Federal Court  Cour fédérale

Date: 20191010

Docket: T-1434-14

Citation: 2019 FC 1272

BETWEEN:

PHARMASCIENCE INC.

Plaintiff

and

PFIZER CANADA ULC

Defendant

ORDER AND REASONS

O'REILLY J.:

I. Overview

[1] Since 2004, the Defendant, Pfizer, has held a patent for pregabalin, a pain medication sold under the brand name LYRICA. The plaintiff, Pharmascience, received a Notice of Compliance [NOC] in 2013 allowing it to market a generic version of pregabalin, PMS-pregabalin. Pharmascience had originally attempted to enter the pregabalin market in 2011 but was prevented from doing so when Pfizer sought an order under the Regulations prohibiting the Minister of Health from issuing Pharmascience an NOC. Pfizer failed in its attempt to obtain that order. Pharmascience then began this action for damages against Pfizer for the sales it allegedly

lost during the period of time when it was kept off the market. Pharmascience relies on s 8(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/98-166, as amended SOR/93-133 (all provisions cited are set out in an Annex).

[2] Pfizer sought to amend its statement of defence in respect of Pharmascience's ability to supply the market with pregabalin. It argued that the question of whether Pharmascience could obtain sufficient quantities of the active pharmaceutical ingredient [API] and get its product into the Canadian generic market during the relevant time-frame had to be determined as part of Pharmascience's damages suit.

[3] It requested an order to that effect from Prothonotary Kevin Aalto, who denied it. Prothonotary Aalto concluded that the requested amendments amounted to an abuse of process because the question of whether there was a sufficient amount of API to supply the Canadian market had already been decided affirmatively by Justice Michael Phelan in *Teva Canada Limited v Pfizer Canada Inc*, 2017 FC 333.

[4] Pfizer appeals Prothonotary Aalto's decision on the basis that he committed a reviewable error by concluding that Pfizer's amendments were an abuse of process.

II. The Decision under Appeal

[5] The amendments Pfizer sought from Prothonotary Aalto did not raise a new issue – Pfizer had already questioned Pharmascience's capacity to supply the generic market in its statement of defence. Rather, the amendments raised more specific questions about Pharmascience's supply

agreement with respect to pregabalin API, a change in Pharmascience's specification for its pregabalin API, the proposed launch date for Pharmascience's product, and Pharmascience's manufacturing capacity.

[6] Prothonotary Aalto denied Pfizer's motion to amend its statement of defence to add those particulars. He sympathized with Pharmascience's arguments: that the API supplier in the *Teva* case could and would have provided sufficient API to supply the entire generic market, and that Pfizer, who was a party to the *Teva* case and failed to discharge its burden of proving Teva's inability to come to market, should not be given "another kick at the can."

[7] Prothonotary Aalto pointed out that re-litigating an issue that has already been finally and conclusively determined amounts to an abuse of process. Here, because he believed the same witnesses who gave evidence in the *Teva* case would testify in this action, he found that it was plain and obvious that Pfizer could not succeed in establishing Pharmascience's inability to supply the market. Further, he observed that since Pfizer would have already been aware, through the *Teva* action, of Pharmascience's supply agreement, Pfizer should not be allowed to re-litigate the ramifications of that agreement in this proceeding.

III. Did the Prothonotary Err?

[8] Prothonotary Aalto's decision disallowing the sought-after amendments is entitled to considerable deference, (*Hospira Healthcare Corporation v. Kennedy Institute of Rheumatology*, [2017] 1 FCR 331, 2016 FCA 215).

[9] Pharmascience says that Prothonotary Aalto correctly determined that the doctrines of issue estoppel and abuse of process applied to Pfizer's request.

[10] I disagree. The doctrines of issue estoppel and abuse of process are not applicable here. The amendments sought by Pfizer would not result in the re-litigation of a previously determined issue.

[11] In the *Teva* action, Teva bore the burden of proving its ability to come to market in a timely way and produced evidence and witnesses supporting its case. Pfizer bore the burden of proving that Teva would have encountered problems in launching its product. Justice Phelan found that Teva had proved that its supplier could deliver plenty of pregabalin API for the Canadian market and that Pfizer's arguments to the contrary were unpersuasive. Justice Phelan accepted the evidence emanating from Teva's personnel on this question, preferring it to the opinion of Pfizer's expert.

[12] In this proceeding, Pharmascience has the burden of proving its ability to come to market in a timely way and Pfizer has the onus of showing Pharmascience would have had difficulty doing so. Presumably, Pharmascience will present fact witnesses and, potentially, experts to prove its case. Pfizer will present witnesses of its own, including, possibly, some of the same persons who testified in the *Teva* case.

[13] As I see it, the conclusion Justice Phelan reached about Teva cannot be superimposed on this case. Pfizer's defence and proposed amendments relate to a factual issue that is particular to

this action. The finding made by Justice Phelan in the *Teva* action, which involved different parties and witnesses, cannot simply be imported into this proceeding.

[14] The Court will hear from Pharmascience's witnesses, not Teva's, on the issue of Pharmascience's sources of API and its ability to launch. It will also hear from Pfizer's witnesses on the potential difficulties Pharmascience, not Teva, might have encountered. The evidence in the two proceedings will inevitably be different. Pharmascience's but-for world likely differs in significant ways from Teva's. Accordingly, no abuse of process will result from litigation of Pfizer's allegations about supply.

[15] As Prothonotary Aalto did not expressly address the question of issue estoppel, I need say little about it. I would simply note that issue estoppel, a branch of the doctrine of *res judicata*, can only be raised where an issue was decided as between the same parties. The parties to the *Teva* case are obviously different than those before me, so issue estoppel does not apply.

IV. Conclusion and Disposition

[16] Prothonotary Aalto committed a reviewable error in concluding that Pfizer's proposed amendments would result in the litigation of issues already decided. I must, therefore, allow Pfizer's appeal, with costs, and permit it to amend its statement of defence accordingly.

ORDER IN T-1434-14

THIS COURT ORDERS that the appeal is allowed, with costs.

"James W. O'Reilly"
Judge

OTTAWA, ONTARIO
October 10, 2019

Annex

Patented Medicines (Notice of Compliance) Regulations, SOR/98-166, as amended SOR/93-133	*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133
Notice of Compliance	Avis de conformité
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 subsection (2).	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 pour la perte visée au paragraphe (2).

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Maracus Klee Jonathan Giraldi Jonathan Stainsby	FOR THE PLAINTIFF
Orestes Pasparakis Adam Haller David Yi	FOR THE DEFENDANT

SOLICITORS OF RECORD:

Aitken Klee Barristers and Solicitors Toronto, Ontario	FOR THE PLAINTIFF
Norton Rose Fulbright Canada LLP Toronto, Ontario	FOR THE DEFENDANT