Federal Court  Cour fédérale

Date: 20180221

Dockets: T-856-17
T-824-17

Citation: 2018 FC 199

Ottawa, Ontario, February 21, 2018

PRESENT: The Honourable Mr. Justice O'Reilly

Docket: T-856-17

BETWEEN:

PURDUE PHARMA AND
EURO-CELTIQUE S.A.

Plaintiffs

and

COLLEGIUM PHARMACEUTICAL, INC.

Defendant

Docket: T-824-17

AND BETWEEN:

PURDUE PHARMA

Applicant

and

COLLEGIUM PHARMACEUTICAL, INC.
MAPI LIFE SCIENCES CANADA INC. AND
THE MINISTER OF HEALTH

Respondents

and

EURO-CELTIQUE S.A.

Respondent/Patentee

ORDER AND REASONS

I. Overview

[1] In 2017, Purdue Pharma began two separate proceedings in this Court. First, it instituted an application for an order under the *Patented Medicines (Notice of Compliance) Regulations* to prevent Collegium Pharmaceutical, Inc from marketing oxycodone tablets in Canada before Purdue's '845 patent expires in 2025. The '845 patent relates to the composition, dosage forms, and process for preparing an oxycodone salt. Second, Purdue (and its co-plaintiff Euro-Celtique SA) began an action against Collegium for infringement of the '845 patent.

[2] In response to the action, Collegium brought a motion to strike Purdue's statement of claim on two grounds – that Purdue had failed to support its claim of infringement with any material facts, and that Purdue had failed to properly plead its prospective infringement allegation, a so-called *quia timet* claim. Prothonotary Kevin Aalto dismissed Collegium's motion; Collegium appeals that ruling arguing that Prothonotary Aalto erred in applying the relevant law on the adequacy of pleadings.

[3] In turn, Purdue brought a motion to partially consolidate the application and the action in the interests of efficiency and fairness. Prothonotary Aalto adjourned this motion pending the completion of pleadings. Pleadings are now closed, and Purdue's motion is before me.

[4] I find that Collegium's appeal should be allowed. That finding renders Purdue's consolidation motion moot. The sole issue, therefore, is whether Collegium's appeal should be allowed.

II. The Decision under Appeal

[5] Before Prothonotary Aalto, Collegium argued that Purdue's statement of claim should be struck entirely. In the alternative, it submitted that the action should be stayed pending the outcome of the application.

[6] Collegium's main argument on its motion to strike was that Purdue had not claimed any infringing activities beyond those falling within the exception under s 55.2 of the *Patent Act* for steps taken to meet Canadian regulatory requirements. Prothonotary Aalto concluded that Collegium's position amounted to a defence to Purdue's action that should be raised at trial, not on a motion to strike.

[7] Further, Prothonotary Aalto found that Purdue's pleadings were sufficient. It had pleaded that Collegium had arranged for the allegedly infringing product to be imported into Canada in connection with Collegium's New Drug Submission (NDS). Further, Purdue alleged that Collegium had already successfully applied to the US Food and Drug Administration (FDA) to

market the product in the US. Collegium had also filed a notice (Form 10-K) with the US Securities and Exchange Commission (SEC) to the effect that Collegium was seeking marketing approval in Canada. In addition, Collegium had issued a press release stating that it was seeking marketing approval in Canada.

[8] Prothonotary Aalto reviewed the jurisprudence that Collegium had cited to him, beginning with *AstraZeneca Canada Inc v Novopharm Limited*, 2009 FC 1209. There, Justice Roger Hughes struck the plaintiff's statement of claim on the basis that it contained bald allegations without material facts in support of them. In particular, the plaintiff alleged that the defendant had imported the medicine in issue into Canada, the defendant was seeking a Notice of Compliance (NOC), the plaintiff had commenced an application to prevent the defendant from obtaining its NOC, and, if the defendant successfully defended the NOC, it would market its infringing product in Canada.

[9] Prothonotary Aalto distinguished *AstraZeneca* on the basis that Purdue had pleaded sufficient material facts to support its infringement allegations, including the *quia timet* claim. Prothonotary Aalto pointed to the reference in the statement of claim to Collegium's Form 10-K and its press release.

[10] In support of its position, Collegium relied on *Eli Lilly Canada Inc v Nu-Pharm Inc*, 2011 FC 255, and *Teva Canada Ltd v Novartis* AG, 2016 FC 18. In *Eli Lilly*, Justice Judith Snider addressed an argument similar to Collegium's reliance on s 55.2. She found that the plaintiff there had not pleaded anything beyond activity that formed part of the process of obtaining

regulatory approval in Canada; therefore, s 55.2 applied, and the claim should be struck. Further, Justice Snider had evidence before her in the form of an affidavit from a representative of the defendant making clear that the defendant was merely taking steps to obtain an NOC. In the *Teva* case, Prothonotary Mireille Tabib followed Justice Snider's approach.

[11] Prothonotary Aalto noted that Collegium had not put forward evidence on its motion comparable to the evidence before Justice Snider in *Eli Lilly*.

[12] With respect to the *quia timet* aspect of Purdue's claim, Prothonotary Aalto referred to the well-established test in *Connaught Laboratories Ltd v Smithkline Beecham Pharma Inc*, (1998), 86 CPR (3d) 36 (FCTD). The plaintiff must set out in the statement of claim facts supporting the following allegations or criteria:

1. That the defendant has deliberately expressed an intention to engage in activity that raises a strong possibility of infringement;
2. That the activity is imminent;
3. That the resulting damage would be very substantial, if not irreparable; and
4. That the facts pleaded are cogent, precise, and material.

[13] Prothonotary Aalto found all four requirements to be met. First, Form 10-K and the press release disclosed Collegium's intentions and a strong possibility of infringement. Second, the imminence requirement was met given the necessity of determining NOC proceedings within two years of their commencement. Prothonotary Aalto relied on two cases for that proposition: *Gilead Sciences Inc v Teva Canada Ltd*, 2016 FC 31; *Teva Canada Ltd v Novartis AG*, above.

Third, Purdue pleaded that damages would exceed $50,000.00, so the requirement of substantiality was met. Fourth, Purdue pleaded sufficient material facts, namely, the contents of Form 10-K and Collegium's press release. Therefore, Prothonotary Aalto dismissed Collegium's motion to strike.

III. Should Collegium's appeal be allowed?

[14] I can allow Collegium's appeal only if Prothonotary Aalto's decision discloses an error of law, or a palpable and overriding error of fact.

[15] Purdue argues that Prothonotary Aalto committed no error of law in his decision. To the contrary, says Purdue, Prothonotary Aalto correctly concluded that Collegium's motion to strike was unsustainable in light of the prevailing jurisprudence.

[16] I disagree with Purdue. As I read the case law, Collegium's motion should have been granted, both in respect of the s 55.2 exemption, and the issue of *quia timet*.

[17] On the other hand, while Collegium maintains that Prothonotary Aalto made errors of law, errors of fact, and errors of mixed fact and law, I will confine myself to the two issues mentioned above – the s 55.2 exceptions, and *quia timet*.

A. *Subsection 55.2*

[18] Prothonotary Aalto derived from the cases on s 55.2 the proposition that, to nourish a motion to strike pleadings alleging infringement solely in respect of exempted activities, a party must tender evidence. I read the cases differently.

[19] In *Eli Lilly*, above, Justice Snider, relying on the *AstraZeneca* case, also cited by Prothonotary Aalto, found that the statement of claim before her did not plead anything beyond prosecution of an NDS. Therefore, the exemption in s 55.2, which provides that there is no infringement of a patent when making, constructing, using, or selling a patented product solely for regulatory purposes, applied. Justice Snider went on to note that there was evidence before her confirming that the defendant had done nothing beyond attempting to meet regulatory requirements. However, I do not read her reasons as requiring that kind of evidence; nor was it required in *AstraZeneca* on which she relied, or in the *Teva* case, above, in which Prothonotary Tabib followed Justice Snider's approach.

[20] Accordingly, I find that Prothonotary Aalto erred in reading the *Eli Lilly* case as turning on the presence of evidence supporting the defendant's position. Rather, a statement of claim will be deficient on its face if it merely alleges activity that falls within the statutory exemption in s 55.2.

[21] Here, the statement of claim alleges that Collegium imported the drug in issue for purposes of its NDS, filed its NDS in 2016, obtained the FDA's approval to market the drug in

the US, began marketing the drug in the US, expressed its intention in Form 10-K to market the drug in Canada, publicly disclosed that intention in a press release, and in 2017 invoked the *PMNOC Regulations* by serving Purdue with an NOA. I see nothing in these allegations that goes beyond Collegium's efforts to meet Canadian regulatory requirements.

B. *Quia Timet*

[22] Purdue maintains that Prothonotary Aalto set out the correct test and addressed each element of it.

[23] I agree. However, I find that Prothonotary Aalto erred in respect of the requirement for imminence.

[24] Prothonotary Aalto conceded that "there is some debate in the jurisprudence regarding whether or not an application for an NOC is 'imminent.'" He noted, though, that NOC proceedings must be heard and decided within two years, and that recent cases had found this necessity to be sufficient to meet the imminence requirement. He cited *Gilead*, above, and *Teva v Novartis*, above.

[25] In fact, in *Gilead*, Prothonotary Tabib found that the plaintiff's statement of claim was deficient because it lacked any allegations that the defendant's application for an NOC was approvable, or that the defendant would receive an NOC as soon as the patent expired or was found invalid. Accordingly, the plaintiff's allegation of infringement was speculative and "contingent upon whether and when Health Canada might approve the submissions for an NOC."

[26] Similarly, in *Teva v Novartis*, Prothonotary Tabib noted that Novartis had failed to allege that Teva had obtained an NOC, or that the drug had been approved and the NOC was simply on hold pending conclusion of the prohibition proceedings or the expiry of the patent. Since Teva's entry into the market was contingent on obtaining an NOC, any potential infringement was speculative, not imminent.

[27] In the latter case, Prothonotary Tabib relied on *Pfizer Research and Development Co NV/SA v Lilly ICOS LLC*, 2003 FCT 753, which held that seeking regulatory approval did not amount to a strong possibility of infringement since it was uncertain whether or when that approval might be granted (para 25).

[28] As I concluded above, nothing in Purdue's allegations goes beyond suggesting that Collegium was attempting to meet Canadian regulatory requirements, or suggests any time frame within which Collegium might succeed in obtaining an NOC. Since Purdue responded to Collegium's NOA with an application under the *Regulations*, Collegium is currently subject to a 24-month stay (until June 8, 2019). The patent does not expire until 2025. In these circumstances, it cannot be said that Collegium's receipt of an NOC is imminent. It may never happen. Therefore, there are no imminent potentially infringing activities.

IV. Conclusion and Disposition

[29] I find that Collegium's motion to strike should have been granted. I will therefore allow its appeal, with costs. Purdue's statement of claim is struck and its action is dismissed. Purdue's motion for consolidation is dismissed as moot.

ORDER IN T-856-17 AND T-824-17

THIS COURT ORDERS that:

1. The Order of Prothonotary Aalto dated November 14, 2017 is set aside;

2. The plaintiffs' statement of claim is struck and its action is dismissed;

3. The defendant is entitled to costs here and below.

4. The plaintiffs' motion for consolidation is dismissed as moot.

"James W. O'Reilly"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-856-17 AND T-824-17
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STYLE OF CAUSE:	PURDUE PHARMA AND EURO-CELTIQUE S.A. v COLLEGIUM PHARMACEUTICAL, INC.
AND DOCKET:	T-824-17
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PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	FEBRUARY 13-14, 2018
ORDER AND REASONS:	O'REILLY J.
DATED:	FEBRUARY 21,2018

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