Date: 20080320

Docket: T-116-07

Citation: 2008 FC 355

Ottawa, Ontario, March 20, 2008

PRESENT: The Honourable Mr. Justice Beaudry

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Applicant

and

ATTORNEY GENERAL OF CANADA
THE MINISTER OF HEALTH

Respondents

AMENDED REASONS FOR ORDER AND ORDER
(according to the Protective Order issued by Justice Mactavish on August 14, 2007)

AMENDING THE REASONS FOR ORDER AND ORDER ISSUED ON MARCH 18, 2008, WHICH ARE NOW CONFIDENTIAL

[1] This is an application by Hospira Healthcare Corporation (Hospira) for an order reversing the February 1, 2008 Order of Prothonotary Aronovitch, to the extent that it declined to order that the respondent Minister of Health (Minister) produce the documents requested by Hospira pursuant to Rule 317.

ISSUES

[2] Hospira submits the following issues to be determined in the present case:

a) Did the prothonotary fail to assess the relevance of the documents sought with reference to the grounds of judicial review?

b) Did the prothonotary err in failing to recognize that the decision to reject Hospira's NDS is not severable from the events that preceded it, namely Hospira's ongoing dealings with the Minister with respect to regulatory criteria for Drug A?

c) Did the prothonotary err in misapplying the test for production under rule 317, where procedural fairness is alleged?

[3] The issues can be restated as a single issue: did the prothonotary refuse the motion based upon a wrong principle or a misapprehension of the facts?

BACKGROUND

[4] The underlying application for judicial review challenges the respondent Minister's refusal to consider a New Drug Submission (NDS) that was filed by Hospira, seeking a notice of compliance (NOC) for Drug A. The respondent Minister's decision was based on the fact that the NDS did not provide clinical trial data to establish the safety and efficacy of Drug A pursuant to the *Food and Drug Regulations*, C.R.C., c. 870.

[5] Drug A has been supplied through the Special Access Programme (SAP) since approximately 1999, for the treatment of Drug A Indications. Because Drug A came into common use as the treatment for Drug A Indications, Hospira could not have conducted the usual clinical trials or generated data required by the *Food and Drug Regulations* to establish safety and efficacy without significant ethical concerns.

[6] Prior to the respondent Minister's decision of December 19, 2006 in a "Screening Rejection Letter", discussions were undertaken between Health Canada and Hospira over a period of some twenty-two months. Health Canada allegedly undertook to Hospira that it would define criteria and specifications with respect to the evidence required to establish the safety and efficacy of Drug A that would respect the unique clinical environment of the drug. Once established, Hospira could then adopt the criteria and specifications in seeking an NOC.

[7] By a letter dated August 17, 2006, Health Canada allegedly reneged on its commitment and declined to provide Hospira with the pragmatically defined safety and efficacy specifications as discussed. Hospira proceeded to file its NDS in the absence of specially defined safety and efficacy criteria on October 27, 2006.

[8] Following the Minister's Screening Rejection Letter on December 19, 2006, Hospira filed an application for Judicial Review. Hospira brought a motion to require the respondent Minister to produce documents which had been identified in the Rule 317 Request for Production. The motion

was decided by the February 1, 2008 Order of Prothonotary Aronovitch, who granted the motion in part.

[9] The prothonotary determined that Hospira could not seek to expand the grounds of the present judicial review, in order to collaterally attack the August 17, 2006 decision of the respondent Minister not to specially define safety and efficacy criteria.

[10] Prothonotary Aronovitch's reasons relating to the scope of documents which can be produced under Rule 317 can be summarized by reference to the following paragraphs of the Order:

> The applicant's request for production under Rule 317 is expansive. It spans seven pages and essentially asks for the production of any and all material, of any kind, that Health Canada may have relating to the drug at issue.
>
> …
>
> With few exceptions, the jurisprudence limits and defines documents that are relevant in a judicial review to the record that was before the decision-maker at the time that he or she made the decision that is the subject of the judicial review. That record has been provided to the applicant. I will open a parenthesis here to say that the record that has been produced to the applicant makes reference to the minutes or summaries of various meetings some which are said to be attached. There is no doubt that these constitute part of the "tribunal record" and have to be produced, if they have not already been produced.
>
> With that caveat, I find no reason in these circumstances to derogate from the general principle that the record be limited to what was before the decision-maker when the NDS was rejected. There is no basis to expand on the documents to be produced. The allegations of breaches of procedural fairness are invoked in respect of an extraneous manner, namely, the Minister's refusal to provide criteria. To the extent that the applicant wishes to rely on the Minister's refusal to do so, it has the wherewithal to establish the fact. The history and substance of the discussions, or the Minister's conduct in

> that connection however, are not relevant in the sense that they are extraneous to the relief sought and will not assist the Court in determining the propriety of the decision made on December 19, 2006.

ANALYSIS

Standard of Review

[11] Discretionary orders of prothonotaries ought not to be disturbed unless they are clearly wrong, in the sense that the exercise of discretion was based upon a wrong principle or a misapprehension of the facts, or where discretion was improperly exercised on a question vital to the final issue of the case (*Merck & Co. v. Apotex Inc.*, [2003] F.C.J. No. 1925, 2003 FCA 488).

[12] The parties agree that the question raised by this appeal is not vital to the final issue of the case, and as such the decision will only be disturbed if it was clearly wrong, as described above.

Relevance of documents sought was properly decided

[13] Hospira submits that the question before the prothonotary was whether the documents sought were relevant to the grounds of judicial review, as pleaded. It argues that the prothonotary applied the wrong test and disregarded the grounds pleaded by characterising the decision under review as being distinct from the circumstances that lead up to the decision. Specifically, Hospira submits that when the grounds of review include questions of procedural fairness, the principle that Rule 317 production is limited to documents before the tribunal, does not apply.

[14] For its part, the respondent Minister submits that the scope of Hospira's request for production goes well beyond what is provided by Rule 317. The Minister submits that a judicial review differs from an appeal or an action, in which cases the more expansive procedure of discovery might be allowed. In an application for judicial review, the purpose of Rules 317 and 318 is to ensure that the record considered by the decision maker is before the Court (*Canada v. Pathak*, [1995] 2 F.C. 455 (C.A.)).

[15] The Minister argues that Hospira attempts to have documents produced by the Minister that relate to the August 17, 2006 decision, the safety and efficacy of the drug, and the drug's eligibility for the SAP, whereas the application before the Court is limited to the decision communicated by letter dated December 19, 2006.

[16] It is my opinion that the prothonotary did not rely on a wrong principle when she determined that the decision of August 17, 2006 was a previous decision which could not be collaterally attacked by the present application for judicial review. If the Minister failed to address an expectation that safety and efficacy criteria would be provided, this argument should have been made in a review of the August 17, 2006 decision. Hospira may not expand the scope of the documents that are the subject of a request for production by alleging grounds for judicial review which are unrelated to the decision being challenged.

[17] I agree with the Minister's submission that the safety and efficacy of the drug are not at issue in the underlying application for judicial review; the Screening Rejection Letter dated

December 19, 2006 did not include any conclusions as to the safety and efficacy of Drug A. Rather, the submission was rejected because no pre-clinical or clinical data was provided, and as such, the NDS did not meet the requirements of the *Food and Drug Regulations*.

[18] For the foregoing reasons, I find no reason to conclude that the prothonotary's Order was clearly wrong, in the sense that the exercise of discretion was based upon a wrong principle or a misapprehension of the facts. Accordingly, this appeal will be dismissed.

ORDER

THIS COURT ORDERS that the application for an order reversing the Prothonotary's Order, dated February 1, 2008 is dismissed. Costs in the cause.

"Michel Beaudry"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-116-07
STYLE OF CAUSE:	**HOSPIRA HEALTHCARE CORPORATION v. ATTORNEY GENERAL OF CANADA THE MINISTER OF HEALTH**
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	February 28, 2008
AMENDED REASONS FOR ORDER AND ORDER:	BEAUDRY J.
DATED:	March 20, 2008

APPEARANCES:

Susan D. Beaubien	FOR THE APPLICANT
F.B. Woyiwada David Cowie	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

MACERA & JARZYNA LLP Ottawa, Ontario	FOR THE APPLICANT
John H. Sims, Q.C., Deputy Attorney General of Canada Ottawa, Ontario	FOR THE RESPONDENTS