Court File No: A-215-20

FEDERAL COURT OF APPEAL

BETWEEN:

INNOVATIVE MEDICINES CANADA, ABBVIE CORPORATION, AMGEN CANADA INC., ASTELLAS PHARMA CANADA, INC., ASTRAZENECA CANADA INC., BRISTOL-MYERS SQUIBB CANADA CO., ELI LILLY CANADA INC., HOFFMAN-LA ROCHE LIMITED, IPSEN BIOPHARMACEUTICALS CANADA, INC., LEO PHARMA CANADA INC., LUNDBECK CANADA INC., NOVARTIS PHARMACEUTICALS CANADA INC., NOVO NORDISK CANADA INC., OTSUKA CANADA PHARMACEUTICAL INC., PFIZER CANADA ULC, SANOFI-AVENTIS CANADA INC., AND TAKEDA CANADA INC.

Appellants

FEDERAL COURT OF APPEAL COUR D'APPEL FÉDÉRALE D É L 21-SEP-2020 P O S D Vanessa George E TORONTO, ON - 5 -

and

THE ATTORNEY GENERAL OF CANADA

Respondent

NOTICE OF CROSS-APPEAL

THE RESPONDENT CROSS-APPEALS in this appeal and asks that the Judgment of Justice Manson, dated June 29, 2020 ("the Judgment"), be varied as follows:

- 1. Paragraph 1 of the Judgment be set aside; and
- 2. Paragraph 2 of the Judgment be varied to read as follows:

"The Amendments made by the Governor in Council are valid;"

THE GROUNDS FOR THIS CROSS-APPEAL are as follows:

- On June 29, 2020, the Federal Court allowed in part the application for judicial review in *Innovative Medicines et al v Canada (Attorney General)*, 2020 FC 725.
- 2) The Application Judge determined that the Governor in Council's decision to enact Subsection 3(4) of the *Amendments* to the *Patented Medicines Regulations* ["New Price Calculation"] was unreasonable and therefore *ultra vires*.
- 3) The Application Judge erred in making this determination. His decision disregards settled principles from this and other courts that govern the interpretation of the *Patent Act* (RSC 1985, c. P-4) and the judicial review of administrative action. Specifically, the Application Judge erred in his application of the reasonableness standard with respect to the New Price Calculation as follows:
 - a) The Application Judge erred by failing to consider the context in which the New Price Calculation was enacted and that it is consistent with both the enabling statute and the purposes Patented Medicine Regime;
 - **b)** The Application Judge erred by selecting his own definition of "price" and "sale" and using that definition to find the impugned provision unreasonable;
 - c) The Application Judge's interpretation of "price" and "sale" conflicts with settled jurisprudence from the Supreme Court of Canada and other courts;
 - d) The Application Judge's decision does not respect the presumption of validity, and in particular the principle that individual issues of validity of provisions relating to the Patented Medicine Prices Review Board should be left to the Board to be decided in individual cases; and

- **e)** The Application Judge erred in his reliance on *Pfizer v Canada (Attorney General)*.
- 4) Patent Act, RSC 1985, c P-4;
- 5) Interpretation Act, RSC 1985, c i-21;
- 6) Department of Health Act, SC 1996 c 8; and
- 7) Such further and other grounds as counsel may advise and this Honourable court allow.

The Attorney General of Canada agrees with the Appellants' proposal that the hearing be held in Toronto, Ontario.

September 21, 2020

ATTORNEY GENERAL OF CANADA

Department of Justice Canada Ontario Regional Office National Litigation Sector 120 Adelaide Street West Suite #400 Toronto, ON M5H 1T1

Fax number: 416-973-0809

Per: Joseph Cheng / James Schneider

Telephone no.: 647-407-9205

E-mail address:

joseph.cheng@justice.gc.ca/ james.schneider@justice.gc.ca

Counsel for the Respondent/Cross-Appellant TO: THE ADMINISTRATOR

Federal Court of Appeal 180 Queen Street West Toronto, ON M5V 1Z4

AND TO: NORTON ROSE FULBRIGHT CANADA LLP

222 Bay Street, Suite 3000, P.O. Box 53

Toronto, Ontario

M5K 1E7

Orestes Pasparakis

Orestes.Pasparakis@nortonrosefulbright.com

Kristin Wall

Kristin.Wall@nortonrosefulbright.com

Christopher A. Guerreiro

Christopher.Guerreiro@nortonrosefulbright.com

Fahad Siddiqui

Fahad.Siddiqui@nortonrosefulbright.com

Tel: 416-216-4000 Fax: 416-216-3930

Solicitors for the Appellants

AND TO: GOWLING WLG (CANADA) LLP

Barristers & Solicitors 160 Elgin Street, Suite 2600 Ottawa, Ontario K1P 1C3

Tel: 613-233-1781 Fax: 613-563-9869

John Norman

(John.Norman@gowlingwlg.com)

Cole Meagher

(Cole.Meagher@gowlingwlg.com)

Jenny Thistle

(Jenny.Thistle@gowlingwlg.com)

Solicitors for the intervener, CORD