Date: 20080910

Docket: A-26-08

Citation: 2008 FCA 258

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

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

Heard at Ottawa, Ontario, on September 10, 2008.

Judgment delivered from the Bench at Ottawa, Ontario, on September 10, 2008.

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

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Ottawa, Ontario, on September 10, 2008)

EVANS J.A.

[1] This is an appeal by Pharmascience Inc. from a decision of the Federal Court (2007 FC 1323) in which Justice Kelen dismissed Pharmascience's application for judicial review of a decision by the Minister of Health, as set out in a letter dated August 21, 2006, from the Therapeutic Product Directorate of Health Canada.

[2] In that decision, the Minister rejected an Abbreviated New Drug Submission (ANDS) submitted by Pharmascience because it did not contain comparative bioavailability studies of the

substance referred to as "component *y*", one of the two active ingredients of Pharmascience's proposed new drug. The Minister of Health considered that information to be necessary in order to determine that the new drug was the bioequivalent of the Canadian reference product with which the ANDS compared the new drug.

[3] On the basis of a pragmatic and functional analysis, Justice Kelen applied the standard of patent unreasonableness in concluding that the Minister had committed no reviewable error when, pursuant to C.08.002.1(1) of the *Food and Drug Regulations*, C.R.C., c. 870 (Regulations), he considered it necessary to require Pharmascience to provide the bioavailability characteristics of component *y*. Since the standard of review of patent unreasonableness was abolished in *Dunsmuir v. New Brunswick*, [2008] 1 S.C.R. 190, we must first consider the appropriate standard of review.

[4] Because the question in dispute concerns the application of the law (C.08.002.1(1) of the Regulations) to the facts, and involves no general legal issue, the standard of review is unreasonableness: *Dunsmuir* at para. 53. In applying this standard, a reviewing court must consider the particular context of the dispute: *Mills v. Ontario (Workplace Safety and Insurance Appeals Tribunal)*, 2008 ONCA 436 at paras. 21-22. In the present case, the contextual factors include: the subjective nature of the Minister's statutory power to require the bioavailability characteristics of a new drug ("where the Minister considers it necessary"), the heavily factual nature of the issue in dispute, the technical nature of the facts, the Minister's superior expertise in assessing what information is "necessary" to determine the bioequivalence of the drugs, and the fact that the health of consumers is potentially at stake.

[5] Despite the difference in the applicable standard of review, we find the reasoning of Justice Kelen to be persuasive. Based on that reasoning and on our review of the record, we are all of the view that the Minister's decision to reject Pharmascience's ANDS because it contained no information about the bioavailability characteristics of component *y* was well "within the range of acceptable and rational solutions" (*Dunsmuir* at para. 47). Justice Kelen's dismissal of Pharmascience's application for judicial review was therefore not in error.

[6] For these reasons, and despite the very able submissions of counsel for Pharmascience, the appeal will be dismissed with costs.

"John M. Evans"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-26-08
(APPEAL FROM A JUDGMENT OF THE FEDERAL COURT DATED DECEMBER 14, 2007, DOCKET NO. T-1693-06)	
STYLE OF CAUSE:	Pharmascience Inc. and Attorney General of Canada
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	September 10, 2008
REASONS FOR JUDGMENT OF THE COURT BY:	DESJARDINS J.A. EVANS J.A. SHARLOW J.A.
DELIVERED FROM THE BENCH BY:	EVANS J.A.

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