Federal Court of Appeal | Cour d'appel fédérale

Date: 20210729

Docket: A-237-19

Citation: 2021 FCA 157

CORAM: **STRATAS J.A.**
WEBB J.A.
RENNIE J.A.

BETWEEN:

ALEXION PHARMACEUTICALS INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

and

MINISTER OF HEALTH
FOR THE PROVINCE OF BRITISH COLUMBIA

Intervener

Heard by online video conference hosted by the registry on October 20 and 21, 2020.

Judgment delivered at Ottawa, Ontario, on July 29, 2021.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: WEBB J.A.
RENNIE J.A.

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REASONS FOR JUDGMENT

STRATAS J.A.

[1] Alexion Pharmaceuticals Inc. developed the patented medicine, Soliris. It now manufactures and markets it. Soliris is a breakthrough treatment for two rare and life-threatening blood-related disorders.

[2] The Patented Medicine Prices Review Board started proceedings into whether Alexion priced Soliris excessively contrary to the *Patent Act*, R.S.C. 1985, c. P-4. It found that it did. It ordered Alexion to forfeit excess revenues earned between 2009 and 2017.

[3] In finding that Alexion priced Soliris excessively (at paras. 167-168), the Board relied upon the fact that the list price of Soliris was higher than the price in one of the seven countries used for comparison purposes. In other words, according to the Board, the price of Soliris had to be lower than that of all seven comparator countries. This was the first time the Board ever imposed that requirement.

[4] Alexion applied for judicial review to the Federal Court. The Federal Court (*per* Gleeson J.) dismissed Alexion's application for judicial review: 2019 FC 734, [2019] 4 F.C.R. 418. It found that the Board's decision was reasonable because it was entitled to significant deference. Alexion now appeals to this Court.

[5] In my view, we should set aside the judgment of the Federal Court. Making the judgment the Federal Court should have made, we should grant Alexion's application for judicial review, quash the Board's decision and remit the matter to it for redetermination, all with costs.

A. An introduction: some jurisprudential background

[6] After the Board's decision and after the Federal Court's dismissal of Alexion's application for judicial review, the Supreme Court of Canada released its seminal decision concerning the substantive review of administrative decisions, *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, 441 D.L.R. (4th) 1.

[7] *Vavilov* did not substantially change the jurisprudence in this Court concerning the unreasonableness of outcomes reached by administrators: *Entertainment Software Association v. Society of Composers, Authors and Music Publishers of Canada*, 2020 FCA 100 at paras. 22-37. The approach is a contextual one that considers the ambit of acceptable and defensible decision-making open to administrators or, put another way, the constraints acting upon administrators. However, *Vavilov* did change the law substantially by requiring that reviewing courts be able to discern a reasoned explanation for administrators' decisions. This change in the law affects the outcome of this appeal.

[8] Before *Vavilov*, the Supreme Court instructed us to do our best to try to sustain the outcomes reached by administrators. Accordingly, to that end, reviewing courts could pick up an administrator's pen and write supplemental reasons supporting the administrators' outcomes. This sometimes put reviewing courts in the invidious and uncomfortable position of acting as a ghostwriter for administrators, coopering up their decisions. See generally *Newfoundland and Labrador Nurses' Union v. Newfoundland and Labrador (Treasury Board)*, 2011 SCC 62, [2011] 3 S.C.R. 708.

[9] Many of us recoiled at this. We saw this as antithetical to the reviewing courts' role as an independent reviewer: see *Lemus v. Canada (Citizenship and Immigration)*, 2014 FCA 114, 372 D.L.R. (4th) 567 at para. 33; *Bonnybrook Park Industrial Development Co. Ltd. v. Canada (National Revenue)*, 2018 FCA 136; 44 Admin. L.R. (6th) 71 at paras. 89-94 in dissent. As well, we were concerned that "in trying to sustain an outcome reached by flawed reasoning, [reviewing courts] might be coopering up an outcome that the administrator, knowing of its error, might not have itself reached": *Lemus* at para. 33.

[10] Had we considered this appeal before *Vavilov*, we would have had to consider whether we should cooper up the Board's decision. But no longer. *Vavilov* recognizes the shortcomings in the former law and fixes them. It now requires us to ask if there is a sufficient reasoned explanation in support of the Board's decision. If there is not, the decision is unreasonable and must be quashed. Here, the Board's decision falls significantly short of the mark.

[11] As well, the reasoned explanation provided by the Board—such as it is—raises real concerns about its substantive reasonableness in some respects. In particular, certain words the Board used suggest that it went beyond its permissible statutory mandate by regulating the reasonableness of pricing, rather than preventing abusive pricing, *i.e.*, excessive pricing made possible by the abuse of the monopoly power given by a patent.

B. *Vavilov* and reasoned explanations

[12] *Vavilov* tells us that a reasoned explanation has two related components:

- *Adequacy*. The reviewing court must be able to discern an "internally coherent and rational chain of analysis" that the "reviewing court must be able to trace" and must be able to understand. Here, an administrator falls short when there is a "fundamental gap" in reasoning, a "fail[ure] to reveal a rational chain of analysis" or it is "[im]possible to understand the decision maker's reasoning on a critical point" such that there isn't really any reasoning at all: *Vavilov* at paras. 103-104.

- *Logic, coherence and rationality*. The reasoning given must be "rational and logical" without "fatal flaws in its overarching logic": *Vavilov* at para. 102. Here, the reasoning given by an administrator falls short when it "fail[s] to reveal a rational chain of analysis", has a "flawed basis", "is based on an unreasonable chain of analysis" or "an irrational chain of analysis", or contains "clear logical fallacies, such as circular reasoning, false dilemmas, unfounded generalizations or an absurd premise": *Vavilov* at paras. 96 and 103-104.

[13] These shortcomings must be evident on "critical point[s]": *Vavilov* at paras. 102-103. The "critical point[s]" are shaped, in part, by "the central issues and concerns raised by the parties": *Vavilov* at paras. 127-128. They are also points that are "sufficiently central or significant" such that they point to "sufficiently serious shortcomings in the decision": *Vavilov* at para. 100. They

must be “more than merely superficial or peripheral to the merits of the decision”: *Vavilov* at para. 100.

[14] Of the two components, the one I have called “adequacy” is the most challenging. What should reviewing courts look at in order to assess adequacy?

[15] The express reasons are only one place for reviewing courts to look. The failure of the administrator’s reasons to mention something explicitly is not necessarily a failure of “justification, intelligibility or transparency”: *Vavilov* at paras. 94 and 122. One must look at the reasons the administrator has written and read them “holistically and contextually” in “light of the record and with due sensitivity to the administrative regime in which they were given”: *Vavilov* at paras. 97 and 103.

[16] Thus, silence in the express reasons on a particular point is not necessarily a “fundamental gap” that warrants intervention by the reviewing court. The administrator’s reasons, read alone or in light of the record in a holistic and sensitive way, might legitimately lead the reviewing court to find that the administrator must have made an implicit finding. The evidentiary record, the submissions made, the understandings of the administrator as seen from previous decisions cited or that it must have been aware of, the nature of the issue before the administrator and other matters known to the administrator may also supply the basis for a conclusion that the administrator made implicit findings: *Vavilov* at paras. 94 and 123; and see, *e.g.*, *Bell Canada v. British Columbia Broadband Association*, 2020 FCA 140.

[17] In reviewing administrators' reasons, a reviewing court is allowed to "connect the dots on the page where the lines, and the direction they are headed, may be readily drawn": *Komolafe v. Canada (Minister of Citizenship and Immigration)*, 2013 FC 431, 16 Imm. L.R. (4th) 267 at para. 11; *Vavilov* at para. 97.

[18] For example, take the situation where an administrator needs to analyze several elements before deciding the matter and is aware of the elements (some implicitly, from submissions made or precedents it has cited) but discusses only a couple of them in detail. The reviewing court might be able to conclude from the circumstances that the administrator knew and considered all the elements but for reasons of concision the administrator did not expressly mention them all. Even where elements of the analysis are left out and, in the whole scheme of things, the omissions are minor or inconsequential, the decision is "not undermine[d] as a whole" and must stand: *Vavilov* at para. 122.

[19] When is a reasoned explanation on a key point inadequate?

[20] The administrator must provide enough to "assur[e] the parties that their concerns have been heard", demonstrate that it "actually listened to the parties" and show it was "actually alert and sensitive to the matter before it": *Vavilov* at paras. 127-128. To this end, this Court has spoken of the need for reviewing courts to understand "the substance of the decision" along with "why the [administrator] ruled in the way that it did" so that it "can assess, meaningfully, whether the [administrator] met minimum standards of legality": *Vancouver International*

Airport Authority v. Public Service Alliance of Canada, 2010 FCA 158, [2011] 4 F.C.R. 425 at para. 16.

[21] In some cases, however, the requirement of a reasoned explanation is higher:

> Where the impact of a decision on an individual's rights and interests is severe, the reasons provided to that individual must reflect the stakes. The principle of responsive justification means that if a decision has particularly harsh consequences for the affected individual, the decision maker must explain why its decision best reflects the legislature's intention.

(*Vavilov* at para. 133.) In such cases, the reviewing court might insist that the administrator show it has understood and grappled with the consequences of its decision: *Vavilov* at para. 134, citing *Chieu v. Canada (Minister of Citizenship and Immigration)*, 2002 SCC 3, [2002] 1 S.C.R. 84.

[22] However, *Vavilov* reminds reviewing courts that they are only reviewing courts. They must not apply the requirement of a reasoned explanation in a way that transforms reasonableness review into correctness review. That would return us to the bad old days in the 1960's and 1970's when reviewing courts would come up with any old excuse to strike down decisions they disliked—and often did: see *Canadian Copyright Licensing Agency (Access Copyright) v. Canada*, 2018 FCA 58, 422 D.L.R. (4th) 112 at paras. 61-65.

[23] Reviewing courts will mistakenly fall into correctness review when they assess reasons "against a standard of perfection" and hold administrators to the "standards of academic logicians": *Vavilov* at paras. 91 and 104.

[24] Reviewing courts must remember that administrators, not the reviewing courts, are the merits-deciders: *'Namgis First Nation v. Canada (Fisheries and Oceans)*, 2019 FCA 149; *Forest Ethics Advocacy Association v. Canada (National Energy Board)*, 2014 FCA 245, [2015] 4 F.C.R. 75; *Association of Universities and Colleges of Canada v. Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22, 428 N.R. 297 at paras. 14-20; *Bernard v. Canada (Revenue Agency)*, 2015 FCA 263, 9 Admin. L.R. (6th) 296 at paras. 13-28. In deciding the merits, administrators, some of whom are not lawyers, may not "deploy the same array of legal techniques that might be expected of a lawyer or judge" and so "'administrative justice' will not always look like 'judicial justice'": *Vavilov* at paras. 92 and 119. To expect otherwise is to overly judicialize administrative processes, threatening their efficiency and potentially undermining the very reasons why the legislator entrusted this jurisdiction to the administrator in the first place: see, *e.g.*, *Canadian Union of Public Employees, Local 301 v. Montreal (City)*, [1997] 1 S.C.R. 793, 144 D.L.R. (4th) 577 at para. 39.

[25] In the end, "a reviewing court must ultimately be satisfied that the [administrator's] reasoning 'adds up'": *Vavilov* at para. 104.

C. *Vavilov* and outcomes

[26] As mentioned above, reasonableness review under *Vavilov* also requires an assessment whether the outcome reached is acceptable and defensible. It must be within the constraints imposed by matters such as the authentic meaning of the governing legislation (including the administrator's mandate, the scope of its discretion, and the nature of the administrator), the

evidence adduced, and the submissions of the parties—matters that will vary according to the context. These constraints affect the ambit of decision-making by the administrator that will pass muster under reasonableness review. Much has been said about how these constraints can practically play out in *Entertainment Software Association* at paras. 26-36.

[27] In this case, the appellant raises the issue whether the Board went beyond the biggest constraint of all: the limits of its power, appropriately interpreted, to find excessive pricing under section 85 of the *Patent Act*. It says that rather than policing excessive pricing under section 85, the Board engaged in regulation and control to ensure reasonable pricing, an exercise it says is outside of section 85.

D. Outcomes and reasoned explanations: the relationship between the two

[28] *Vavilov* is predicated on the idea that there is an intimate relationship between reasoned explanations and outcomes.

[29] Conceptually *Vavilov* frequently discusses the two concepts as if they are separate. But, as a practical matter, they may be intertwined. For example, the administrator might not have supplied a reasoned explanation in support of an outcome because one is not possible on the wording of the empowering legislation. The inadequacy of the reasoning is a problem but the bigger problem may be that the administrator is trying to reach an unreasonable outcome. In many cases, the two are different sides of the same coin.

[30] As a practical matter, imposing a requirement on an administrator to ensure that a reasoned explanation is discernable forces it to think through the problem, grapple with it, and decide it on its merits. This, after all, is the task the legislature has given it to do.

[31] Some administrators just assert an outcome but unless a reasoned explanation can be discerned, a reviewing court cannot tell if the administrator has done its job. Conversely, an outcome explained by the administrator that appears significantly incomplete or irrational on its face might be evidence that the outcome cannot be supported by the facts and the law.

[32] Below, I explain that a reasoned explanation for some key portions of the Board's decision cannot be discerned. But that may be just part of the unreasonableness problem in this case. It may be that the Board was trying to reach an outcome that on the facts and the law was not reasonably open to it. So at times in this analysis, the failure to discern a reasoned explanation closely relates to the possible unreasonableness of the outcome the Board was trying to reach. In other words, in the analysis that follows, the requirements of a reasoned explanation and an acceptable and defensible outcome will often overlap.

[33] In the end, for the reasons that follow, this matter should be sent back to the Board for redetermination. In redetermining this matter, it will be for the Board—in an open-minded, non-tendentious way—to examine the evidence, interpret the legislation, fairly apply the legislation to the evidence and ensure that a reasoned explanation for its outcome can be discerned.

E. Analysis of the Board's decision

[34] Section 85 is the law. The Board's analysis should start with the law. Whatever the Board does must be consistent with the law.

[35] Subsection 85(1) empowers the Board to determine "whether a medicine is being or has been sold at an excessive price in any market in Canada". Five factors are relevant:

(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).

[36] In an excessive pricing case, the Board must interpret section 85. It does so by considering its text, context and purpose: *Vavilov* at para. 120; *Re Rizzo & Rizzo Shoes Ltd.*, [1998] 1 S.C.R. 27, 154 D.L.R. (4th) 193; *Bell ExpressVu Limited Partnership v. Rex*, 2002 SCC 42, [2002] 2 S.C.R. 559; *Canada Trustco Mortgage Co. v. Canada*, 2005 SCC 54, [2005] 2 S.C.R. 601. This also applies to the determination of the other relevant factors the Board may consider under subsection 85(2). In interpreting section 85, the Board must show that it is "alive to [the] essential elements" of text, context and purpose, at least "touch[ing] upon only the most salient aspects": *Vavilov* at paras. 120-122.

[37] It must also interpret section 85 in a genuine, non-tendentious, non-expedient way: *Vavilov* at paras. 120-121. Result-oriented analysis is no part of the exercise: *ibid.*; see also *Williams v. Canada (Public Safety and Emergency Preparedness)*, 2017 FCA 252, [2018] 4 F.C.R. 174 at paras. 41-52; *Canada v. Cheema*, 2018 FCA 45, [2018] 4 F.C.R. 328 at paras. 73-86; *Hillier v. Canada (Attorney General)*, 2019 FCA 44, 431 D.L.R. (4th) 556 at paras. 18 and 24-27; *Canada (Attorney General) v. Utah*, 2020 FCA 224, 455 D.L.R. (4th) 714 at para. 15 (all in the context of courts but equally applicable to administrators).

[38] The Board has enacted guidelines to assist itself and others in applying section 85: Patented Medicine Prices Review Board of Canada, *Compendium of Policies, Guidelines and*

Procedures, updated February 2017, online: www.pmprb-cepmb.gc.ca. It has the power to do so: *Patent Act*, s. 96(4). The Guidelines themselves are only non-binding guidance, not law. They must be consistent with the law of the land, here section 85: *Maple Lodge Farms Ltd. v. Government of Canada*, [1982] 2 S.C.R. 2, 137 D.L.R. (3d) 558 at 6-7 S.C.R.; *Kanthasamy v. Canada (Citizenship and Immigration)*, 2014 FCA 113, [2015] 1 F.C.R. 335 at para. 53, rev'd on another ground 2015 SCC 61, [2015] 3 S.C.R. 909. The Board has no power to amend section 85 through the Guidelines.

[39] As non-binding guidance, the Guidelines can be departed from. But any departures from the Guidelines must be reasonable, at least in the sense that they are not inconsistent with a reasonable interpretation of section 85. And there must be a reasoned explanation for any departures from the Guidelines.

[40] The Federal Court suggested (at para. 60) that when deciding whether a medicine is selling at an excessive price, the Board "is not required to apply any defined test" and "there is no correct test". Perhaps the Federal Court was alluding to the fact that section 85 is rather broad and the elements to be considered seem somewhat loose. But most definitely there is a test in section 85 and to be reasonable the Board's decision must interpret it and follow it: *Canada (Attorney General) v. Almon Equipment Limited*, 2010 FCA 193, [2011] 4 F.C.R. 203, still valid and consistent with *Vavilov*. Section 85, as interpreted in accordance with its text, context and purpose, supplies the test. While section 85 gives the Board a very wide discretion, discretion always is subject to the limits imposed by the authentic meaning of the legislation granting it and must always remain within those limits: *Roncarelli v. Duplessis*, [1959] S.C.R. 121, 16 D.L.R.

(2d) 689; *Shell Canada Products Ltd. v. Vancouver (City)*, [1994] 1 S.C.R. 231, 110 D.L.R. (4th) 1.

[41] In this case, Alexion submitted to the Board that the Board's decision to require Soliris to be below the price in the seven comparator countries was contrary to section 85 in that it exalts the factor of international prices under paragraph 85(1)(*c*) above all other factors and effectively reads out of the section the factor of the consumer pricing index in paragraph 85(1)(*d*): Alexion's Redacted Amended Response to the Statement of Allegations, dated February 16, 2016 (Appeal Book, v. 1, p. 205). It makes the same submission to us. In this Court, Alexion adds that in doing this the Board read out six of the seven countries it normally uses for comparison purposes, fastening onto only one, the one with the lowest price.

[42] Alexion's submission is key to the outcome of the case and goes to the most central concern that a reviewing court can have: whether an administrator is staying within the powers given by its governing legislation, reasonably interpreted.

[43] Yet, the Board did not appear to deal with Alexion's submission, either expressly or implicitly. It said (at para. 134) that it may "determine the relevance and weight of each factor" but much of its analysis is merely conclusory: "based on a thorough consideration of the submissions of the parties and the evidence in this proceeding, and after applying its own expertise and judgment…" (at para. 121).

[44] At best, on this point the Board obfuscated, making it impossible for a reviewing court to know whether the Board has helped itself to a power it does not lawfully have. By obfuscating, the Board has effectively put itself beyond review on this point, asking the Court to sign a blank cheque in its favour. But this Court does not sign blank cheques. Administrators cannot put themselves in a position where they are not accountable: *Canada (Citizenship and Immigration) v. Canadian Council for Refugees*, 2021 FCA 72, 79 Imm. L.R. (4th) 1 at paras. 102-105; *Canada (Citizenship and Immigration) v. Tennant*, 2018 FCA 132 at paras. 23-24.

[45] Of more concern is that, as will be seen, the Board may have helped itself to powers the statute has not given it. The absence of a reasoned explanation on certain points means that we cannot be more definitive than that.

[46] In this case, the Board seems to have decided that it could determine the matter on the basis of the subsection 85(1) factors. Thus, under the wording of subsection 85(2), it could not resort to subsection 85(2). For good measure, at one point the Board explicitly said (paras. 135-140) that it would not consider the subsection 85(2) factors, in particular the cost of making and marketing the medicine.

[47] But absent some further explanation in the Board's reasons—and there is none here—the Board appears to have gone ahead and considered the issue of cost under subsection 85(2). It looked at prices in other markets as a reasonable surrogate for estimating the cost of making and marketing the medicine, a subsection 85(2) factor (at para. 160). As well, the Board found (at paras. 33, 166 and 202) that the price charged in other countries and in particular, the U.K.

allowed it to draw a conclusion that Soliris is covering its costs and earning a nominal rate of return. It also considered costs when it said (at para. 182) that "it is fair to assume that the price in the comparator countries is set so as to cover costs". The Board also considered (at para. 152) some commentary on the pricing situation in countries beyond the seven comparator countries for which it had no evidence of the actual price in those countries. This is a matter that normally can only be done under subsection 85(2) and with evidence in support.

[48] A more fundamental concern is that the Board has misunderstood the mandate Parliament has given to it under section 85. At a minimum, a reasoned explanation on this is missing.

[49] 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.

[50] In this area, the *Patent Act* aims at a balance between incentivizing the research and development of patented medicines and their introduction into Canada through the grant of a monopoly and protecting against abuse of that monopoly: *Manitoba Society of Seniors* at para. 21; *ICN Pharmaceuticals Inc.* General price control is no part of the exercise.

[51] Judging by the reasons it gave, the Board disregarded most of the foregoing authorities. Instead, it plucked one excerpt from *Celgene* to interpret its mandate (at para. 108) as relating to consumer protection at large. This led it to suggest that its mandate was to ensure reasonable pricing, not to prevent the sort of abusive pricing that undermines the balance of objectives in the preceding paragraph. The Board did this in two general ways:

- the Board spoke of its supposed "consumer protection" mandate (at paras. 107-109, 161, 233, 244 and 246). The case law set out above does not suggest the Board has such a mandate.

- the Board referred to its supposed general "reasonable pricing" mandate, a mandate to ensure that the prices of patented medicines do not rise to "unacceptable levels"; it also spoke of the statutory standard to be applied or the price of Soliris as being whether it was "unreasonable" as opposed to "excessive":

Board's reasons at paras. 108, 152, 161-162, 166, 216. Again, the case law set out above suggests that this is not the Board's task.

[52] In this regard, Section 85 speaks of "excessive" pricing, not "reasonable" pricing. The two seem much different. If in fact they are not different, in the circumstances of this case the Board had to explain why. Nowhere does the Board do so. Indeed, nowhere does it grapple with the concept of "excessive pricing" or show that it had to deal with this issue of legislative interpretation as a key part of this case.

[53] The Board draws the standard of "reasonable pricing" from, among other things, certain statements in Parliamentary debates. But here, caution must be exercised. Such statements have "frailties [that] are many" and are of "limited weight": *Rizzo* at para. 35; *H.L. v. Canada (Attorney General)*, 2005 SCC 25, [2005] 1 S.C.R. 401 at para. 106. The authentic meaning of the legislation, here section 85, is the law, not what some politicians may have said about it at some place, at some time, for whatever reason: *Schmidt v. Canada (Attorney General)*, 2018 FCA 55, [2019] 2 F.C.R. 376 at para 31; ***Williams*** at paras. 50-51. As well, on occasion one will see in the reasons for judgment of a court loose wording that is not intended to set out the authentic meaning of the legislation as revealed by a consideration of its text, context and purpose. For example, sometimes a judge will use informal summary words and phrases rather than technical legal phrasing for the purposes of economy and clarity. Administrators must always remember that such informal phrasing does not prevail over the authentic meaning of the legislation which is the law: *Utah* at para. 28 and cases cited therein.

[54] It is true that Soliris is a very expensive medicine and has a potentially large impact on health care budgets. Many medicines that take decades to develop, like Soliris, for ultra-rare conditions, such as the condition Soliris treats, are very expensive. But, absent some sort of reasoned explanation (if one is available), this says nothing about whether the price is "excessive" within the meaning of section 85.

[55] There were many other signs of the Board pursuing a general price regulation mandate. In its decision, the Board took into account the following:

- the effects of the pricing of Soliris on provincial budgets (paras. 27 and 166-167). This may be a logical factor if the Board is supposed to be engaged in price control, *i.e.*, the task of ensuring that pricing is "reasonable". But it is hard to see its relevance to the standard in section 85 of excessive pricing. At the very least, the Board had to give a reasoned explanation explaining the relevance of provincial budgets. It did not do so.

- the mere fact that the price of Soliris has been under scrutiny in Ireland and New Zealand (at para. 152) but without information on the actual price in those jurisdictions (see para. 154). Without further explanation, this does not logically lead to a finding that the price in Canada is "excessive".

- some commentators in other jurisdictions had suggested that the price of Soliris is "exorbitant" and "astronomical" and that "Alexion refused to provide a

reasonable and sustainable price" (at para. 152). But a finding that the price of a medicine is very high and not sustainable on other countries' health budgets does not, without explanation, necessarily lead to the conclusion that it is "excessive" in Canada or in the sense meant in section 85.

- the price of Soliris in the UK has been under attack for being unreasonable (at para. 162). The fact that it is under attack does not necessarily mean that it is unreasonable, even if "unreasonableness" were the statutory standard in this case.

- patented medicines are generally more expensive internationally, and in particular in the U.S.A., than in Canada (at para. 163). This seems to be a relevant factor for general price regulation. If it is relevant to "excessive" pricing under section 85, the Board should have explained why.

- the price charged by Alexion in the United States suggests that Alexion is willing to supply Soliris at a much lower price (at para. 165) and that benchmarking to the LIPC would be "generous to Alexion" (at para. 162). While this might be an indicator whether the price of a patented medicine is reasonable, it is not necessarily an indicator of excessiveness. At a minimum, this requires explanation.

- the fact that Canadians should have the benefit of the lowest price being paid in any of the comparator countries (at paras. 166-167). The Board added that "at no

> time in the future should Canadians be paying a higher price for Soliris than the price in the lowest priced comparator country" (at para. 202). Statements like these, unless explained against the statutory standard, smack as price control, not policing for excessiveness.

[56] At no point did the Board examine in a rigorous way the purposes of section 85 and the *Patent Act* as a whole, including the important balance referred to in paragraph 50, above.

[57] One of the most controversial parts of the Board's decision in this case was its departure from the Guidelines—which normally refer to the highest international price as a key comparator—to find Soliris was excessive because it was more than the lowest international price.

[58] Where a decision maker does depart from longstanding practices, established internal authority, or guidelines it bears the burden of explaining that departure in its reasons. If the decision maker does not satisfy this burden, the decision will be unreasonable*: Vavilov* at para. 131.

[59] The obligation on the Board to explain its decision to depart from the Guidelines in this case was high because of its prime significance to Alexion. It increased Alexion's potential liability almost twenty-fold: Federal Court reasons at para. 27; Board reasons at para. 11. And that decision was key to the outcome in the sense that it conveniently got around some evidentiary shortcomings that might have otherwise stood in the way of an order against

Alexion: the Board suggested at para. 193-196 that the evidence may not be sufficient to find the price was excessive on the more usual "HIPC measure". Finally, the Board's decision to depart from the Guidelines had the effect of restricting Soliris in the foreseeable future to a price "no higher than the lowest price" in the seven comparator countries: Board reasons at para. 1.

[60] As well, the Board's departure from the Guidelines and its imposition of a requirement that the medicine be lower than all seven comparator countries was unprecedented. It was a marked departure from its own authorities. In the circumstances of this case, a coherent, relatively detailed explanation is called for. Without it, the departure appears arbitrary and without regard to principles or laws, nothing more than the product of "untrammeled discretion": *Roncarelli,* above.

[61] The Board said (at para 166) that it had "unique circumstances" before it that justify its departure from the Guidelines but it did not specify what those circumstances were, beyond noting the following:

- A report from the United Kingdom that criticized the price of Soliris in the United Kingdom as potentially unreasonable (at para. 162). The Board found this showed that allowing Alexion to sell at that price would be generous. However, the report did not make an explicit finding about the reasonableness or excessiveness of the price in the United Kingdom.

- Canadian prices for other drugs were generally lower than those in the United States and the price of Soliris in Canada exceeded the price in the United States at some points (paras. 163-164). The panel also stated incorrectly that prices in Canada were 20% higher than the US in 2016.

In oral argument, the Attorney General could not point out any other "unique circumstances" that the Board might have relied upon.

[62] The two factors the Board set out suggest only that Soliris is also expensive in other jurisdictions and Soliris bucks the general trend of drugs being cheaper in Canada than in the United States. But, by themselves, these two factors do not logically support departing from the Guidelines unless, of course, the Board was doing so just to get a specific result, which itself would be a ground for setting aside its decision: *Vavilov* at paras. 120-121.

[63] The Federal Court considered the Board's reasons for departing from the Guidelines to be "substantial and compelling": Federal Court's reasons at paras. 63-68. I see no basis for that conclusion. The Board's reasons—viewed holistically and in light of the record, alert to both explicit and implicit findings—are thin and impoverished. It is not enough to allude vaguely to "unique circumstances" and then just name two circumstances that do not appear to be unique and that fall short of logically supporting the sort of significant, unprecedented departure from the Guidelines the Board took here.

[64] As well, it is noteworthy that in this area of its reasons, the Board never justifies its decision on the basis of section 85 or, specifically, the text, context or purpose of section 85. Had it provided a reasoned explanation of the proper meaning of section 85 earlier in its reasons, the Court might be able to understand why the unprecedented use of the lowest international price was warranted. But no reasoned explanation on that point is discernable.

[65] The Board ordered Alexion to forfeit excess revenues earned between 2009 and 2017 to the Crown. It did so under the authority of section 83. This remedial order is either substantively unreasonable or a reasoned explanation for it cannot be discerned.

[66] The Board did not explicitly or implicitly consider the text, context or purpose of section 83. If it did so, its reasons, explicit or implicit, cannot be discerned.

[67] As we have seen, under section 85 the Board used the lowest international price of the seven comparator countries as the benchmark to determine if a price is excessive. But then under section 83 it ordered a remedy on the basis of the highest international price. The Board did not explain this inconsistency in a clear and coherent way, including how that approach was consistent with the text, context and purpose of section 83. Also, earlier in its reasons the Board declined to rule on certain evidentiary objections about the data concerning the highest international price (at paras. 193-196) but does not explain how it can then order a remedy based on this same data. Without an adequate explanation, it seems arbitrary and without regard to principles or laws, nothing more the product of an untrammeled discretion.

[68] In making its remedial order, the Board did not consider the actual prices received by Alexion for Soliris. It had evidence of these before it. But it used list prices instead. As a result, the amount that Alexion was ordered to pay to the Crown included revenues that Alexion had never actually received. This does not appear to be consistent with the language of section 83 or its purpose. At a minimum, the Board never provides a reasoned explanation regarding how it is consistent with section 83.

F. Conclusion

[69] For the foregoing reasons, the Board's decision cannot stand. It must be quashed and remitted to the Board for re-determination.

[70] After receiving submissions from the parties on the redetermination, the Board is free to make whatever decision seems appropriate to it based on a reasonable interpretation of the legislation as applied to the evidence in the case. It may or may not reasonably find excessive pricing under section 85. If it does, it may or may not make a remedial order under section 83. If it does, that order may be higher or lower than the one previously made depending on how section 83, reasonably interpreted, applies to the evidence in the case. In making its decision, the Board must ensure that a reasoned explanation is discernable on the key issues—the issues on which the case will turn and the issues of prime importance raised in the parties' submissions.

G. Proposed disposition

[71] I would allow the appeal, set aside the judgment of the Federal Court dated June 12, 2019 in file T-1596-17 and, making the judgment the Federal Court should have made, grant Alexion's application for judicial review and remit the matter to the Patented Medicine Prices Review Board for redetermination. Alexion shall have its costs here and below.

"David Stratas"
J.A.

"I agree
Wyman W. Webb J.A."

"I agree
Donald J. Rennie J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-237-19

APPEAL FROM A JUDGMENT DATED MAY 23, 2019 OF THE HONOURABLE MR. JUSTICE GLEESON, NO. T-1596-17

STYLE OF CAUSE:	ALEXION PHARMACEUTICALS INC. v. ATTORNEY GENERAL OF CANADA AND MINISTER OF HEALTH FOR THE PROVINCE OF BRITISH COLUMBIA
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	HEARD BY ONLINE VIDEO CONFERENCE HOSTED BY THE REGISTRY ON OCTOBER 20 AND 21, 2020.
REASONS FOR JUDGMENT BY:	STRATAS J.A.
CONCURRED IN BY:	WEBB J.A. RENNIE J.A.
DATED:	JULY 29, 2021

APPEARANCES:

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