second Person

ORDER AND REASONS

[1] Genentech, Inc. [Genentech] and Hoffmann-La Roche Limited [Roche] have filed an "application/motion" seeking an order pursuant to section 5(3.7) of the *Patented Medicines*

(Notice of Compliance) Regulations (SOR/93-133) [*Regulations*] varying the confidentiality rules imposed by Pfizer Canada Inc. [Pfizer] pursuant to section 5(3.5) of the *Regulations* for new drug submission documents provided with eight notices of allegations served by Pfizer with respect to Pfizer's new drug submissions for its trazimera product.

[2] A preliminary objection was raised by Pfizer as to the jurisdiction of the Court to hear this matter in the absence of an underlying action commenced by Genentech and Roche pursuant to section 6 of the *Regulations*. For the reasons that follow, I find that the Court does not have jurisdiction to entertain a motion under section 5(3.7) of the *Regulations* in the absence of an underlying action.

I. Analysis

[3] By way of background, the *Regulations* underwent significant amendments that came into force on September 21, 2017. As a result, a NOC proceeding is now brought by way of action, rather than application. The timelines for commencing a proceeding (45 days) and for the statutory stay (24 months) remain unchanged.

[4] One of the significant changes to the *Regulations* relates to the early disclosure of documentation. Sections 5(3)(c)(iii) of the *Regulations* now requires that the second person serve on the first person, together with its notice of allegation, a searchable electronic copy of the portions of its new drug submission or supplement that are under its control and relevant to determine if any patent or certificate of supplementary protection referred to in the notice of allegation would be infringed. The first person is then obligated by section 5(3.3) of the *Regulations* to forward the notice of allegation and accompanying documents to the owner of the patent in respect of which an allegation is made in the notice of allegation and to the owner of a

patent that is set out in any certificate of supplementary protection in respect of which an allegation has been made.

[5] Given the commercially sensitive and confidential nature of portions of the information contained in the new drug submission or supplement, section 5(3.5) of the *Regulations* permits the second person to unilaterally impose on the first person and the patent owner any reasonable rules for maintaining the confidentiality of any portion of the new drug submission or supplement. These confidentiality rules, which generally provide for who may have access to the documents and how the documents are to be handled, are akin to the provisions of protective agreements that the parties routinely enter into in litigation involving intellectual property matters or that may be included in protective orders issued by the Court in such matters.

[6] In the event that a first person or patent owner believes that the second person's confidentiality rules are unreasonable (i.e. too restrictive), it may bring a motion to the Court to set aside or vary the confidentiality rules pursuant to section 5(3.7) of the *Regulations*. Section 5(3.7) of the *Regulations* provides:

On the motion of the first person or of the owner of the patent – or on its own initiative after giving an opportunity to the be heard to that first person, that owner and the second person – the Federal Court may set aside or vary any or all of those confidentiality rules in any manner that it considers just.	Sur requête de la première personne ou du propriétaire du brevet — ou de sa propre initiative, après avoir donné l'occasion d'être entendus à cette première personne, à ce propriétaire et à la seconde personne — la Cour fédérale peut annuler ou modifier toute règle de confidentialité de la manière qu'elle considère comme juste.

[7] In this case, Pfizer (the second person) served eight notices of allegations [NOAs] on Roche, together with documents from its new drug submissions [NDS]. The NOAs and NDS documents were provided by Roche to Genentech, the patent owner. Pfizer imposed confidentiality rules on Roche and Genentech in relation to the NDS documents that Roche and Genentech believe to be unreasonable and unduly restrictive. As a result, Roche and Genentech brought the present application/motion.

[8] Pfizer has raised a preliminary objection to the application/motion, arguing that the "notice of application/motion" was not filed in accordance with the *Federal Courts Rules*, SOR/98-106 [*Rules*] or the *Regulations* and as such, the Court does not have jurisdiction to receive the materials for filing or to hear the application/motion. Specifically, Pfizer asserts that Rule 63(1) of the *Rules* provides that unless otherwise provided by or under an Act of Parliament, the originating document for the commencement of an action is a statement of claim and the originating document for the commencement of an application is a notice of application. Rule 63(2) provides that "where by or under an Act of Parliament a proceeding is to be commenced by way of a document different from the originating document required under these Rules, the rules applicable to the originating document apply in respect of that document". Pfizer asserts that section 5(3.7) does not expressly authorize the commencement of a proceeding by way of a motion, but rather simply confirms that relief may be sought by motion, as such term is used in the *Rules*. As such, Pfizer asserts that a motion under section 5(3.7) can only be brought in the context of an action commenced under section 6 of the *Regulations*.

[9] Pfizer acknowledges that Rule 372 provides for the bringing of a motion before the commencement of proceedings, but asserts that Rule 372 is not applicable to the circumstances

of this matter. Rule 372 is found in Part 8 of the *Rules*, which addresses the preservation of rights in proceedings. Pfizer asserts that Genentech's and Roche's application/motion does not involve the preservation of rights and, accordingly, Rule 372 is not applicable. Even if the motion could be characterized as seeking a preservation of rights, Pfizer asserts that Genentech and Roche do not meet the remaining requirements for a preliminary motion as there is no urgency and Genentech and Roche have not undertaken to commence an action within a set period of time.

[10] Genentech and Roche assert that Rule 300 of the *Rules* permits proceedings to be commenced by an originating notice of motion where such proceedings are required or permitted by or under an Act of Parliament. Genentech and Roche assert that the motion referenced in section 5(3.7) of the *Regulations* should not be interpreted in the same manner as that term is used in the *Rules*, as Parliament intended a motion under section 5(3.7) to be an originating proceeding that could be brought prior to a section 6 action. Put differently, in enacting section 5(3.7), Genentech and Roche assert that Parliament authorized the commencement of a proceeding by way of a notice of motion.

[11] In support of this position, Genentech and Roche point to section 6.03(4) of the *Regulations*, which provides:

On motion of the second person or on its own initiative, after giving an opportunity to be heard to the parties to the action, the Federal Court may set aside or vary any or all of those confidentiality rules in any manner that it considers just.	Sur requête de la seconde personne ou de sa propre initiative, après avoir donné l'occasion d'être entendues aux parties à l'action, la Cour fédérale peut annuler ou modifier toute règle de confidentialité de la manière qu'elle considère comme juste.

[12] While section 6.03(4) refers to a different set of confidentiality rules imposed by the first person in relation to documents produced pursuant to section 6.03(1)(a), Genentech and Roche argue that it is the difference in language between sections 5(3.7) and 6.03(4) that is important to consider. They note that section 6.03(4) refers to "the action", whereas there is no such reference in section 5(3.7). They argue that the absence of a reference to an action supports their assertion that Parliament intended a section 5(3.7) motion to be brought in the absence of an underlying action.

[13] Having considered the written submissions of the parties and the additional submissions provided at the case management conference held February 23, 2018, I find that section 5(3.7) of the *Regulations* was not intended by Parliament to permit bringing a separate proceeding by way of motion or application. Section 5(3.7) does not refer in any way to the commencement of a proceeding, which Parliament could easily have done if that was its intention. Rather, section 5(3.7) uses the term "motion" in the same manner as it is used elsewhere in the *Regulations*, such as in section 6.03(4) and section 6.04(1). Motions under section 6.03(4) and 6.04(1) are clearly intended to be brought in the context of an action.

[14] As words contained in a regulation are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme and object of the regulations, I find that the term "motion" in the *Regulations* is to be interpreted in the same manner throughout the *Regulations* and in the same manner as the term is employed in the *Rules.* Accordingly, I find that the term "motion" in section 5(3.7) refers to an interlocutory proceeding in the context of an underlying section 6 action and does not mean an originating proceeding commenced by way of a notice of motion.

[15] This interpretation is supported by the fact that the *Regulations* do not contain any other section that provides a first person or patent owner with the right to bring a motion to challenge the confidentiality rules imposed by a second person under section 5(3.5). If "motion" in section 5(3.7) were interpreted to mean an originating proceeding outside of an action commenced pursuant to section 6 of the *Regulations*, there would be no ability for a first person or patent owner to challenge the confidentiality rules in the context of a section 6 action. Surely Parliament did not intend that where an action was already commenced, a first person or patent owner would have to commence a separate proceeding in which to challenge the confidentiality rules.

[16] Moreover, section 5(3.7) permits the Court, on its own initiative, to set aside or vary any or all of a second person's confidentiality rules. The Court cannot institute its own proceedings and therefore, the Court could only exercise this power within the context of an existing action.

[17] I also note that there is nothing in the Regulatory Impact Analysis Statement for the *Regulations* that would support Genentech's and Roche's interpretation of section 5(3.7). There is no reference to the creation of a stand-alone, originating proceeding commenced by way of a notice of motion under section 5(3.7), nor any other commentary that would support Genentech's and Roche's interpretation.

[18] While I acknowledge that there is no reference to an action in section 5(3.7) as there is in section 6.03(4), I find the absence of a reference to an action cannot be taken as an authorization to commence a proceeding by way of a notice of motion.

[19] In the absence of any authorization by Parliament in the *Regulations* to commence a proceeding by way of a motion, there is no provision in the *Rules* that can be relied upon by Genentech and Roche to permit the filing of this application/motion. As was admitted by Genentech and Roche during the case management conference, Rule 372 has no application to this proceeding.

[20] Accordingly, I find that the Court does not have jurisdiction to determine a motion under section 5(3.7) of the *Regulations* in the absence of an underlying action. The relief requested by Genentech and Roche was premature. Moreover, their application/motion materials should not have been accepted for filing by the Registry, but rather referred to the Court for directions pursuant to Rule 72 given their irregularity.

[21] In conclusion, a first person or patent owner seeking to vary or set aside confidentiality rules imposed by a second person may only bring a motion under section 5(3.7) of the *Regulations* in the context of a section 6 action.

THIS COURT ORDERS that:

1. The application/motion is dismissed, without prejudice to the right of Genentech, Inc. and/or Hoffmann-La Roche Limited to bring a motion to set aside or vary Pfizer Canada Inc.'s confidentiality rules pursuant to section 5(3.7) of the *Regulations* in any action commenced pursuant to section 6 of the *Regulations*.

2. There shall be no order as to costs.

"Mandy Aylen"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-317-18
STYLE OF CAUSE:	GENENTECH, INC and HOFFMANN-LA ROCHE LIMITED v PFIZER CANADA INC
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DATED:	MARCH 1, 2018

APPEARANCES:

MR. TONY CREBER MR. ALEX CARMENZIND	FOR THE APPLICANT (PATENT OWNER) GENENTECH, INC
MR. TONY CREBER MR. ALEX CARMENZIND	FOR THE APPLICANT (FIRST PERSON) HOFFMANN-LA ROCHE LIMITED
Mr. WARREN SPRIGINGS MS. MEGHAN DUREEN	FOR THE RESPONDENT PFIZER CANADA INC.

SOLICITORS OF RECORD:

Gowlings WLG Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANT (PATENT OWNER) GENENTECH, INC.
Gowlings WLG Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANT (FIRST PERSON) HOFFMANN-LA ROCHE LIMITED
Sprigings Barristers and Solicitors Toronto, Ontario	FOR THE RESPONDENT (SECOND PERSON) PFIZER CANADA INC.