Federal Court of Appeal | Cour d'appel fédérale

CANADA

Date: 20101214

Docket: A-126-10

Citation: 2010 FCA 345

CORAM: **SEXTON J.A.**
EVANS J.A.
SHARLOW J.A.

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Appellant

and

ATTORNEY GENERAL OF CANADA
THE MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on December 14, 2010.

Judgment delivered from the Bench at Ottawa, Ontario, on December 14, 2010.

REASONS FOR JUDGMENT OF THE COURT BY: SHARLOW J.A.

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Ottawa, Ontario, on December 14, 2010)

SHARLOW J.A.

[1] This is an appeal of the judgment of the Federal Court (2010 FC 213) dismissing the application of Hospira Healthcare Corporation for judicial review of a decision of the Minister of Health rejecting, at the screening stage, Hospira's new drug submission for a certain drug. The decision is set out in a letter dated December 19, 2006.

[2] It is common ground that when a new drug submission is screened out, no substantive review is undertaken of the information provided in support of the submission. Thus, in this case the

Minister has not undertaken a substantive review of the several volumes of material Hospira provided in support of its new drug submission. According to counsel for Hospira, those volumes contain such evidence as was available to Hospira with respect to the safety and efficacy of the drug in question. We have no basis for determining whether that description of the material is accurate.

[3] The parties agree that the material did not include pre-clinical or clinical data from clinical trials performed by Hospira or on its behalf. The record contains uncontradicted evidence that no such clinical trials could ethically be done because the drug in question is, and was when the new drug submission was made, recognized within Canada and in many other countries as the "standard of care" drug for certain cancers.

[4] The mandate of the Minister under the *Food and Drug Regulations*, C.R.C., c. 870, is to determine whether a proposed new drug meets certain standards of safety and efficacy, and if so to issue a notice of compliance signifying that those standards have been met. The particular regulations in issue in this case are paragraphs C.08.002(2)(*g*) and (*h*) which read as follows:

C.08.002. (2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:	C.08.002 (2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :
…	…
(*g*) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;	*g*) les rapports détaillés des épreuves effectuées en vue d'établir l'innocuité de la drogue nouvelle, aux fins et selon le mode d'emploi recommandés;

(*h*) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended …	*h*) des preuves substantielles de l'efficacité clinique de la drogue nouvelle aux fins et selon le mode d'emploi recommandés …

[5] It is not clear from the record whether the Minister, when making the decision in issue in December of 2006, interpreted these provisions as precluding the issuance of a notice of compliance in response to a new drug submission that is not supported by pre-clinical and clinical data from clinical trials performed by or on behalf of the party seeking the notice of compliance. Both parties now agree that this interpretation is not correct (see also *Wellesley Therapeutics Inc. v. Canada*, 2010 FC 573). We agree with them.

[6] In our view, the Minister has a discretion as to the nature and form of the information that will be accepted as meeting the requirements of paragraphs C.08.002(2)(*g*) and (*h*). It may well be that in the vast majority of cases, the requirements of those provisions would and should be met by pre-clinical and clinical data from clinical trials performed by the party seeking the notice of compliance. However, the Minister has the discretion to permit the requirements of these provisions to be met by some other means including, for example, reports of clinical trials conducted by others. At the same time, we accept the submission of counsel for the Minister that the safety and efficacy of a drug cannot be established solely on the basis that its use has been permitted under the Special Access Programme, even if permission has been given thousands of times as is the case with the drug in issue.

[7] It follows that paragraphs C.08.002(2)(*g*) and (*h*) of the *Food and Drug Regulations* did not require the Minister to reject Hospira's new drug submission at the screening stage on the basis that the Minister had no discretion to accept a new drug submission without pre-clinical and clinical data from clinical trials conducted by Hospira.

[8] The decision letter is somewhat ambiguous as to why the Hospira new drug submission was rejected. It could have been based on the incorrect statutory interpretation referred to above, which would mean that the decision is fatally flawed by an error of law.

[9] On the other hand, the decision letter could also be interpreted as an exercise of the Minister's discretion to require clinical trials in this particular case. In our view, the Minister could reasonably have made that decision, assuming the Minister was aware of the existence of the discretion not to require clinical trials and had taken into account the material submitted.

[10] In light of the ambiguity in the Minister's reasons, we conclude that Hospira is entitled to succeed. For these reasons, the appeal will be allowed with costs here and below, the judgment of the Federal Court will be set aside and, making the judgment that should have been made by the Federal Court, the application for judicial review will be allowed, the Minister's decision will be quashed and Hospira's new drug submission will be referred back to the Minister for reconsideration in accordance with these reasons.

"K. Sharlow"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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