Federal Court of Appeal | Cour d'appel fédérale

Date: 20221101

Docket: A-267-20

Citation: 2022 FCA 185

CORAM: **LOCKE J.A.**
MACTAVISH J.A.
MONAGHAN J.A.

BETWEEN:

JANSSEN INC., JANSSEN ONCOLOGY, INC. and BTG INTERNATIONAL LTD.

Appellants

and

APOTEX INC.

Respondent

Heard at Ottawa, Ontario, on September 14, 2022.

Judgment delivered at Ottawa, Ontario, on November 1, 2022.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: MACTAVISH J.A.
MONAGHAN J.A.

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REASONS FOR JUDGMENT

LOCKE J.A.

[1] This appeal concerns a pair of Orders made by the Federal Court (*per* Justice Michael L. Phelan) shortly before trial in proceedings under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the Regulations). In the first Order, dated October 16, 2020 and cited as 2020 FC 974, the Federal Court granted a motion by the respondent, Apotex

Inc. (Apotex), for an extension of time to file an addendum to the report of its expert Dr. Robert Nam (the Addendum). In the second Order, dated October 23, 2020 and bearing no citation, the Federal Court allowed an amendment to Apotex's counterclaim (the Amendment). Both the Addendum and the Amendment concerned new allegations by Apotex that claims of the patent in suit (Canadian Patent No. 2,661,422 (the 422 Patent)) that had not been asserted against Apotex were invalid for obviousness.

[2] It should be noted that the trial proceeded following the Addendum and the Amendment, and the Federal Court ultimately found, in a separate decision (2021 FC 7), that all of the claims of the 422 Patent were invalid for obviousness. That decision is the object of separate appeals, which are addressed separately (2022 FCA 184).

I. Preliminary Issue

[3] A preliminary issue concerns section 6.11 of the Regulations, which requires that leave of this Court be sought to appeal an "interlocutory order made in an action brought under subsection 6(1) or a counterclaim brought under subsection 6(3)," and that such leave be sought no later than 10 days after the order under appeal. There is no doubt that the Orders under appeal here are interlocutory, and that no leave was sought. The parties' memoranda of fact and law are also silent on the issue of leave. It seems that the parties simply neglected to address the question of leave.

[4] I issued a Direction on October 30, 2020, shortly after the notice of appeal was submitted. It permitted the issuance of the notice of appeal despite it taking issue with two Orders of the Federal Court in a single notice of appeal. The parties may have interpreted that Direction as a grant of leave under section 6.11. It was not. Leave is to be granted by the Court, whereas a Direction is issued by a single judge. Subsection 16(1) of the *Federal Courts Act*, R.S.C. 1985, c. F-7, requires that "every application for leave to appeal to the Federal Court of Appeal … be heard in that court before not fewer than three judges sitting together."

[5] In the absence of a formal and timely request for leave, I would deny leave and refuse to rule on the appeal. However, having heard the parties and considered the issues, I will explain my conclusion that, even if leave to appeal were granted, I would dismiss the appeal on its merits.

II. Federal Court's Decisions under Appeal

[6] In the first Order under appeal, the Federal Court correctly noted the test for granting an extension of time as set out in *Canada (Attorney General) v. Hennelly* (1999), 244 N.R. 399, 89 A.C.W.S. (3d) 376 (F.C.A.) (*Hennelly*). The underlying consideration is that justice must be done between the parties. The following factors should be considered: (i) whether there is a continuing intention to pursue the issue, (ii) whether there is merit to the issue, (iii) whether any prejudice arises from the delay, and (iv) whether there is a reasonable explanation for the delay. The Federal Court found that most of the factors readily favoured allowing the Addendum, and only the factor of merit required a more detailed discussion.

[7] The Federal Court acknowledged that the counterclaim in place at the time did not clearly allege that the claims of the 422 Patent that were not asserted against Apotex were obvious. However, the Federal Court found that facts pleaded by Apotex showed an intention to address the non-asserted claims. The Federal Court also found that the service of the Addendum on the appellants several months before had given them notice of this intention. The Federal Court concluded that it was in the interests of justice to accept the Addendum to ensure that the Court had a complete and proper record on which to render its decision. It also suggested, without ordering, that the counterclaim might be amended to clarify the issues in dispute. Further, the Federal Court granted leave under Rule 279(a) of the *Federal Courts Rules*, S.O.R./98-106, to the extent necessary, to allow the filing of expert evidence on an issue not defined in the pleadings.

[8] The Federal Court also addressed the appellants' argument that paragraph 6(3)(a) of the Regulations prohibited a counterclaim alleging invalidity of the non-asserted claims because it was advanced in the context of an action under subsection 6(1) thereof. The Court noted that the argument was akin to a motion to strike a pleading, and should have been raised months before. It concluded that it was not appropriate to use a motion to extend a deadline for this purpose, and granted the extension of time without prejudice to the appellants raising the issue again at trial.

[9] The second Order under appeal followed the respondent's submission of the Amendment in draft form to the Court, with a request for directions with regard thereto. After receiving submissions from the appellant objecting to the Amendment, the Federal Court simply allowed the Amendment without providing reasons.

III. Analysis

A. *The first Order: extension of time*

[10] The only factor relevant to the grant of a deadline extension with which the appellants take issue is whether the Addendum had merit. Firstly, the appellants argue that the counterclaim as it existed prior to the first Order did not allege obviousness of the non-asserted claims, and that it is improper to consider the Addendum in the context of the Amendment because it represents a moving target. The appellants note that Apotex's defence and counterclaim prior to the Amendment alleged invalidity of the 422 Patent as a whole on grounds of insufficient disclosure and improper subject matter. However, for other grounds of invalidity, including obviousness, specific claims were mentioned, and these were limited to the asserted claims. Secondly, the appellants argue that paragraph 6(3)(a) of the Regulations excludes counterclaims alleging invalidity of non-asserted claims in the context of an action under subsection 6(1) thereof.

[11] In my view, neither of these arguments is sufficient to set aside the first Order. I see no reviewable error in the way the Federal Court considered the motion to extend the deadline for filing expert evidence, even if the Addendum was not properly supported by the counterclaim until after the Amendment. The Federal Court applied the proper legal test (*per Hennelly*), and focused on ensuring that the issues to be addressed at trial were properly indicated. I am not persuaded that the Addendum lacks merit. Moreover, any weakness in the merits of the argument that the Federal Court could determine the validity of non-asserted claims in the context of an

action under subsection 6(1) is merely one consideration, and would not necessarily operate as a trump to deny the requested extension of time.

[12] As regards the impact of paragraph 6(3)(a) of the Regulations, this is addressed in some detail in the separate decision on the appeals from the decision rendered by the Federal Court following trial. For the purposes of this decision, it is necessary only to say that an analysis of paragraph 6(3)(a) does not clearly support the appellants' interpretation. In my view, the text of paragraph 6(3)(a) is open to different interpretations, and the parties have cited no jurisprudence interpreting it. Further, it was not the Federal Court's task to reach a conclusion on the interpretation of paragraph 6(3)(a) in the context of a motion to extend a deadline. In light of the lack of relevant jurisprudence, the Federal Court was entitled to grant the extension of time to introduce the Addendum, and permit the parties to argue the point at trial. I see no reviewable error in its decision to do so.

B. *The second Order: amendment of counterclaim*

[13] I also see no error in the Federal Court's Order permitting the Amendment. Though the Federal Court expressed no new reasons in granting the second Order, it is clear from the first Order that it favoured the Amendment to ensure that the issues addressed in the Addendum were properly put before the Court.

[14] As mentioned above in respect of the first Order, the appellants argue that the Amendment should not have been allowed because paragraph 6(3)(a) of the Regulations forbids counterclaims in proceedings under section 6 thereof that put in issue the validity of non-asserted

claims. I have already concluded that paragraph 6(3)(a) is open to different interpretations. The appellants acknowledge that amendments to pleadings that are not doomed to fail are generally allowed to determine the real issues in dispute provided that doing so does not create an injustice. I see no injustice. I disagree with the appellants that it is plain and obvious that the Amendment discloses no reasonable cause of action. The Federal Court was entitled to allow the Amendment.

[15] The appellants also argue that the Federal Court erred by considering Apotex's request to amend the counterclaim in the absence of a formal motion as contemplated by the Federal Court's Notice to the Parties and the Profession regarding Informal Requests for Interlocutory Relief, dated August 27, 2017, an argument it also advanced before the Federal Court. However, I see no indication that the Notice was intended to override the discretion of a judge to manage a case as it proceeds to trial. I also see no unfairness in the fact that the whole process of receiving Apotex's proposed Amendment, seeking the appellants' submissions on the point, and issuing the Order, all took place on one day. The issue was straightforward, and had already been foreseen in the context of the Order permitting the Addendum.

IV. Conclusion

[16] I would dismiss the present appeal with costs.

"George R. Locke"
J.A.

"I agree
Anne L. Mactavish J.A."

"I agree
K. A. Siobhan Monaghan J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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