Federal Court of Appeal | Cour d'appel fédérale

Date: 20110622

Docket: A-397-10

Citation: 2011 FCA 209

CORAM: **SHARLOW J.A.**
TRUDEL J.A.
STRATAS J.A.

BETWEEN:

EPICEPT CORPORATION

Appellant

and

CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES

Intervener

and

THE MINISTER OF HEALTH

Respondent

and

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Intervener

Heard at Toronto, Ontario, on June 22, 2011.

Order delivered at Toronto, Ontario, on June 22, 2011.

REASONS FOR ORDER BY: STRATAS J.A.

Federal Court of Appeal | Cour d'appel fédérale

Date: 20110622

Docket: A-397-10

Citation: 2011 FCA 209

CORAM: **SHARLOW J.A.**
TRUDEL J.A.
STRATAS J.A.

BETWEEN:

EPICEPT CORPORATION

Appellant

and

CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES

Intervener

and

THE MINISTER OF HEALTH

Respondent

and

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Intervener

REASONS FOR ORDER

STRATAS J.A.

[1] In this appeal, the intervener, Canadian Generic Pharmaceutical Association (CGPA), moves, among other things, for an order dismissing this appeal for mootness. If the CGPA succeeds

in convincing us that the appeal is moot and should not be heard, the appellant asks us to stay the appeal rather than dismiss it.

[2] The facts giving rise to the mootness issue before us are as follows.

[3] The appellant filed a new drug submission with the respondent Minister concerning a drug known as Ceplene. In its submission, the appellant requested the Minister to grant Ceplene "innovative drug status" prohibiting the Minister from granting approval for any generic equivalent drug for at least eight years from the date of issuance of a notice of compliance to Ceplene under section C.08.004.1 of the *Food and Drug Regulations*, C.R.C., c. 870, as amended by S.O.R./2006-241.

[4] Based on her interpretation of section C.08.004.1 of the Regulations, the Minister decided that Ceplene was not an "innovative drug" because its active ingredient, histamine dihydrochloride, had been previously approved by the Minister in other drugs.

[5] The appellant challenged the Minister's decision in an application for judicial review. The Federal Court dismissed the application, agreeing with the Minister's interpretation of section C.08.004.1 of the Regulations: 2010 FC 956. The appellant now appeals to this Court.

[6] In November 2010, while this appeal was pending, the appellant withdrew its new drug submission for approval of Ceplene.

[7] Originally, this appeal mattered because the appellant believed it was entitled to and needed protection for the data contained in the new drug submission before the Minister. Now that it has withdrawn the new drug submission, that protection is no longer needed. There is no new drug submission for Ceplene before the Minister, and nothing left for the Minister to decide, whatever this Court decides. With no practical consequences left in this appeal, we are really being asked to provide a legal opinion on this issue of interpretation, and nothing else.

[8] In our view, for the foregoing reasons, this appeal is moot. However, we can hear a moot appeal: *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342.

[9] In its written submissions, the appellant says that it intends to re-file its new drug submission for Ceplene and it says that it will apply for data protection at that time. Therefore, says the appellant, the issue in this appeal will arise again so we might as well hear the appeal now.

[10] However, the evidence shows that there is uncertainty regarding whether the appellant will ever re-file its new-drug submission. Indeed, if this Court hears this appeal and dismisses it, the appellant says that it will not re-file its new drug submission. Further, on cross-examination on this motion, the appellant's Chief Executive Officer admitted that financing problems, the results of a new study being conducted, or both might cause the appellant not to re-file. These considerations underscore our concern that we are really being asked to provide a legal opinion that, in the end, will not be of any practical use.

[11] Even if the appellant does re-file, the re-filing will not take place for many years, in part due to the new study, mentioned above. The appellant is conducting this study to support a new drug application filed with the United States Food and Drug Administration. After the years to complete this study, the provisions of the Regulations may no longer be the same. Further, the new drug submission will contain different studies and different data and the Minister might have additional reasons for refusing data protection under the Regulations. Any future decision made by the Minister, if challenged on judicial review, should be considered by the Federal Court on the specific bases relied upon by the Minister, and then, if necessary, appealed to this Court.

[12] In the meantime, there may be other parties in the Federal Court and this Court seeking protection for the data in their new drug submissions and they may well raise in this Court the issue of interpretation that we have in this appeal. If we were to hear and decide the issues in this appeal today in this hypothetical context, we might well affect or even bind parties not before this Court today who will wish to argue those issues in a concrete context.

[13] In these circumstances, for the foregoing reasons, we would exercise our discretion against hearing and deciding this moot appeal.

[14] The appellant asks us to "stay" this appeal until it re-files its new drug submission with the Minister. The parties founded their submissions upon the classic three part test for a court staying other bodies' proceedings pending an appeal or other matter, or for an injunction: *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1995] 3 S.C.R. 199. This is not what is being sought here. In

reality, the appellant is seeking a long-term adjournment of this appeal. Whether or not such an adjournment is to be granted is a matter of discretion, taking all of the circumstances into account.

[15] Many of the facts, canvassed above, concerning whether we should hear the moot appeal are relevant to our discretion whether to adjourn this appeal.

[16] The appellant is concerned that if this appeal is dismissed, rather than "stayed," this Court might be taken to have affirmed the order made by the Federal Court. That is not the case. This Court's dismissal of the appeal for mootness is not a decision on whether the appellant is entitled to data protection.

[17] On the facts of this case, we would not grant the appellant's request to adjourn this appeal. The potential length of the adjournment, possibly for several years, and the overall uncertainty regarding whether the appellant will ever re-file a new drug submission weigh heavily in our exercise of discretion.

[18] Accordingly, we will grant the CGPA's motion to dismiss the appeal for mootness, with costs of the motion payable by the appellant to the CGPA. We will also dismiss the appellant's cross-motion for a stay or adjournment, with costs. The respondent Minister shall have her costs of the appeal, payable by the appellant.

"David Stratas"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-397-10
(APPEAL FROM THE ORDER OF THE HONOURABLE MR. JUSTICE NEAR DATED SEPTEMBER 24, 2010, DOCKET NO. T-2009-09)	
STYLE OF CAUSE:	EPICEPT CORPORATION v CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES AND THE MINISTER OF HEALTH AND CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	June 22, 2011
REASONS FOR ORDER BY:	(SHARLOW, TRUDEL & STRATAS JJ.A.)
DELIVERED FROM THE BENCH BY:	STRATAS J.A.

APPEARANCES:

Jason C. Markwell Kristin E. Wall	FOR THE APPELLANT
Christopher C. Van Barr	FOR THE INTERVENER, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES
F.B. (Rick) Woyiwada	FOR THE RESPONDENT
Edward Hore Geoffrey Langen	FOR THE INTERVENER, CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

SOLICITORS OF RECORD:

Ogilvy Renault LLP Toronto, Ontario	FOR THE APPELLANT
Gowling Lafleur Henderson LLP Ottawa, Ontario	FOR THE INTERVENER, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES
Myles J. Kirvan Deputy Attorney General of Canada	FOR THE RESPONDENT
Hazard and Hore Barristers and Solicitors Toronto, Ontario	FOR THE INTERVENER, CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION