Federal Court  Cour fédérale

Date: 20200522

Docket: T-28-20

Citation: 2020 FC 635

Ottawa, Ontario, May 22, 2020

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

ASTRAZENECA CANADA INC.
AND ASTRAZENECA AB

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

ORDER AND REASONS

I. Overview

[1] The plaintiff, Astrazeneca, began this action against the defendant, Sandoz, after Sandoz filed a Notice of Allegation against Astrazeneca alleging non-infringement, invalidity, and ineligibility in respect of Astrazeneca's patent for saxagliptin tablets sold under the brand name ONGLYZA (Canadian Patent No 2,402,894). In its action, Astrazeneca seeks a declaration that

Sandoz would infringe the ‘894 patent, relying on s 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations).

[2] The trial of this action is scheduled for 10 days in October 2021. However, the ‘894 patent will expire before that, on March 5, 2021.

[3] In this motion, Astrazeneca seeks an Order confirming that its infringement action will not be rendered moot on the expiry of the patent. In the alternative, Astrazeneca urges the Court to exercise its discretion to decide the issue of infringement even if it is moot. Sandoz does not oppose the motion.

[4] I agree with Astrazeneca that the issue of infringement is not moot, even though it will be determined after the patent’s expiry. Even if it were moot, the circumstances justify deciding the issue.

II. Mootness

(1) The Regulatory Framework

[5] Under the Regulations, a patentee can bring an action seeking a declaration that a second person who makes, uses, or sells a drug “would infringe” a listed patent (s 6(1)). A declaration of infringement bars the second person from obtaining a Notice of Compliance (NOC) and entering the market.

[6] The commencement of an action imposes a 24-month stay on the second person's ability to obtain a NOC (s 7(1)(d)). However, in response to a patentee's action, a second person can counterclaim arguing that the patent is invalid (s 6(3)).

(2) Is this action moot?

[7] A proceeding is moot if there no longer remains any tangible or concrete dispute between the parties (*Borowski v Canada* (*Attorney General*), [1989] 1 SCR 342 at 353).

[8] In my view, the dispute between the parties will remain a live issue even after the expiry of the '894 patent.

[9] When Sandoz served its Notice of Allegation on Astrazeneca in November 2019, and when Astrazeneca responded with its Statement of Claim in January 2020, there were obviously live issues of infringement, invalidity, and ineligibility in play between the parties. The question is whether those questions will survive the expiry of the patent in March 2021. The answer, in my view, is yes.

[10] The issue of whether Sandoz's proposed product would infringe the '894 patent will still be an important question after the expiry of the patent. Astrazeneca's action seeks a declaration under s 6 of the Regulations about whether Sandoz's conduct – allegedly practising the invention of the '894 patent – "would infringe" the patent. That declaration will be of more than theoretical interest after the expiry of the patent.

[11] The effect of Astrazeneca's action is to prevent Sandoz from obtaining a NOC and entering the market. An analysis of the issue of infringement will help answer the question of whether Sandoz was justifiably kept off the market. The same is true for the analysis of invalidity and ineligibility.

[12] In addition, on the granting of a declaration under s 6(1), the Court can grant the plaintiff any remedy available under the *Patent Act*, including an injunction or damages. It is not clear at this point, of course, that any remedies beyond a declaration would be appropriate in the circumstances. But, consideration of the issue of remedies is premised on the granting of the declaration that Astrazeneca seeks by way of its action. It cannot be said that the issue of remedies will be moot after the patent expires. As Astrazeneca points out, damages could be imposed if Sandoz was found to have begun commercial manufacture of its product.

[13] I recognize that the substantive issues – infringement, invalidity, and ineligibility – could, in theory, be left to be decided in a later proceeding if Sandoz were to seek damages under s 8 of the Regulations for having been kept off the market because of Astrazeneca's action. In other words, if I were to find that the present action will be rendered moot by the expiry of the patent, the same issues could be addressed as part of any damages claim that Sandoz might later pursue.

[14] For two reasons, I do not believe that postponing the issues in this action to a later s 8 proceeding is appropriate.

[15] First, unlike its predecessor, the current regulatory scheme envisages the determination of substantive patent issues within a single proceeding (s 6.01). It would be inconsistent with that intent if substantive issues relating to patents soon to expire would be dealt with differently than those arising in respect of younger ones. For example, it would be incongruous if the determination of the former would depend on the exercise of the Court's discretion rather than a patentee's right of action under s 6.

[16] Second, s 8 actions have typically been confined to damages calculations, leaving substantive patent matters to s 6 proceedings. For example, attempts to re-litigate infringement within a s 8 action have been discouraged: *Apotex Inc v Pfizer Canada Inc*, 2013 FC 493 at para 26.

[17] Accordingly, I do not find that the issues in this action will be rendered moot by the expiry of the patent.

[18] But even if they were moot, I would exercise my discretion to determine them within this action. As discussed, the issues may not go away with the expiry of the patent. They may have to be determined at a later point within a s 8 proceeding. Consistent with my observations above, it is more appropriate for the substantive patent issues to be addressed in a s 6 action than in a s 8 proceeding.

[19] Further, it would be more efficient and economical to continue with the present action than to require the parties to address the issues in a later s 8 proceeding. The parties have already agreed to a timetable for the completion of the steps necessary to be ready for trial in 18 months.

[20] Finally, there is no suggestion that the Court would be playing a legislative role by deciding the issues in this action even if they were technically moot.

III. Conclusion and Disposition

[21] In my view, the issues in this action will not be rendered moot when the patent in issue expires. However, even if they were moot, I would exercise my discretion to decide them in this action rather than postponing them to a possible future s 8 proceeding. Astrazeneca sought costs only if this motion was opposed by Sandoz, which it was not. Therefore, there is no order as to costs.

ORDER IN T-28-20

THIS COURT ORDERS that:

1. This action will not be rendered moot on the expiry of the ‘894 patent.
2. Even if the action were moot, the Court would exercise its discretion to determine the issues arising in it.
3. There is no order as to costs.

"James W. O'Reilly"
Judge

ANNEX

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133	*Règlement sur les médicaments brevetés (avis de conformité)* (DORS/93-133)
Right of Action	Droits d'action
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.	**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.
…	[…]
(3) The second person may bring a counterclaim for a declaration	(3) La seconde personne peut faire une demande reconventionnelle afin d'obtenir une déclaration :
(a) under subsection 60(1) or (2) of the Patent Act in respect of any patent claim asserted in the action brought under subsection (1); or	a) soit au titre des paragraphes 60(1) ou (2) de la Loi sur les brevets à l'égard de toute revendication se rapportant à un brevet faite dans le cadre de l'action intentée en vertu du paragraphe (1);
(b) under 125(1) or (2) of that Act in respect of any claim, asserted in the action brought under subsection (1), in the patent set out in the certificate of supplementary protection in question in	b) soit au titre des paragraphes 125(1) ou (2) de la même loi, à l'égard de toute revendication, faite dans le cadre de l'action intentée en vertu du paragraphe (1), se rapportant au brevet mentionné dans le certificat de protection

that action.

6.01 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 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.

Notice of Compliance

7 (1) The Minister shall not issue a notice of compliance to a second person before the latest of

…

(d) the day after the expiry of the 24-month period that begins on the day on which an action is brought under subsection 6(1);

8 (1) A second person may apply to the Federal Court or another superior court of competent jurisdiction for an order requiring all plaintiffs in an action brought under subsection 6(1) to compensate the second person for the loss referred to in

supplémentaire en cause dans cette action.

6.01 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 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.

Avis de conformité

7 (1) Le ministre ne peut délivrer d'avis de conformité à la seconde personne avant le dernier en date des jours suivants :

[…]

d) le lendemain du dernier jour de la période de vingt-quatre mois qui commence à la date à laquelle une action a été intentée en vertu du paragraphe 6(1);

8 (1) La seconde personne peut demander à la Cour fédérale ou à toute autre cour supérieure compétente de rendre une ordonnance enjoignant à tous les plaignants dans l'action intentée en vertu du paragraphe 6(1) de lui verser une indemnité

subsection (2).

(2) Subject to subsection (3), if an action brought under subsection 6(1) is discontinued or dismissed or if a declaration referred to in subsection 6(1) is reversed on appeal, all plaintiffs in the action are jointly and severally, or solidarily, liable to the second person for any loss suffered after the later of the day on which the notice of allegation was served, the service of which allowed that action to be brought, and of the day, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations.

pour la perte visée au paragraphe (2).

(2) Sous réserve du paragraphe (3), si l'action intentée en vertu du paragraphe 6(1) fait l'objet d'un désistement ou est rejetée, ou si la déclaration visée au paragraphe 6(1) est renversée lors d'un appel, tous les plaignants sont responsables solidairement envers la seconde personne de toute perte subie après la date de signification de l'avis d'allégation, laquelle signification a permis que cette action soit intentée ou, si elle est postérieure, la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré n'eût été le présent règlement.

FEDERAL COURT

SOLICITORS OF RECORD

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