Federal Court Cour fédérale

Date: 20181025

Docket: T-741-18

Citation: 2018 FC 1078

BETWEEN:

AMGEN INC. AND AMGEN CANADA INC.

Plaintiffs/Defendants by Counterclaim

and

PFIZER CANADA INC.

Defendant/ Plaintiff by Counterclaim

ORDER AND REASONS

[1] The within motion has been filed by Pfizer Canada Inc. (Pfizer) for an order under section 6.08 of the *Patented Medicines (Notice of Compliance Regulations) (Regulations)* dismissing this action on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process. Pfizer submits that the Plaintiff, Amgen Canada Inc. (Amgen) has improperly, repeatedly and unsuccessfully asserted the patent in issue in this action, Canadian Patent No.1,341,537 (the 537 Patent) under the *Regulations*.

[2] Amgen markets and sells the biologic drugs NEUPOGEN (filgrastim) and NEULASTA (pelfilgrastim) in Canada. Amgen has listed the 537 Patent on the Canadian Patent Register against both NEUPOGEN and NEULASTA and is the alleged owner of the 537 Patent. Pfizer has filed a new drug submission (NDS) with the Minister of Health seeking a Notice of Compliance (NOC) to market its biologic drug product NIVESTYM, a biosimilar of NEUPOGEN. As required by the *Regulations*, Pfizer served Amgen with its Notice of Allegations (NOA) on or about March 7, 2018. On April 20, 2018, Amgen commenced this action under section 6(1) of the *Regulations*.

[3] Pfizer relies on prior proceedings commenced by Amgen under the *Regulations* in support of the within motion and argues that Amgen has lost its right to further assert the 537 Patent under the *Regulations*. For the reasons set out below, Pfizer's motion is dismissed.

Prior Proceedings

Court File T-2072-12

[4] In this application, Amgen asserted the 537 Patent under the *Regulations* against Apotex Inc. (Apotex) where Apotex was seeking an NOC for GRASTOFIL, a biosimilar of NEUPOGEN. In its NOA, Apotex challenged the validity of the 537 Patent and Amgen commenced an application for an order prohibiting the Minister of Health from issuing an NOC to Apotex until after the 537 Patent expired. In his decision dated November 10, 2015, Hughes J. found that Apotex's allegations of invalidity of the 537 Patent on the grounds of obviousness

were justified. Pursuant to the *Regulations*, he dismissed Amgen's application and Apotex subsequently received its NOC for GRASTOFIL.

Court File T-1710-15

[5] Prior to Hughes J.'s November 10, 2015 decision in T-2072-12, Amgen asserted the 537 Patent under the *Regulations* in a second application. Apotex was seeking an NOC for GRASTOFIL in a different dosage strength. Amgen commenced its application under the *Regulations* on October 9, 2015 for an order prohibiting the Minister of Health from issuing an NOC for this GRASTOFIL product until after the 537 Patent expired. Amgen maintained the application after Hughes J.'s decision, and on August 23, 2016, Apotex brought a motion to dismiss the T-1710-15 application under section 6(5)(b) of the *Regulations*.

[6] At the hearing of that motion, Amgen conceded that the second GRASTOFIL application should be treated as the first (there would be no new argument or evidence than what was adduced in the first GRASTOFIL application), but argued that the application ought not to be dismissed because it was still in the process of seeking leave to appeal to the Supreme Court of Canada from the decision of the Federal Court of Appeal to dismiss the appeal from the Federal Court as moot.

[7] This argument was rejected and on October 4, 2016 the second GRASTOFIL application was dismissed as an abuse of process. Apotex obtained the NOC for the new dosage of GRASTOFIL and began to market the product in Canada.

[8] After Apotex entered into the Canadian market with its GRASTOFIL products, Amgen commenced an action under the *Patent Act* for infringement of the 537 Patent. That action, along with Apotex's counterclaim of invalidity and action for section 8 damages were discontinued, and GRASTOFIL remains on the market.

Court File T-145-17

[9] On January 30, 2017 Amgen commenced an application for an order prohibiting the Minister of Health from issuing an NOC to BGP Pharma ULC dba Mylan (Mylan) for FULPHILA, a biosimilar of NEULASTA until after the expiry of the 537 Patent. On February 28, 2017, Mylan advised Amgen that it intended to bring a motion to dismiss the application as an abuse of process pursuant to section 6(5)(b) of the Regulations. On March 13, 2017, Amgen discontinued the FULPHILA application. Mylan is not, however, currently on the market with this product.

Current Proceeding

Court File T-741-18

[10] As noted above, on March 7, 2018, Pfizer served Amgen with an NOA. The NOA includes the same allegations of obviousness that were successful before Hughes J. in the first GRASTOFIL application. On April 20, 2018 Amgen commenced the within proceeding pursuant to section 6(1) of the revised *Regulations* – it is an action rather than an application.

[11] In its Statement of Claim (which still follows delivery of an NOA), Amgen alleges that the making, constructing, using, selling offering for sale, importing or exporting of NIVESTYM in accordance with Pfizer's NDS would infringe at least one of Claims 1-3, 5-6, 13-15, 20-22, 25, 28, 32, 43-47 of the 537 Patent. In its Statement of Defence and Counterclaim, Pfizer has alleged, among other things, that the 537 Patent is invalid and void, including for the reasons set out by Hughes J. in his November 10, 2015 decision in the first GRASTOFIL application.

[12] On this motion, Pfizer thus seeks to have the action dismissed under section 6.08 of the *Regulations* as an abuse of process. The language of section 6.08 is identical to the wording of the old section 6(5)(b) and as such, Pfizer argues that the principles and jurisprudence established under section 6(5)(b) should govern the disposition of its motion – Hughes J. having found that the allegations of invalidity of the 537 Patent on the grounds of obviousness to be justified should, according to Pfizer, prevent Amgen from asserting the 537 Patent in other proceedings under the *Regulations*, be they applications or actions so as to also prevent Amgen from benefiting from the automatic 24 month stay under the *Regulations* that prevents competitors from obtaining NOCs and entering the market. Pfizer further submits that if Amgen wanted to preserve its right to assert the 537 Patent, it ought to have de-listed it from the Patent Register, allowed competitors to obtain their NOCs and enter the market and only then pursue an action for infringement under the *Patent Act*. Pfizer argues that by failing to prevent Amgen from pursuing the within action under the *Regulations*, the 537 Patent is "rehabilitated" and that there is thereby, a potential for inconsistent rulings under the *Regulations* that would threaten the credibility of the Court's adjudicative process.

Is the current proceeding an abuse of process?

Revised Regulations

[13] The current *Regulations* (revised *Regulations*) came into force on September 21, 2017, replacing summary prohibition applications with full actions to determine with finality, the substantive issues of patent infringement and invalidity. The Regulatory Impact Analysis Statement published in Canada Gazette, Part I, Vol. 151 No. 28 on July 15, 2017 (RIAS) confirmed that the revisions addressed the inadequacies of the old *Regulations*, among them that:

- placed constraints on procedure for obtaining and adducing evidence – parties were required to rely on a "paper record" without full discovery or *viva voce* witness testimony;

- denied effective rights of appeal due to the "mootness" problem once an NOC was issued; and

- required patent holders/assignees to commence subsequent actions to assert their patent rights – applications under the old *Regulations* did not determine patent infringement or invalidity, only whether an NOA's allegations in that regard were "justified".

[14] The language of section 6.08 of the revised *Regulations* is essentially the same as the predecessor provision, section 6(5)(b) under the old *Regulations*:

> An action brought under subsection 6(1) may, on the motion of a second person, be dismissed, in whole or in part, on the ground

> that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents or certificates of supplementary protection.

[15] As Aylen CMJ recently noted in *Gentech Inc. v. Amgen Canada Inc.*, 2018 FC 303:

> Section 6.08 is not a new provision introduced with the coming into force of the amended *Regulations* in September 2017. Rather, an earlier embodiment of section 6.08 was found in section 6(5)(b) of the previous version of the *Regulations* and the language of section 6(5)(b) was almost identical to the current language of section 6.08. Moreover, the language of section 6.08 tracks the language of Rule 221(1)(c) and (f) of the *Federal Courts Rules.*

[16] Pfizer relies on the first Apotex GRASTOFIL proceeding and argues that after the Court has found (as Hughes J. did) that an invalidity allegation for a patent is justified, it is an abuse of the Court's process to invoke the *Regulations* (and obtain the injunctive relief of up to 24 months that accompanies that invocation) in respect of that same patent. Pfizer argues that Amgen should suffer the same fate in the within proceeding as it did in the second Apotex GRASTOFIL application, which was dismissed under section 6(5)(b) of the *Regulations*. Pfizer submits that the within proceeding is the fourth commenced by Amgen under the *Regulations* and refers to the well settled jurisprudence under the *Regulations* that denies attempts by first persons at "second chances" – *Sanofi-Aventis Canada Inc. v. Novopharm*, 2007 FCA163; *Pfizer Canada Inc. v. Novopharm Ltd.*, 2008 FCA 263; *Gilead Sciences Inc. v. Apotex Inc*. 2015 FC 610.

[17] The problem for Pfizer on the within motion, however, is that Hughes J.'s findings in the first Apotex GRASTOFIL application cannot simply be grafted on to the within action. Regard must be had to the operation of the entire NOC regime under the old and revised *Regulations* and

what exactly was in issue and decided by Hughes J. under the old regime and to what extent it applies, if at all, to the current action.

[18] Hughes J. decided that under the *Regulations* as they were then in force, Apotex's allegations of invalidity of the 537 Patent on the grounds of obviousness were justified. On that basis Amgen's application seeking an order prohibiting the Minister of Health from issuing a NOC to Apotex for GRASTOFIL is the dosage strength indicated in its NDS was dismissed. Apotex obtained the NOC and entered the market where it was open to Amgen to commence a patent infringement action in respect of the 537 Patent and it was open to Apotex to assert its invalidity.

[19] Applications under the old *Regulations* determined only whether a second person's allegations were "justified" and whether the Minister of Health would be prohibited from issuing an NOC. The issue of a patent's validity and/or infringement "were not conclusively determined" (*Apotex v. Pfizer Canada Inc.*, 2011 FCA 77; and *RIAS*).

[20] Further, as noted by Amgen, once the Minister of Health issued the NOC, patent considerations were regarded as irrelevant and any appeal from an application that was dismissed were rendered moot (*Janssen v. Teva Canada Limited*, 2015 FCA 36; *Abbott Laboratories v. Apotex*, 2007 FCA 368; *Eli Lilly v. Novopharm*, 2007 FCA 359). In those circumstances, unsuccessful applicants could be precluded from bringing subsequent applications for a prohibition order under the old *Regulations* – but their recourse, and the determination of patent validity and infringement could be subject to further and full adjudication through an action

and/or counterclaim. As noted by the Federal Court of Appeal in *Sanofi-Aventis Canada v. Novopharm Ltd.*, 2007 FCA 163 at para. 36, decisions rendered in applications under the (old) *Regulations* "are not binding on actions for patent infringement or to declare a patent invalid".

[21] As there has been no final disposition of any such action or counterclaim in the case of the 537 Patent or case for its impeachment, at all times and to this day, the 537 Patent is a valid and subsisting patent.

[22] What Hughes J. did not and could not determine under the old *Regulations* is what is in issue in the within action under the new *Regulations* – whether the 537 Patent is valid and if valid, whether Pfizer's NIVESTYM product infringes any of the asserted claims. If found in Pfizer's favour, Pfizer will obtain the NOC for NIVESTYM from the Minister of Health and may enter the market where it will not be vulnerable to any further action by Amgen, either because the 537 Patent will have been found to be invalid, or because NIVESTYM will have been found not to infringe. These are final determinations, subject only to a full right of appeal.

[23] Thus the revised *Regulations* not only instituted the more fulsome adjudicative process of an action with its procedural safeguards of examinations for discovery and *viva voce* evidence, the issues to be decided are different as between the revised and old *Regulations* – substantive patent validity and infringement is now determined, not simply whether allegations are justified. Amgen is not pursuing a "second chance". The within action is effectively its first and only chance.

[24] Under the revised *Regulations*, Amgen will be prohibited from commencing any further action against Pfizer for infringement of the 537 Patent. The revised *Regulations* state that a first person/patentee who has listed its patent on the patent register and who receives an NOA from a second person but does not commence an action under the *Regulations* is precluded from bringing any subsequent action for infringement against the second person, unless the first person/patentee "did not have a reasonable basis for bringing an action" (RIAS para. 3322). Thus the within action is Amgen's only course of action.

[25] Pfizer argues nonetheless that the within action should be summarily dismissed under section 6.08 of the revised *Regulations* because of the section 6(1) decision in T-2072-12 under the old *Regulations* and the section 6(5)(b) decision in T-1710-15 under the old *Regulations*. Pfizer also argues that in the event its motion is granted, because the 537 Patent is listed on the Patent Register, Amgen cannot bring an action for patent infringement under the *Patent Act*. Amgen is thereby forever precluded from asserting infringement of its valid and subsisting patent.

[26] Pfizer states that to have avoided these consequences, Amgen ought to have promptly de-listed the 537 Patent before receiving (without knowing when) any further NOAs from any second person. This is an absurd result, never intended by the new *Regulations*. Amgen's vested patent rights remain its patent rights and its patent claims are presumed valid as a matter of law until proven otherwise.

[27] The revised *Regulations* changed the procedure and the issues to be determined under the *Regulations,* removing what was the potential dual track of determining whether allegations of non-infringement and invalidity were justified in an application for the purposes of the issuance of an NOC, followed by an action to finally determine the issue(s) of infringement and validity. The revised *Regulations* were intended to grant the parties the right to have patent issues litigated and adjudicated on a full record with an effective right of appeal in one proceeding. Parliament left the decision to the first person to choose listing on the patent register and litigate the patent issues within the 24 months provided by the revised *Regulations* or de-list and allow potential competitors to obtain an NOC without delivery of an NOA, and litigate the patent issues under the *Patent Act* after a competitor has entered into the market.

[28] Accordingly, I am not satisfied beyond doubt that it is plain and obvious that the within action is scandalous, frivolous, vexatious or is otherwise an abuse of the Court's process. It is neither relitigation nor redundant. Actions commenced under the revised *Regulations* determine different issues than in applications commenced under the old *Regulations*. This is not to say, however, that some decisions made under section 6(5)(b) of the old *Regulations* could not have some application in motions brought pursuant to section 6.08 of the revised *Regulations*, but the present motion is not such as a case. The fact that Amgen was (i) unsuccessful in persuading Hughes J. in T-2072-12 that Apotex's allegations of invalidity on the grounds of obviousness were unjustified; and (ii) had its application dismissed in T-1710-15 under section 6(5)(b) of the old *Regulations* do not preclude it from asserting the 537 Patent against Pfizer in the within action under the new *Regulations,* where infringement and invalidity will be substantively determined.

[29] This motion must be dismissed, and while one of the first of such motions to be brought under section 6.08 of the revised *Regulations*, I am satisfied that, for the reasons above, costs should be payable to Amgen, in any event of the cause.

ORDER IN T-741-18

THIS COURT ORDERS that:

1. The motion be and is hereby dismissed, with costs to the Plaintiffs in any event of the cause.

2. In the event the parties cannot agree on the quantum of costs to be paid, they may file written submissions no longer than 2 pages in length within 15 days of the date of this order.

"Martha Milczynski"

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-741-18
STYLE OF CAUSE:	AMGEN INC. AND AMGEN CANADA INC. v PFIZER CANADA INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATES OF HEARING:	SEPTEMBER 28, 2018
ORDER AND REASONS:	MILCZYNSKI, P.
DATED:	OCTOBER 25, 2018

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