

Date: 20070906

Docket: A-198-07

Citation: 2007 FCA 276

**CORAM: RICHARD C.J.
SEXTON J.A.
SHARLOW J.A.**

Docket: A-198-07

BETWEEN:

FERRING INC.

Appellant

and

**THE MINISTER OF HEALTH, APOTEX INC.
and NOVOPHARM LIMITED**

Respondents

Docket: A-161-07

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Appellant

and

**MINISTER OF HEALTH, THE ATTORNEY GENERAL OF CANADA
and APOTEX INC.**

Respondents

Docket: A-162-07

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Appellant

and

**MINISTER OF HEALTH, THE ATTORNEY GENERAL OF CANADA
and APOTEX INC.**

Respondents

Docket: A-163-07

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Appellant

and

**MINISTER OF HEALTH, THE ATTORNEY GENERAL OF CANADA
and NOVOPHARM LIMITED**

Respondents

Heard at Ottawa, Ontario, on September 4, 5 and 6, 2007.

Judgment delivered from the Bench at Ottawa, Ontario, on September 6, 2007.

REASONS FOR JUDGMENT OF THE COURT BY:

RICHARD C.J.

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REASONS FOR JUDGMENT OF THE COURT

(Delivered from the Bench at Ottawa, Ontario, on September 6, 2007)

RICHARD C.J.

[1] These four appeals, heard together, are from judgments of Justice Hughes of the Federal Court rendered on March 20, 2007 (2007 FC 300). His decision disposed of four applications for judicial review of decisions of the Minister of Health resulting in the issuance of notices of

compliance that permit the respondents Apotex Inc. and Novopharm Limited to manufacture and market generic versions of certain drug products.

[2] The appellants Ferring Inc. and Sanofi-Aventis Canada Inc., the unsuccessful applicants in the Federal Court, are innovators of the drug products to which Apotex and Novopharm compared their generic drug products when seeking their notices of compliances. In the Federal Court and in this Court, the innovators have argued on a number of grounds that the Minister was wrong to issue notices of compliance to Apotex and Novopharm without first requiring them to address, under the Patented Medicines (Notice of Compliance) Regulations, certain patents listed on the patent register after Apotex and Novopharm had filed their respective abbreviated new drug submissions.

[3] Much of the argument on appeal was based on the interpretation and application of subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 following the decision of the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560, 2006 S.C.C. 49. These regulations were amended by SOR/2006-242 effective October 5, 2006 and introduce a new regime.

[4] We do not consider it necessary to discuss the arguments in detail because we are in substantial agreement with the decision of Justice Hughes and with his reasons.

[5] We differ from Justice Hughes on only one point. As an alternative basis for dismissing the application of Ferring Inc., Justice Hughes concluded that Ferring Inc. did not have standing to bring an application for judicial review of the decision of the Minister. We do not agree. In our view, Ferring Inc. did have standing to challenge that decision because it was made by the Minister in the course of his administration of the NOC Regulations. However, that does not alter the outcome because Justice Hughes dismissed the application of Ferring Inc. on the merits.

[6] We have concluded that the analytical approach adopted by the Minister in these four appeals was adequate for the factual circumstances of these cases. Whether it is adequate for all possible circumstances, including the circumstances of appeal A-189-07, which has been dismissed on the ground of mootness, is a question upon which we express no opinion.

[7] We also note that there remains some confusion about the appropriate standard of review to be applied by the Federal Court in an application for judicial review of a determination by the Minister that a generic drug manufacturer is not required to address a particular patent under the NOC Regulations. In our view, the standard of review is correctness for questions of law, and patent unreasonableness for questions of fact (*AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2004 FC 1277, per Justice Kelen at paragraph 33).

[8] I would add that where there is a mixed question of law and fact then the standard of review is patent unreasonableness unless the question of law is extricable from the question of fact in which case the question of law is determined on the basis of correctness.

[9] Accordingly, these appeals will be dismissed with costs.

[10] A copy of these reasons shall be filed in Court File Numbers A-161-07, A-162-07 and A-163-07.

"J. Richard"
Chief Justice

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-198-07

APPEAL FROM A DECISION OF JUSTICE HUGHES DATED MARCH 20, 2007 IN FILE
T-165-07

STYLE OF CAUSE: Ferring Inc.
v.
Minister of Health, Apotex Inc. and
Novopharm Limited

PLACE OF HEARING: Ottawa

DATES OF HEARING: September 4, 5 and 6, 2007

REASONS FOR JUDGMENT OF THE COURT BY: Richard C.J.

DELIVERED FROM THE BENCH BY: Richard C.J.

APPEARANCES:

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Mr. David Cowie

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Mr. Benjamin Hackett
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FOR NOVOPHARM LIMITED

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-161-07

APPEAL FROM A DECISION OF JUSTICE HUGHES DATED MARCH 27, 2007

STYLE OF CAUSE: Sanofi-Avenis Canada Inc.
v.
Minister of Health, Attorney General
of Canada and Apotex Inc.

PLACE OF HEARING: Ottawa

DATES OF HEARING: September 4, 5 and 6, 2007

REASONS FOR JUDGMENT OF THE COURT BY: Richard C.J.

DELIVERED FROM THE BENCH BY: Richard C.J.

APPEARANCES:

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Ms. Nancy Pei
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NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-162-07

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STYLE OF CAUSE: Sanofi-Avenis Canada Inc.
v.
Minister of Health, Attorney General
of Canada and Apotex Inc.

PLACE OF HEARING: Ottawa

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FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-163-07

APPEAL FROM A DECISION OF JUSTICE HUGHES DATED MARCH 20, 2007 IN FILE
T-2188-06

STYLE OF CAUSE: Sanofi-Avenis Canada Inc.
v.
Minister of Health, Attorney General
of Canada and Novopharm Limited

PLACE OF HEARING: Ottawa

DATES OF HEARING: September 4, 5 and 6, 2007

REASONS FOR JUDGMENT OF THE COURT BY: Richard C.J.

DELIVERED FROM THE BENCH BY: Richard C.J.

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