Federal Court of Appeal | Cour d'appel fédérale

Date: 20221205

Docket: A-215-20

Citation: 2022 FCA 210

CORAM: **STRATAS J.A.**
WOODS J.A.
LOCKE J.A.

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., HOFFMANN-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

and

THE ATTORNEY GENERAL OF CANADA

Respondent

and

CANADIAN ORGANIZATION FOR RARE DISORDERS

Intervener

Heard by online video conference hosted by the Registry, on February 28 and March 1, 2022.

Judgment delivered at Ottawa, Ontario, on December 5, 2022.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: LOCKE J.A.

CONCURRING REASONS BY: WOODS J.A.

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REASONS FOR JUDGMENT

STRATAS J.A.

A. Introduction

[1] In a judicial review in the Federal Court, the appellants challenged portions of a regulation (S.O.R./2019-298) that amends the *Patented Medicines Regulations*, S.O.R./94-688 (as amended). In their challenge, the appellants said that portions of the regulation were invalid because they went beyond the scope of the regulation-making power in the *Patent Act*, R.S.C. 1985, c. P-4.

[2] The amendments in the regulation, among other things, affect how the Patented Medicine Prices Review Board determines whether the price of a patented medicine is excessive under section 85 of the *Patent Act*. The amendments in the regulation:

(1) supply new factors for the Board to consider;

(2) specify a new way for the Board to calculate the price of medicines (discounts and rebates are relevant); and

(3) change the list of comparator countries for which pricing information must be filed.

[3] When this matter reached our Court, all three items were live and in issue. However, a few months after the hearing in our Court, the Governor in Council repealed items (1) and (2): S.O.R./2022-162. Item (3) has not been repealed. It remains live.

[4] In this Court, the parties agree that the challenge to items (1) and (2) is now moot and should not be heard. They also agree that this Court should determine the challenge to item (3), specifically the challenge to section 6 in S.O.R./2019-298 which enacts item (3).

[5] The Court agrees with the parties. Their position is consistent with *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342, 57 D.L.R. (4th) 231.

[6] The Federal Court concluded that the Governor in Council's decision to enact section 6 of S.O.R./2019-298—to change the list of comparator countries—was reasonable and, thus, the section was valid: 2020 FC 725 (*per* Manson J.).

[7] For the reasons that follow, I agree with the Federal Court. Therefore, I would dismiss the appeal with costs.

B. Analysis

(1) The appellants' general submission

[8] The appellants submit that the change to the list of comparator countries in the regulations conflicts with the proper purposes of section 85 of the *Patent Act* and the proper purposes underlying the *Patent Act* itself, as shaped by the limits on federal power over patents in subsection 91(22) of the *Constitution Act, 1867*.

[9] Thus, the appellants submit that the Governor in Council's decision to enact section 6 of S.O.R./2019-298 is unreasonable. In consequence, the appellants ask us to strike out section 6. If we do that, the list of comparator countries that previously existed would be restored.

(2) Section 85 of the *Patent Act*

[10] To evaluate the appellants' submission, we must first examine section 85 of the *Patent Act*. It is the core of the Patented Medicine Prices Review Board's power to determine, in the words of section 85, "whether a medicine is being or has been sold at an excessive price in any market in Canada".

[11] Subsection 85(1) sets out five factors for the Board to consider. These appear in five paragraphs in subsection 85(1):

(a) "the prices at which the medicine has been sold in the relevant market";

(b) "the prices at which other medicines in the same therapeutic class have been sold in the relevant market";

(c) "the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada";

(d) "changes in the Consumer Price Index";

(e) "such other factors as may be specified in any regulations made for the purposes of this subsection".

If and only if after considering these factors the Board is unable to determine if a price is excessive, it may also consider "the costs of making and marketing the medicine" and any other factors it considers relevant: s. 85(2).

(3) What "countries other than Canada" are relevant to paragraph 85(1)(*c*)?

[12] Since the first enactment of the *Patented Medicines Regulations* in 1994, patentees have had to file information concerning the "the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each

of [the] countries" set out in a schedule to the Regulations. The prices in these comparator countries are the ones the Board examines under paragraph 85(1)(*c*).

[13] From 1994 until the amendment at issue in this case, the comparator countries were Germany, France, Italy, Sweden, Switzerland, the United Kingdom and the United States.

[14] The amendment at issue in this case changes the comparator countries to Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden and the United Kingdom. As can be readily seen, the list of comparator countries has grown and the United States and Switzerland have been dropped from the list.

(4) The regulation-making power in subsection 101(1) of the *Patent Act*

[15] Subsection 101(1) of the *Patent Act* gives the Governor in Council the power to enact and amend regulations. Paragraph 101(1)(*a*) allows the Governor in Council to specify the "information…that shall be provided to the Board" in order for the Board to carry out its mandate. For good measure, paragraph 101(1)(*d*) allows the Governor in Council to specify factors for the purposes of section 85.

[16] All parties accept that subsection 101(1), literally read, supports the making of a regulation requiring patentees to submit information about their relevant pricing in certain countries so that the Board can consider the factor in paragraph 85(1)(*c*), namely "the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries

other than Canada". In effect, the countries listed in the regulation become comparators to be taken into account under paragraph 85(1)(*c*).

[17] But the appellants say that in this case, looking at the entire context, the Governor in Council has acted unreasonably. It has chosen certain countries in order to advance an agenda or fulfil a purpose contrary to section 85 and the *Patent Act*. In the appellants' view, the Governor in Council has acted outside of the regulation-making power under subsection 101(1) of the *Patent Act*, as shaped by the limits on federal power over patents in subsection 91(22) of the *Constitution Act, 1867*. Specifically, they say that the Governor in Council is improperly pursuing the purpose of regulating or controlling prices or setting reasonable prices—something not authorized by section 85 of the *Patent Act* and something that only provinces can do—rather than policing excessive pricing stemming from the abuse of the monopoly powers granted under patents.

(5) Previous authorities concerning the purposes of section 85 and the Board's policing power over excessive pricing

[18] The issue of the proper scope of section 85 has been a fertile area of litigation. There is a forest of authorities. Fortunately, we need only take the most prominent of these authorities and apply them to this case.

[19] Most recently, this Court has analyzed those authorities and has concluded as follows:

> Over and over again, authorities have stressed that the excessive pricing provisions in the *Patent Act* are directed at controlling patent abuse, not reasonable pricing, price-regulation or consumer protection at large: *Innovative Medicines Canada v. Canada (AG)*, 2020 FC 725, 174 C.P.R. (4th) 333 at paras. 76-89; *Canada (Attorney General) v. Sandoz Canada Inc.*, 2015 FCA 249, 390 D.L.R. (4th) 691 at para. 26; *ICN Pharmaceuticals Inc. v. Patented Medicine Prices Review Board* (1996), 108 F.T.R. 190, 66 C.P.R. (3d) 45 aff'd 119 F.T.R. 70, [1997] 1 F.C. 32 (C.A.); *Manitoba Society of Seniors Inc. v. Canada (Attorney-General)* (1991),70 Man. R. (2d) 141, 77 D.L.R. (4th) 485 (M.B.Q.B.) at paras. 19-21. In one authority, the Supreme Court loosely and occasionally speaks of these provisions having a consumer protection purpose and cites some politicians' speeches to that effect: *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3. But it ties that purpose to the specific need to prevent patent abuse: at paras. 28-29, citing *ICN Pharmaceuticals Inc.* Were the excessive pricing provisions of the federal *Patent Act* aimed at reasonable pricing, price-regulation or consumer protection at large, they would be constitutionally suspect: see, e.g., *Innovative Medicines Canada*; *Merck Canada Inc. v. Canada (Attorney General)*, 2020 QCCS 4541.

(*Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157, 185 C.P.R. (4th) 83 at para. 49; see also *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3.) The bottom line is that pure price regulation or price setting is invalid; policing excessive pricing is valid.

(6) The purpose behind section 6 of S.O.R./2019-298: the change to the list of comparator countries

[20] The Attorney General submits that the list of comparator countries was changed in order to modernize the tools the Board uses to detect excessive pricing. The Attorney General notes that the list of comparator countries has not been changed since 1994. But, the Attorney General says, circumstances have changed in the quarter-century since that time.

[21] The Attorney General submits that the need for the change was first recognized in a strategic plan in 1994. And later documents show that both the Board and Health Canada have recognized that the tools to detect excessive pricing are no longer suitable for the task.

[22] At the centre of the Attorney General's submissions is the Regulatory Impact Analysis Statement offered in support of the change: *Canada Gazette Part II*, vol. 153, no. 17, at 5946-5996. The Regulatory Impact Analysis Statement suggests that the Governor in Council changed the list because, over the last quarter-century, the original criteria used to select comparator countries had become incomplete and flawed. The Governor in Council chose the eleven countries in the revised list because they were comparable to Canada in three important respects: their measures to constrain free-market pricing, their economic standing, and their market characteristics: Regulatory Impact Analysis Statement at 5953-5954; and see the Federal Court's reasons at paras. 155-156. At a more general level, as the Federal Court found (at para. 103), the amendments "update the Board's arsenal of regulatory tools and information reporting authority in order to effectively protect Canadian consumers from excessively priced patented medicines".

[23] In particular, the Governor in Council dropped the United States and Switzerland from the list of comparator countries because, unlike Canada, they do not have measures regulating the free-market pricing of patented medicines. In the view of the Governor in Council, they were inapt comparators.

[24] Considering all the evidence before it, the Federal Court found that the enactment of a list of eleven comparator countries, by itself, does not constitute an improper form of price control

and price regulation. All that is happening under this change is the collection of pricing information from seven up to eleven listed countries, nothing more. The filing of comparative information to facilitate the Board's task of determining excessiveness is, by itself, benign. If the Board later uses that comparative information to set or control prices—rather than police excessive pricing—an aggrieved party can establish on judicial review that the Board has exceeded its jurisdiction. In short, the sin is not in the gathering of information; if a sin is committed, it will be later when the information is improperly used.

[25] I agree with the Federal Court. What the Board does with the comparative information from the eleven countries—whether it uses it improperly for price regulation or properly for the policing of excessive pricing—comes later. The requirement to supply pricing information, by itself, says nothing about what the Board will do. As the Board once said in one of its decisions, "performing a comparison does not dictate a conclusion that must result from the comparison" and the same can be said for a requirement to submit pricing information as a prerequisite to the comparison: *Leo Pharma Inc. v. Canada (Attorney General)*, 2007 FC 306, 57 C.P.R. (4th) 174 at para. 18, quoting the Board in that case.

(7) How we should assess the regulation in issue in this case

[26] This Court's decision in *Portnov v. Canada (Attorney General)*, 2021 FCA 171 requires us to follow the methodology in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653 when assessing a challenge to the validity of regulations, not the methodology in *Katz Group Canada Inc. v. Ontario (Health and Long-Term Care)*, 2013

SCC 64, [2013] 3 S.C.R. 810. The appellants add that *Portnov*, a unanimous decision of this Court, binds future panels of this Court. In oral argument, the Attorney General did not disagree.

[27] I agree with the appellants and, thus, will assess the regulation following the methodology in *Vavilov*. Under our law concerning horizontal *stare decisis*, we are bound to follow *Portnov* unless we are persuaded it is manifestly wrong or it can be distinguished: *Miller v. Canada (Attorney General)*, 2002 FCA 370, 220 D.L.R. (4th) 149; *R. v. Sullivan*, 2022 SCC 19, 413 C.C.C. (3d) 447. The Attorney General does not argue that *Portnov* is manifestly wrong and does not try to distinguish it.

[28] I note that some other courts have already applied *Portnov*, implicitly or explicitly, with approval: *Le v British Columbia (Attorney General)*, 2022 BCSC 1146; *Pacific Wild Alliance v. British Columbia (Forests, Lands, Natural Resource Operations and Rural Development)*, 2022 BCSC 904 at paras. 68-75. As well, considerable academic commentary suggests that *Vavilov* has overtaken *Katz* and so *Portnov* is good law: see, for example, John Mark Keyes, "Judicial Review of Delegated Legislation—The Road Beyond *Vavilov*" (2022) 35 C.J.A.L.P. 69; Mark Mancini and Martin Olszynski, "Reviewing Regulations Post-*Vavilov: Ecology Action Centre v Canada* (Part II)" in *ABlawg* (blog) (online: http://ablawg.ca/wp-content/uploads/2021/12/Blog_MM_MO_Ecology_Action_Centre_2.pdf); Paul Daly, "Regulations and Reasonableness Review" in *Administrative Law Matters* (online: https://www.administrativelawmatters.com/blog/2021/01/29/regulations-and-reasonableness-review/).

[29] Recently, the Alberta Court of Appeal has declined to follow *Portnov*: *Auer v Auer*, 2022 ABCA 375; *TransAlta Generation Partnership v Alberta (Minister of Municipal Affairs)*, 2022 ABCA 381. The Alberta Court of Appeal suggests that *Katz*, not *Vavilov*, is the governing authority when we are dealing with regulations passed by the Governor in Council.

[30] This matters. Under *Vavilov*, as suggested in *Portnov*, we conduct reasonableness review of the decision to enact the regulation to change the comparator countries. Though the challenger bears the burden of proving that the decision is unreasonable under *Vavilov*, the challenger does not have to overcome a presumption the decision is reasonable. Under *Katz*, the challenger must overcome a presumption the regulation is valid: *Katz* at para. 25. It can be overcome only if the regulation is "irrelevant", "extraneous" or "completely unrelated" to the "statutory purpose": *Katz* at paras 24 and 28. Reasonableness review does not enter into the matter at all. This is a "hyperdeferential" test, one unique in all of administrative law: Daly, "Regulations and Reasonableness Review", above.

[31] In the expectation that the Supreme Court may one day consider the question whether *Vavilov* or *Katz* should apply to regulations, I wish to offer a few words, beyond those already given in *Portnov*, in further support of *Portnov*.

[32] *Vavilov* tells us (at para. 143) to look first to it for the methodology we should follow. It also tells us that earlier cases, like *Katz*, remain good law only if they are consistent with it: see also *Portnov* at para. 26. *Katz* is not consistent with *Vavilov*, as *Portnov* explains. This suggests that, as *Portnov* says, we must follow the methodology in *Vavilov*, not *Katz*.

[33] As well, the Supreme Court has recently doubled down on *Vavilov* in a way that supports *Portnov*: *Law Society of Saskatchewan v. Abrametz*, 2022 SCC 29, 470 D.L.R. (4th) 328. Before *Abrametz*, some thought that the *Vavilov* methodology applies only to administrators' substantive decisions, not their procedural decisions. But in *Abrametz*, the Supreme Court applied the *Vavilov* methodology to an administrator's procedural decision: see paras. 26-30. Evidently *Vavilov* applies to all administrative decisions, regardless of formal differences in their content. In fact, this trend has been underway for a long time. All sorts of administrative decisions, including many that create instruments said to be "law", have been reviewed under *Vavilov* or its predecessor, *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190), not *Katz*: *Canadian National Railway Co. v. Canada (Attorney General)*, 2014 SCC 40, [2014] 2 S.C.R. 135 (orders-in-council enacted by the Governor in Council); *Catalyst Paper Corp. v. North Cowichan (District)*, 2012 SCC 2, [2012] 1 S.C.R. 5, *Lucky Luc Carriage and Sleigh Service v. Montreal (City)*, 2022 QCCA 1610 at paras. 56-59, *Colchester County (Municipality) v. Colchester Containers Limited*, 2021 NSCA 53 at paras. 32-37, *1193652 B.C. Ltd. v. New Westminster (City)*, 2021 BCCA 176 at paras. 56-59 and *1120732 B.C. Ltd. v. Whistler (Resort Municipality*, 2020 BCCA 101, 445 D.L.R. (4th) 448 at paras. 39 and 44-46 (municipal by-laws); *West Fraser Mills Ltd. v. British Columbia (Workers' Compensation Appeal Tribunal)*, 2018 SCC 22, [2018] 1 S.C.R. 635 (regulations made by an administrator); *Green v Law Society of Manitoba*, 2017 SCC 20, [2017] 1 S.C.R. 360 (rules made by an administrator). Just as the methodology in *Vavilov* applies to a whole range of administrative decisions, it applies to administrative decisions to make regulations.

[34] *Portnov* reminds us (at para. 23) that, in its real essence and true nature, a regulation is just like a municipal by-law, an order-in-council, an administrative rule, or an administrative ruling on the merits. Each creates compulsory obligations that, depending on what is being regulated, affect very many people or just a few. Each is the end-product of a substantive administrative decision made by an administrative decision-maker. Each is subject to constraints and limits imposed by the statutory regime. On its own terms, *Vavilov* says it applies to decisions of that very sort. Indeed, *Vavilov* (at para. 66) refers specifically to regulations (at least those made by an administrative decision-maker under delegated authority) and suggests that issues about their validity are closely connected to the interpretation of the regulation-making power, the review of which is done according to *Vavilov*: see also *Canada (Canadian Human Rights Commission) v. Canada (Attorney General)*, 2018 SCC 31; [2018] 2 S.C.R. 230 at paras. 38 and 111.

[35] Regulations, municipal by-laws, orders-in-council, administrative rules and administrative rulings on the merits *appear* to be different from each other but only if we fasten onto differences in form: each has its own, distinct, formal label and each may have different, formal prerequisites for enactment. But in administrative law, in developing our methodologies, too often we have fastened onto differences in form. We have developed different rules for matters that, in their real essence and true nature, are substantially the same. The result? Unnecessary complexity, confusion and incoherence.

[36] *Vavilov* says this judicial fastening onto differences in form must stop. Complexity, confusion and incoherence must be replaced with simplicity, clarity and coherence: *Vavilov*,

paras. 7 and 10. These are furthered if we use the same methodology—the methodology in *Vavilov*—to review matters that, in their real essence and true nature, are substantially the same.

[37] The majority of the Alberta Court of Appeal in *Auer* offers (at para. 63) the view that regulations, particularly those by the Governor in Council, are different and must be treated differently because they are "law-making". This harkens back to the law decades ago, now thoroughly discredited, that administrative decisions should be reviewed differently depending on whether they fall into the formal categories of "legislative", "quasi-judicial" or "judicial": see the cases cited in *Portnov* at paras. 21-22.

[38] That view also overlooks the fact that orders-in-council enacted by the Governor in Council, municipal by-laws, administrative rules and some administrative rulings on the merits are all instances of "law-making". And, as mentioned in paragraph 33 above, the Supreme Court has said that each of these instances of "law-making" are to be reviewed using *Vavilov* (or its predecessor, *Dunsmuir*), not *Katz*.

[39] I sympathize somewhat with the underlying motivation of the Supreme Court in *Katz* and the Alberta Court of Appeal's application of *Katz* in the two recent cases: for good reasons based on the separation of powers between the judiciary and the executive, courts should not lightly interfere with decision-making by the Governor in Council, especially when its policy content is high. But the Supreme Court in the later case of *Vavilov*, sensitive to context, says the same thing. Under *Vavilov*, the broader the regulation-making power in a statute, particularly in matters of policy that are quintessentially the preserve of the executive, the less constrained the

regulation-maker will be in enacting the regulation: *Entertainment Software Association v. Society of Composers, Authors and Music Publishers of Canada*, 2020 FCA 100, [2021] 1 F.C.R. 374 at para. 28 (applying *Vavilov* and earlier cases consistent with it), aff'd 2022 SCC 30.

[40] This is especially so for the Governor in Council. The Governor in Council is "at the apex of the executive", serves as "the grand co-ordinating body for the divergent provincial, sectional, religious, racial and other interests throughout the nation", and represents "different geographic, linguistic, religious, and ethnic groups": *Canada (Citizenship and Immigration) v. Canadian Council for Refugees*, 2021 FCA 72, 458 D.L.R. (4th) 125 at paras. 36-38. Thus, subject to limiting statutory language passed by our elected representatives, the Governor in Council's regulation-making power is often relatively unconstrained. The key is the limiting statutory language. *Vavilov* goes straight to that key, focusing on what meanings the language of the regulation-making power can reasonably bear. *Katz* doesn't. It focuses on matters of form, namely, the nature of the instrument being enacted, a regulation, and the maker of the instrument, the Governor in Council. Then it asks only one thing: whether the regulation, presumed to be valid, is so "irrelevant", "extraneous" or "completely unrelated" to the "statutory purpose" that it must be struck.

[41] This difference between *Vavilov* and *Katz* can lead to drastically different results. Take a regulation passed by the Governor in Council. Suppose it is not "irrelevant", "extraneous" or "completely unrelated" to the "statutory purpose". But suppose, for reasons based on statutory interpretation principles applied by courts for decades, it cannot be supported on any reasonable

interpretation of the regulation-making power in the statute. *Katz* would allow the regulation to stay on the books. *Vavilov* would strike it down.

[42] With that circumstance in mind, we can see that preferring *Vavilov* over *Katz* is not about furthering judicial interventionism or being "seduced by…[*Portnov's*] reasoning": *Auer* at paras. 61-63. It is about maintaining balance in the separation of powers and ensuring that all holders of public powers are accountable to the law: *Canada (Citizenship and Immigration) v. Tennant*, 2018 FCA 132 at paras. 23-24.

[43] Finally, so far, two academic commentaries criticize the recent decisions of the Alberta Court of Appeal and support *Portnov*: Paul Daly, "Resisting which Siren's Call?" in *Administrative Law Matters* (blog) (online: https://www.administrativelawmatters.com/blog/2022/11/24/resisting-which-sirens-call-auer-v-auer-2022-abca-375-and-transalta-generation-partnership-v-alberta-minister-of-municipal-affairs-2022-abca-381/); Mark Mancini, "Simplicity in the Law of Judicial Review of Regulations: *Auer* and *TransAlta*" in *Double Aspect* (blog) (online: https://doubleaspect.blog/2022/11/27/simplicity-in-the-law-of-judicial-review-of-regulations-auer-and-transalta/).

(8) Applying the methodology in *Vavilov* (as *Portnov* suggests)

[44] Under *Vavilov*, the presumptive standard of review is reasonableness. When we conduct reasonableness review, we are to assess the constraints on the administrative decision-maker and

whether the decision-maker has remained within them, with the focus on any reasons given by the decision-maker. The primary constraint on an administrative decision-maker is its empowering legislation. In this case, the empowering legislation is the regulation-making power in subsection 101(1) of the *Patent Act*, as understood in light of section 85 and the purposes underlying that section and the Act as a whole, as shaped by the constitutional limits of the federal power over patents. In this case, the Governor in Council had to interpret the scope of the regulation-making power and enact a regulation that, in its reasonable view, was within that power.

[45] Here, because no exception set out in *Vavilov* to reasonableness review applies, the standard of review is reasonableness.

[46] The Federal Court found that the Governor in Council reasonably enacted the regulation changing the list of comparator countries. I agree with the Federal Court. For the reasons set out in sections (4) to (6) of these reasons and following *Vavilov*, I conclude that the decision to enact the amendment changing the list of comparator countries is based on a reasonable interpretation of the regulation-making power in subsection 101(1) of the *Patent Act*, a power that, on an analysis of text, context and purpose, can be viewed as relatively unconstrained. It is reasonable to conclude that it is consistent with section 85 and the *Patent Act* and their purposes, as shaped by subsection 91(22) of the *Constitution Act, 1867*. Reasonableness is enhanced by the consistency with judicial decisions on those matters.

[47] As the Federal Court noted (at para. 136), the regulation-making authority conferred on the Governor in Council by subsection 101(1) of the *Patent Act* is broad. That authority, reasonably construed, supports the change to the list of comparator countries.

[48] Reasonableness also requires that a reviewing court can discern a reasoned explanation of the decision. In this case, a reasoned explanation can be discerned from the Regulatory Impact Analysis Statement: modernization, as explained above. Statements such as these are a commonly accepted source of reasons behind decisions made by the Governor in Council: *Portnov* at para. 34; *Coldwater First Nation v. Canada (Attorney General)*, 2020 FCA 34, [2020] 3 F.C.R. 3; *Canada (Minister of Transport, Infrastructure and Communities) v. Farwaha*, 2014 FCA 56, [2015] 2 F.C.R. 1006.

[49] Even if, contrary to the reasoning in *Portnov*, *Katz* remains good law and must be applied instead of *Vavilov*, the result in this case would be the same.

[50] As mentioned in paragraph 30 above, *Katz* adopts a "hyperdeferential" approach to the challenge of regulations. If the appellants' challenge fails under reasonableness review in *Vavilov*, it must surely fail under the far more deferential, more immunizing standard set out in *Katz*.

(9) Other submissions advanced by the appellants

[51] The appellants suggest that the Governor in Council's decision to change the list of comparator countries was unreasonable because it was done for an improper purpose: a purpose extraneous to section 85 and the *Patent Act* and a purpose beyond federal powers. The improper purpose is said to be the reduction of the price of medicines generally in order to deliver health care savings and to pave the way for national pharmacare.

[52] No doubt an administrative decision to make a regulation or other instrument under a statute for reasons extraneous to its terms or purposes would be unreasonable: see, *e.g.*, *Stemijon Investments Ltd. v. Canada (Attorney General)*, 2011 FCA 299, 341 D.L.R. (4th) 710 (an administrative decision-maker fettering its discretion rather than having regard to governing legislation acts unreasonably).

[53] In support of their improper purpose submission, the appellants cite a letter written by the federal Minister of Health in May 2017. That letter speaks of "improving the affordability, accessibility and appropriate use of prescription drugs" and "lowering high drug prices" by modernizing "the regulatory framework that guides the work of the Patented Medicine Prices Review Board". The appellants also cite a May 2017 Health Canada consultation document. It states that the federal government is "firmly committed" to the work of improving "the affordability, accessibility and appropriate use of prescription drugs" to "better meet health care system needs" and is "taking action to significantly lower the cost of prescription drugs". That document adds that the Board's "current regulatory framework does not provide it with adequate

tools to effectively protect Canadians from excessive prices, or for optimal price setting in today's pharmaceutical environment".

[54] The appellants also cite a statement made by the Minister of Health in the House of Commons in June 2019. There, the Minister announced that the government was in the process of "modernizing the Patented Medicine Prices Review Board in order to once again make sure we lower the cost of drugs": *House of Commons Debates*, 42-1, vol. 148, No. 433 (June 13, 2019) at 29103.

[55] The Federal Court did not place much weight on this evidence. And neither should we.

[56] The lowering of the overall cost of medicines, thereby resulting in savings to the public purse, is a natural consequence of the amendments which were passed to modernize this regulatory regime. The Regulatory Impact Analysis Statement quite candidly admits this natural consequence: the amendments "contribute to the Government's commitment [to improve the accessibility, affordability, and appropriate use of medicines] by lowering the prices of patented medicines in Canada": Regulatory Impact Analysis Statement at 5949. And that statement is true: legitimately rolling back excessive prices of medicines under section 85 of the *Patent Act* will tend to reduce the cost of those medicines, thereby reducing the impact on the public purse.

[57] But, as the Federal Court stated (at para. 103), an honest recognition that the amendments may cause overall cost savings as a natural consequence of the measure does not mean that that is the pith and substance of the amendments. As the Federal Court found, for the reasons it gave,

the purpose is the modernization of tools the Board uses to police the excessive pricing of patented medicines.

[58] It is important not to confuse the motive, policy and politics behind a regulation with its pith and substance: *Thorne's Hardware Ltd. v. The Queen*, [1983] 1 S.C.R. 106 at 112; *Katz* at paras. 27-28.

[59] Evidence of motive, policy and politics may be more relevant where a party alleges that the decision to enact a regulation, supposedly prompted by a legislatively authorized, constitutional purpose, is colourable. This is a most serious allegation: an artifice has been created to camouflage or disguise a true purpose that is beyond the legislative or constitutional authority of the decision-maker. This, "incidentally", seems to be the only basis for attacking regulations under *Katz*. It is a narrow one.

[60] To prove this, only the clearest evidence will suffice: for examples where the evidence was clear enough, see *Roncarelli v. Duplessis*, [1959] S.C.R. 121, 16 D.L.R. (2d) 689, *Re Multi-Malls Inc. and Minister of Transportation and Communications* (1977), 14 O.R. (2d) 49, 73 D.L.R. (3d) 18 (C.A.), and *Doctors Hospital v. Minister of Health et al.* (1977), 12 O.R. (2d) 164, 68 D.L.R. (3d) 220 (Div. Ct.). The Federal Court was not persuaded that the evidence was sufficiently persuasive to prove colourability, and neither should we.

[61] General aspirational statements offered by politicians, such as many of the statements about the government's general policies or objectives the appellants offered in this case, offer

little help. Caution must be exercised when relying on "what some politicians may have said about [legislative purposes and motives] at some place, at some time, for whatever reason": *Alexion* at para. 53, citing *Schmidt v. Canada (Attorney General)*, 2018 FCA 55, [2019] 2 F.C.R. 376 at para. 31; see also *Williams v. Canada (Public Safety and Emergency Preparedness)*, 2017 FCA 252, [2018] 4 F.C.R. 174, at paras. 50-51. This is especially so where the statements are made in politically fraught or controversial circumstances. The Supreme Court has observed that "statements of purpose in the legislative record may be rhetorical and imprecise" and "[d]econtextualized statements by members of Parliament can be poor indicators of…purpose": *R. v. Sharma*, 2022 SCC 39 at para. 89, citing *Canada (Attorney General) v. Whaling*, 2014 SCC 20, [2014] 1 S.C.R. 392 at paras. 67-68 and *R. v. Heywood*, [1994] 3 S.C.R. 761, 120 D.L.R. (4th) 348 at 788 S.C.R.; see also *Mohr v. National Hockey League*, 2022 FCA 145 at para. 63. And, of course, statements by persons other than the administrative decision-maker, by themselves, say little about the purposes behind the decision, unless there is some persuasive tie to the decision-maker.

[62] The Federal Court offered many of the above points in support of its view that this portion of the amendments was valid and that much of the extraneous evidence the appellants offered was of no relevance or weight (at paras. 99-104 and 154-162). It concluded (at para. 162) that the "Governor in Council's decision to amend the basket of comparator countries is…reasonable". I agree with this conclusion and much of the Federal Court's analysis.

(10) Conclusion on the appeal

[63] For the foregoing reasons, I conclude that the appellant's challenge to the regulation changing the list of comparator countries must fail. The Governor in Council's decision to make the regulation was reasonable.

(11) Conclusion on the cross-appeal

[64] A cross-appeal is also before the Court. It concerns two other aspects of the amendments: the additional factors to be considered, and the taking into account of discounts and rebates: namely, items (1) and (2) in para. 2, above.

[65] As mentioned at the outset of these reasons, those issues are now moot and the parties say we should not determine them. I agree.

C. Proposed disposition

[66] Therefore, I would dismiss the appeal with costs. I would dismiss the cross-appeal for mootness and would make no order as to costs.

"David Stratas"
J.A.

"I agree
George R. Locke J.A."

WOODS J.A. (Concurring reasons)

[67] Since *Portnov v. Canada (Attorney General)*, 2021 FCA 171 binds this Court, I need not express a view on paragraphs 28-43 of my colleague's reasons. Also, as my colleague says at paragraphs 49-50 of his reasons, the regulation is valid even under *Katz Group Canada Inc. v. Ontario (Health and Long-Term Care)*, 2013 SCC 64, [2013] 3 S.C.R. 810. I otherwise concur.

"Judith M. Woods"
J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-215-20

APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE MANSON DATED JUNE 29, 2020, NO. T-1465-19

STYLE OF CAUSE:	INNOVATIVE MEDICINES CANADA *et al.* v. THE ATTORNEY GENERAL OF CANADA *et al.*
PLACE OF HEARING:	HEARD BY ONLINE VIDEO CONFERENCE HOSTED BY THE REGISTRY
DATE OF HEARING:	FEBRUARY 28 AND MARCH 1, 2022
REASONS FOR JUDGMENT BY:	STRATAS J.A.
CONCURRED IN BY:	LOCKE J.A.
CONCURRING REASONS BY:	WOODS J.A.
DATED:	DECEMBER 5, 2022

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