Federal Court of Appeal  Cour d'appel fédérale

Date: 20210609

Docket: A-80-21

Citation: 2021 FCA 113

CORAM: **DE MONTIGNY J.A.**
RIVOALEN J.A.
LOCKE J.A.

BETWEEN:

SUNOVION PHARMACEUTICALS CANADA INC.
and SUMITOMO DAINIPPON PHARMA CO., LTD.

Appellants

and

TARO PHARMACEUTICALS INC.

Respondent

Heard by online video conference hosted by the registry, on June 7, 2021.

Judgment delivered at Ottawa, Ontario, on June 9, 2021.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: DE MONTIGNY J.A.
RIVOALEN J.A.

Federal Court of Appeal  Cour d'appel fédérale

Date: 20210609

Docket: A-80-21

Citation: 2021 FCA 113

CORAM: **DE MONTIGNY J.A.**
RIVOALEN J.A.
LOCKE J.A.

BETWEEN:

SUNOVION PHARMACEUTICALS CANADA INC.
and SUMITOMO DAINIPPON PHARMA CO., LTD.

Appellants

and

TARO PHARMACEUTICALS INC.

Respondent

REASONS FOR JUDGMENT

LOCKE J.A.

[1] The appellants appeal from a decision of the Federal Court (2021 FC 37, per Furlanetto J., the Decision), in the context of an action (the Action) under the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the Regulations). The Decision granted a motion by the respondent to amend its statement of defence in the Action to introduce allegations of

invalidity of the patents in suit that were not included in its notice of allegation (NOA) served prior to the commencement of the Action.

[2] Under the Regulations as they stood prior to September 21, 2017, a “second person” (here, the respondent, which is the defendant in the Action) was limited to relying on allegations made in its NOA. It could not introduce new allegations of invalidity or non-infringement of the patent(s) in suit. The Decision concluded that this limitation does not apply to actions commenced under the Regulations as amended on September 21, 2017. This is the focus of the disagreement between the parties in this appeal.

[3] The Federal Court described the Regulations, and distinguished the versions before and after the 2017 amendments. The Federal Court noted that the former version of the Regulations contemplated an application by a “first person” for an Order prohibiting the Minister of Health from issuing a notice of compliance, in which the first person bore the burden of establishing that the allegations made in the NOA were not justified. This burden applied even to allegations of invalidity. Because the proceeding was an application, there were no pleadings or live testimony as there are in the action contemplated under the current version of the Regulations. Therefore, the notice of application and the first person’s evidence had to be based on the allegations in the NOA.

[4] The Federal Court also noted that the amendments to the Regulations removed the dual track nature of litigation under the former version, in which an application under the Regulations (sometimes called a prohibition application) could be followed by a separate action to finally

determine issues of patent infringement and validity. The current version of the Regulations deals with all of these issues together.

[5] On the question of the second person's right to add allegations in its statement of defence that were not made in the NOA, the Federal Court considered the Regulatory Impact Assessment Statement (RIAS) that accompanied the amendments to the Regulations. The RIAS acknowledges the requirement in subparagraph 5(3)(*b*)(ii) that the NOA include a detailed statement of any grounds of invalidity that are alleged, but states that "[t]his requirement does not circumscribe or otherwise limit the issues and arguments that may be raised in a proceeding brought under the Regulations." In my view, this passage is telling as to the intent of the provision. The Federal Court relied on the RIAS to conclude that a second person in an action under the Regulations is not limited to the invalidity allegations made in its NOA. I agree.

[6] The appellants express concern that their decision to commence the Action, and thereby to risk liability to the respondent under section 8 of the Regulations if the Action is unsuccessful, was based on the allegations made in the NOA. The appellants argue that it is unfair to permit the respondent to add new invalidity allegations to its defence because they (the appellants) were denied the right to consider these new allegations when accepting the risk of liability. The appellants also argue that permitting the introduction of new invalidity allegations that were not included in the NOA would encourage second persons to split their case by delivering a bare NOA that is fleshed out only later after the first person has accepted liability under section 8 by commencing an action.

[7] The Federal Court noted two checks on a second person's incentive to try to profit from withholding invalidity allegations in this way. First, subsection 8(6) of the Regulations provides that, "[i]n assessing the amount of compensation […] the court shall take into account all matters that it considers relevant […] ". This provision gives the Court considerable discretion to consider factors that could affect the amount of liability under section 8, including whether the first person was improperly influenced to start an action because of an incomplete NOA.

[8] A second check on a strategy based on the introduction of new invalidity allegations after the commencement of an action under the Regulations is the Court's discretion to grant or dismiss a motion to amend a pleading. If a Court is convinced that a proposed amendment seeks to introduce invalidity allegations of which the moving party was aware when its NOA was served, the Court may dismiss the motion on the basis that permitting the amendment would not serve the interests of justice. The second person would then be denied the right to make its case based on the omitted allegations.

[9] While neither of these checks is a guarantee that the first person will not face liability based on an unexpected invalidity allegation, the possibility that the second person would see its section 8 claim reduced (partially or entirely) pursuant to subsection 8(6), or that it would lose the opportunity to add a new invalidity allegation, would likely reduce or eliminate any incentive to hold something back from its NOA.

[10] The appellants note that a counterclaim is a distinct proceeding from an action. They argue that their liability in a section 8 claim would be limited to issues disputed in the action

brought under the Regulations, and would not extend to issues raised only in a counterclaim, which is a distinct proceeding. Accordingly, they argue, any new invalidity allegations that the respondent wishes to make should be added by way of amendment of the counterclaim, not amendment of the defence. This would permit the respondent to rely on the new allegations without exposing the appellants to liability based on allegations that were not included in the NOA.

[11] The Federal Court dismissed this argument on the basis that the Regulations do not support the distinction the appellants seek to make between the Action and the counterclaim. I agree. Nothing in the text, context or purpose of the Regulations suggests to me that this was the legislator's intent.

[12] In conclusion, I find no error in the Federal Court's reasons. I would dismiss the present appeal with costs in the amount of $5,000.

"George R. Locke"
J.A.

"I agree.
Yves de Montigny J.A."

"I agree.
Marianne Rivoalen J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-80-21
STYLE OF CAUSE:	SUNOVION PHARMACEUTICALS CANADA INC. and SUMITOMO DAINIPPON PHARMA CO., LTD. v. TARO PHARMACEUTICALS INC.
PLACE OF HEARING:	BY ONLINE VIDEO CONFERENCE
DATE OF HEARING:	JUNE 7, 2021
REASONS FOR JUDGMENT BY:	LOCKE J.A.
CONCURRED IN BY:	DE MONTIGNY J.A. RIVOALEN J.A.
DATED:	JUNE 9, 2021

APPEARANCES:

David Tait James S.S. Holtom	FOR THE APPELLANTS
Scott Beeser Jonathan Stainsby Yaseen Manan	FOR THE RESPONDENT

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Toronto, Ontario	FOR THE APPELLANTS
Aitken Klee LLP Ottawa, Ontario	FOR THE RESPONDENT