Federal Court of Appeal | Cour d'appel fédérale

**Date: 20160715**

**Docket: A-501-15**

**Citation: 2016 FCA 196**

**CORAM:** **NOËL C.J.**
**STRATAS J.A.**
**RENNIE J.A.**

**BETWEEN:**

**AMGEN CANADA INC.**
**and AMGEN INC.**

**Appellants**

**and**

**APOTEX INC.**
**and THE MINISTER OF HEALTH**

**Respondents**

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on July 15, 2016.

REASONS FOR ORDER BY: STRATAS J.A.

CONCURRED IN BY: NOËL C.J.
RENNIE J.A.

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## REASONS FOR ORDER

**STRATAS J.A.**

[1] Apotex moves for an order dismissing this appeal because it has become moot. For the following reasons, I would grant the motion and dismiss this appeal with costs.

## A. Basic facts

[2] In the Federal Court, Amgen applied for an order under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 prohibiting the Minister of Health from issuing a notice of compliance to Apotex for its Grastofil pharmaceutical product. The Federal Court (*per* Hughes J.) dismissed Amgen's application: 2015 FC 1261. Amgen appeals.

[3] In its motion, Apotex says this appeal is now moot. After the Federal Court's judgment, the Minister—not subject to prohibition and free to act—issued a notice of compliance to Apotex for its product. Apotex says that the subject-matter of the appeal—whether the Federal Court should have prohibited the Minister from issuing the notice of compliance—is moot. There is no longer anything to prohibit. Thus, this Court should not hear the appeal and, instead, should dismiss it.

[4] Amgen opposes the motion. In its first written representation on the motion, Amgen pointed out that the notice of compliance the Minister issued concerned one dosage strength of pharmaceutical product but not another. It submitted that whether a notice of compliance should be granted for that other dosage strength was still live.

[5] Apotex was granted the opportunity to file an affidavit in reply to address that point: *Amgen Canada Inc. v. Apotex Inc.*, 2016 FCA 121. Cross-examinations took place on that affidavit. In later written representations, the parties advise that there were disputes during the cross-examinations. Although the Court made it clear in advance that it would be willing to

resolve such disputes, no party asked the Court to do so. In a later written representation, counsel for Amgen suggested that if the Court "forms the view that Amgen should bring a motion on refusals to sort out the underlying facts, Amgen is, of course, willing to do so." But this Court does not read materials and advise parties about whether they should bring a motion. The evidentiary record on this motion is as it stands now.

[6] Based on that evidentiary record, I find that the other dosage strength raised by Amgen is not before the Minister. The Minister could not be the subject of a prohibition application concerning that product. Thus, it is not within the ambit of this appeal. This appeal concerns only the dosage strength of Grastofil for which the Minister has issued a notice of compliance.

**B. Should this matter be determined now or be left for the panel hearing the appeal?**

[7] This motion has been brought as an interlocutory matter before the hearing of the appeal. But just because it has been brought now does not mean it must be decided now. This motion could be adjourned and left for the panel hearing the appeal.

[8] When to determine a motion is a matter of discretion: *Association of Universities and Colleges of Canada v. Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22, 428 N.R. 297 at paragraph 11. The discretion is guided by Rule 3 of the *Federal Courts Rules*, SOR/98-106: the need to "secure the just, most expeditious and least expensive determination of every proceeding on its merits." In applications for judicial reviews, the commandment in

subsection 18.4(1) of the *Federal Courts Act*, R.S.C. 1985, c. F-7—that they be "heard and determined without delay and in a summary way"—may also bear upon the discretion.

[9] This Court usually determines motions on the basis of written material filed by the parties: Rule 369. However, where there are certain ambiguities or complexities or where otherwise appropriate, this Court can request oral submissions. In these circumstances, judicial economy may favour leaving the motion to the appeal panel, unless for some reason time is of the essence or other considerations favour immediate determination.

[10] Where the motion is clear-cut or obvious, it might as well be decided right away. Efficiency and judicial economy support this: *Collins v. Canada*, 2014 FCA 240, 466 N.R. 127 at paragraph 6; *Canadian Tire Corp. Ltd. v. P.S. Partsource Inc.*, 2001 FCA 8, 267 N.R. 135. However, if reasonable minds might differ on the outcome of the motion, the ruling should be left to the panel hearing the appeal: *McKesson Canada Corporation v. Canada*, 2014 FCA 290, 466 N.R. 185 at paragraph 9; *Gitxaala Nation v. Canada*, 2015 FCA 27 at paragraph 7. Sometimes the novelty, quality or incompleteness of the submissions may make it sensible to leave the motion for the appeal panel to determine: *Gitxaala Nation*, above at paragraphs 9-12.

[11] Here, I am of the view that the motion should now be determined. As will be seen, the result of the motion is clear-cut and obvious: the facts and the law impel me to a firm conclusion. All of the parties to this motion submit that it can and should be decided now and have offered complete submissions. Further, this Court has determined interlocutory mootness motions similar to this before the appeal hearing: see, *e.g.*, *Janssen Inc. v. Teva Canada Limited*, 2015 FCA 36.

Finally, deciding this motion now—rather than at a hearing some months away—advances judicial economy.

**C. Is this appeal moot?**

[12] This appeal is moot. The facts above show that there is no longer a live controversy. An order prohibiting the Minister from issuing the notice of compliance would serve no purpose. She has already issued the notice of compliance.

[13] There are many cases to this effect. A good example is *Apotex Inc. v. Bayer AG*, 2004 FCA 242, 325 N.R. 289. In that case, Apotex appealed to this Court from a decision by the Federal Court not to prohibit the Minister from issuing a notice of compliance. Before the appeal was heard, the Minister issued a notice of compliance. This Court held that the appeal became moot. The live controversy—whether the Minister should be stopped from issuing a notice of compliance—had disappeared. This is the situation here.

[14] In *Janssen*, above, this Court put it this way (at paragraph 7):

> Asking a court to prohibit a notice of compliance after it has issued is like asking someone to close the barn door after the horses have escaped. A long and unquestioned line of authority from this Court "establishes that an appeal from an order dismissing an application for a prohibition order under the [Regulations] becomes moot when the notice of compliance is issued": *Biovail Corporation v. Canada*, 2006 FCA 92, 348 N.R. 117 at paragraph 5. This is because "once the notice of compliance is issued…it is no longer possible for the Court to prohibit the Minister from issuing the notice of compliance": *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2011 FCA 16, 88 C.P.R. (4th) 379 at paragraph 1.

**D. Should the Court exercise its discretion to hear this moot appeal?**

[15] Although there is no longer a live matter before the Court, the Court may nevertheless exercise its discretion to hear and decide it: *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342 at pages 358-62.

[16] To guide that discretion, the Supreme Court in *Borowski* offered three considerations:

1. *The absence of adversarial parties.* If there are no longer parties on opposing sides that are keen to advocate their positions, the Court will be less willing to hear the matter.

2. *Lack of practicality; wasteful use of resources.* If a proceeding will not have any practical effect upon the rights of the parties, it has lost its primary purpose. The parties and the Court should no longer devote scarce resources to it. Here, the concern is judicial economy. However, in exceptionally rare cases, the need to settle uncertain jurisprudence can assume such great practical importance that a court may nevertheless exercise its discretion to hear a moot appeal: *M. v. H.*, [1999] 2 S.C.R. 3, 171 D.L.R. (4th) 577 at paragraphs 43-44.

3. *The court exceeding its proper role.* In some cases, pronouncing law in a moot appeal in the absence of a real dispute is tantamount to making law in the abstract, a task reserved for the legislative branch of government not the judicial branch.

[17] Amgen says that these considerations should cause this Court to exercise its discretion in favour of hearing the appeal. It says that if it succeeds in the appeal, it will not be exposed to damages under section 8 of the Regulations.

[18] On this, Amgen is correct. Under subsection 8(1) of the Regulations, a damages claim arises only if, among other things, the prohibition application under the Regulations is "dismissed." In this case, the Federal Court dismissed Amgen's prohibition application, triggering Apotex's right to bring a section 8 claim. If, however, in this appeal this Court were to rule that the Federal Court should have granted the prohibition application, Apotex's right to bring a section 8 claim would disappear. So, according to Amgen, a decision on this appeal will determine whether Apotex can bring a section 8 claim.

[19] Amgen also points to a new development it disclosed in a last-minute affidavit, received by the Court without objection from Apotex. The new development is that Apotex has issued a statement of claim in the Federal Court seeking section 8 damages. The section 8 claim is now not just a possibility but a reality. Amgen says this development underscores the real, practical effect this appeal will have on the parties' rights.

[20] This Court has held that the mere possibility of a section 8 claim is not enough to keep an appeal such as this alive. A mere possibility affects rights only in a "remote" or "speculative" sense. See, e.g., *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2006 FCA 328, 53 C.P.R. (4th) 447 at paragraph 18. But here, a live section 8 claim is now on the table. If Amgen succeeds in this

appeal—*i.e.*, this Court rules that the Federal Court should have granted the prohibition application—Apotex's section 8 claim in the Federal Court will immediately end.

[21] Apotex does not take any serious issue with this analysis. Rather, it notes that Amgen, as a patentee, "retains its right to commence an infringement action and to defend [the] section 8 [claim] with its patent." Thus, Apotex submits that the dismissal of this appeal will not affect Amgen's rights in any practical sense. Hearing this appeal would only squander the resources of the Court and the parties. Therefore, Apotex urges us to not to hear this moot appeal.

[22] My discretion must be guided by both the *Borowski* considerations and the previous authorities of this Court that follow *Borowski* and bear substantial similarity to the facts here. Absent demonstration of manifest error in these authorities or a principled basis upon which they can be distinguished—and no demonstration has been seriously attempted here—I must follow them: *Miller v. Canada (Attorney General)*, 2002 FCA 370, 220 D.L.R. (4th) 149. These authorities all say—on facts virtually identical to these—that in a matter arising under the Regulations, this Court should not entertain an appeal from a denial of prohibition where the patentee can bring an action for patent infringement and can assert its patent against the section 8 claim: see, *e.g.*, *Pfizer Canada Inc. v. Apotex Inc.* (2001), 11 C.P.R. (4th) 245 at page 253 (F.C.A.); *Apotex Inc. v. Bayer AG*, above; *Sanofi-Aventis*, above at paragraph 17; *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2011 FCA 16, 88 C.P.R. (4th) 379. According to all these authorities and even others, the pending appeal loses its practical utility in circumstances such as these and, if it is heard, would serve only to waste the resources of the Court and the parties. Judicial economy will not be served.

[23] The fact that a section 8 claim is on the table is not a principled basis for distinguishing these authorities. That fact answers only the objection that rights are affected only in a "remote" or "speculative" sense and, thus, not in a real and practical way. It does not answer the objection that the patentee can raise patent infringement and so the appeal has no real or practical effect on the parties' rights. Overall, it does not answer the objection that hearing and determining this appeal would be inconsistent with judicial economy.

[24] The *Borowski* considerations and the authorities of this Court applying these considerations to facts substantially similar to those here are front of mind in determining this motion. They prompt me to exercise my discretion against the continuance of this appeal. Looking at the particular facts of this case and assessing how they will likely play out, I am not persuaded that the continuance of this appeal will further judicial economy. Quite the opposite.

**E. Proposed disposition**

[25] For the foregoing reasons, I would grant Apotex's motion and dismiss this appeal with costs.

"David Stratas"
J.A.

"I agree
Marc Noël C.J."

"I agree
Donald J. Rennie J.A."

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

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|---|---|
| **DOCKET:** | A-501-15 |
| **STYLE OF CAUSE:** | AMGEN CANADA INC. AND AMGEN INC. v. APOTEX INC. AND THE MINISTER OF HEALTH |

**MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES**

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| **REASONS FOR ORDER BY:** | STRATAS J.A. |
| **CONCURRED IN BY:** | NOËL C.J.<br>RENNIE J.A. |
| **DATED:** | JULY 15, 2016 |

**WRITTEN REPRESENTATIONS BY:**

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