PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act*,
R.S.C., 1985, c. P-4, as amended

AND IN THE MATTER OF
Horizon Pharma (the "Respondent")
and the medicine Cysteamine Bitartrate sold by the Respondent under the trade name Procysbi

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Submissions regarding the decision of the Federal Court of Appeal in *Alexion Pharmaceuticals Inc v. Attorney General of Canada*

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I. Overview

1) The Federal Court of Appeal rendered its decision in *Alexion Pharmaceuticals Inc v Attorney General of Canada* (*"Alexion"*)[1] on July 29, 2021.

2) The Federal Court of Appeal overturned the decision of the Federal Court and quashed the decision of the Patented Medicine Prices Review Board ("the Board" or "the Panel").

3) The Federal Court of Appeal found that the Panel did not provide a sufficiently reasoned explanation in support of its decision in *Alexion*. Consequently, the matter was remitted back to the *Alexion* Panel with directions to provide whatever decision seems appropriate to it along with a reasoned explanation.

4) The Federal Court of Appeal was careful to note that it is the administrative tribunal that decides the merits of a case and not the Court.[2] In the words of Stratas J.A, "… *Vavilov* reminds reviewing courts that they are only reviewing courts".[3]

5) Board Staff submits that the decision of the Federal Court of Appeal in *Alexion* does not dictate a particular result in Procysbi. Rather, the decision cautions the Board about the importance of satisfying the *Vavilov* standard of thorough and detailed reasons in support of whatever findings the Board chooses to make.

6) Board Staff further submits that, in view of the evidence and argument provided to the Board in Procysbi, the Board has an ample factual and legal foundation to make a determination of excessive pricing, according to section 85 of the *Patent Act*, and to meet the *Vavilov* standard.

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[1] *Alexion Pharmaceuticals Inc. v Canada (Attorney General),* 2021 FCA 157 (CanLII).
[2] *Ibid* at para 24.
[3] *Ibid* at para 22; *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 ("*Vavilov*").

II. Review of the Federal Court of Appeal's decision

7) In *Alexion*, the focus of the Federal Court of Appeal was the adequacy of the reasons of the *Alexion* Panel, as can be appreciated from the bolded references in the following paragraphs quoted from *Alexion*, as well as paragraphs 44, 45, 55, 59, 60, 63, 65, 66, 70 in *Alexion*:

> [7] … 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.
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> [10] … 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.**
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> [33] … 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.**
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> [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).
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> [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). …
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> [54] It is true that Soliris is a very expensive medicine and has a potentially large impact on health care budgets. … **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.

> [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.
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> [64] … 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.**
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> [67] As we have seen, under section 85 the Board used the lowest international price of the seven comparator countries as the benchmark … 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.
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> [68] In making its remedial order, the Board did not consider the actual prices received by Alexion for Soliris. … At a minimum, the **Board never provides a reasoned explanation** regarding how it is consistent with section 83.

8) Thus, the Federal Court of Appeal emphasized that the Board must explain very clearly and in great detail why it has reached its decision and why that decision is in harmony with the legislation and the evidence.

9) Finally, the Federal Court of Appeal acknowledges that the Board is a specialized tribunal with the expertise and experience required to reach whatever decision it finds appropriate in light of the law and the evidence before it. Nevertheless, the Federal Court of Appeal reminded the Board that, to the extent that a factor in section 85 is going to be weighed more heavily than others, as occurred in *Alexion*, this must be expressly and fully explained.

III. Section 85 of the *Patent Act*

10) The Federal Court of Appeal confirmed at paragraph 40 of *Alexion* that section 85 of the *Patent Act* gives the Board a very wide discretion.

11) Moreover, the Supreme Court of Canada confirmed in *Vavilov* at paragraph 28 that "expertise simply inheres in an administrative body by virtue of the specialized function designated for it by the legislature" and, at paragraph 40, that the expertise of an administrative tribunal remains a relevant consideration.

12) Accordingly, it is the Board and not the Court that is entrusted by Parliament with the expertise and decision-making power on how to exercise its discretion.

IV. The Role of the Guidelines

13) The Federal Court of Appeal confirmed the non-binding nature of the Guidelines,[4] reflecting the clear and unassailable wording of section 96(4) of the *Patent Act:* "… such guidelines are not binding on the Board or any rights holder or former rights holder."

14) The fact that Parliament expressly provided in section 96(4) that the Guidelines are not binding provides a clear indication that Parliament intended for the Guidelines to be general parameters that Board Panels are not required to apply. It is a recognition by Parliament that the Guidelines cannot and do not apply to every possible factual permutation that the Board will encounter.

15) However, the Federal Court of Appeal also expressed its opinion that a reasoned explanation should be provided for a departure from the Guidelines.

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[4] *Alexion*, *supra* note 1 at paras 38-39.

16) Although the Federal Court of Appeal did find that there is a burden on the Panel to justify any departure from the Guidelines, it does not suggest that this is an onerous burden.

17) Even more importantly, the Board's Guidelines are not directed to the tribunal's decision-maker (in the case of the Board, the Panel Members). Rather, the Guidelines provide general parameters to Board staff and patentees; the Guidelines are not intended to, and do not, have any bearing on Panels when engaging in their quasi-judicial functions. In other words, the Guidelines are administrative, not adjudicative. The Guidelines are most accurately characterized as a triage procedure for Board Staff and patentees to assist them in determining whether an adjudicative hearing is likely to arise in any given situation.

18) In the context of Procysbi, the reasoned explanation for deviation from the Guidelines is provided in the Written Submissions of Board Staff ("Written Submissions") and was expanded upon in oral submissions. For ease of reference the following paragraphs in the Written Submissions elaborate why the Guidelines do not properly implement the section 85 factors in the context of Procysbi:

    a) The level of therapeutic improvement from Procysbi does not fit within the existing categories in the Guidelines (see paragraphs 256–271 of Written Submissions);
    b) Even if Procysbi did fit within the existing categories in the Guidelines, the price tests associated with those categories are not appropriate on the facts of this case. Professor Schwindt's evidence in that regard is instructive (see paragraphs 263 – 283 of the Written Submissions).

19) When considering the role of the Guidelines, it is important to also keep in mind that section 85 gives the Board broad discretion. It does not prescribe how the factors are to be weighed in particular cases, as it recognizes that different facts may require a different application of the factors. In other words, Parliament

deliberately chose to delegate jurisdiction to weigh the factors to the expertise of the Board and not to a court. Consequently, while the Guidelines may provide assistance to the Board in how the assess the factors, the Supreme Court of Canada has also been clear that an administrative tribunal that is given broad discretion cannot fetter that discretion, such as by blindly following non-binding Guidelines.[5]

V. The balancing in the *Patent Act*

20) At paragraph 50 of *Alexion*, it was noted that the *Patent Act* provides a balance between (a) incentivizing research and the development of patented medicines through the granting of a monopoly, and (b) the need to protect against abuse of that monopoly. The submissions of Board Staff in Procysbi are consistent with this overall purpose: Board Staff has argued that the *Patent Act* read as a whole strikes this balance, and that on the facts of this particular case, Procysbi is excessively priced. In other words, all of the provisions of the *Patent Act* work together in harmony to achieve this balance. This is conclusively illustrated by the historical development of the Patent Act, as outlined in great detail in paragraphs 14 to 42 of the Reply Submissions of Board Staff.[6]

VI. The distinction between reasonable and excessive prices

21) The Federal Court of Appeal at paragraph 52 of *Alexion* noted the need for the Board in its reasons to grapple with the concept of "excessive pricing," and at paragraph 27, posited a difference between excessive pricing and reasonable pricing.

22) In his expert report and in his testimony, Professor Schwindt explained that economists have tools to deal with the identification and quantification of

[5] *Vavilov*, *supra* note 3 at para 108.
[6] See also Written Submissions paras 217-228; Reply Submissions of Board Staff paras 8-42; Transcript of Argument Vol 15 at 3401-3420 and Vol 17 at 4033-4034.

"excessive prices" and how those tools could be utilized in regard to determining a non-excessive price of Procysbi. Professor Schwindt's analysis supports Board Staff's submission that the price of Procysbi is excessive and that the application of the price tests proposed by Board Staff for Procysbi were not synonymous with price regulation and control. Rather, the approach proposed by Board Staff, in the current matter, was an application of the tools used by economists to determine excessive prices.

VII. Costs of Medicine cannot be considered under section 85(1)

23) The Federal Court of Appeal, at paras. 46 and 47 of *Alexion*, delineated a bright line between what type of evidence could be considered under section 85(1) in contrast to section 85(2). In the opinion of the Federal Court of Appeal, costs of a medicine have no place in the analysis under section 85(1). This is consistent with the submission of Board Staff that the evidence of Dr. Hay (and of Mr. Rosen in response) can **only** be considered **if** the Panel in the present matter cannot reach a conclusion under section 85(1).

VIII. The Board's Role with respect to excessive prices

24) Regarding the role of the Board with respect to excessive prices, Board Staff respectfully submits that this Board must follow the binding guidance provided by the Supreme Court of Canada, including its interpretation of prior Federal Court of Appeal case law. In several binding authorities, the Supreme Court and the Federal Court of Appeal have recognized that the Board was created to protect consumers from excessive pricing, and the *Patent Act* must be interpreted within that context.

25) At paragraph 49 of *Alexion,* is the Federal Court of Appeal suggests that the Supreme Court of Canada "loosely and occasionally" speaks of a consumer protection mandate related to the excessive pricing provisions in the *Patent Act*.

This overlooks the Supreme Court of Canada's clear guidance in *Celgene* that the excessive pricing regime in the *Patent Act* relates to protecting consumers from excessively priced patented medicines. It also does not address the guidance given by the Supreme Court of Canada with respect to the Federal Court of Appeal's prior decision in *ICN*. [7]

26) The Supreme Court of Canada unanimously held in *Celgene* that, when interpreting its legislation, the Board is entitled to be "guided by the **consumer protection** goals of its mandate," [emphasis added] i.e. "protecting Canadian purchasers". [8] In support of this finding, the Supreme Court of Canada made substantial references to comments of the Ministers of Consumer and Corporate Affairs during House of Commons debates, which were clear and emphatic that the legislation was intended to "strengthen consumer protection:" [9] (our emphasis in bold):

> But that does not mean that the Board misinterpreted the words "sold" and "selling" in the context of ss. 80(1)(*b*), 83(1) and 85. In rejecting the technical commercial law definition, the Board was guided by the consumer protection goals of its mandate, concluding that Celgene's approach would undercut these objectives by preventing the Board from protecting Canadian purchasers of Thalomid and other foreign-sold SAP patented medicines.
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> The Board's **interpretive choice** is supported by the legislative history. The Board was established in amendments contained in Bill C-22, *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, which received Royal Assent on November 19, 1987, as S.C. 1987, c. 41. Introducing the Bill for second reading, the Hon. Harvie Andre made the following relevant comments about the Board's objectives:
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> In essence, the amendments I propose in Bill C-22 will create a climate favourable to new investment in research and development by giving patent holding pharmaceutical firms in Canada a guaranteed period of protection. <u>These changes will</u>

[7] *Celgene Corp. v Canada (Attorney General),* 2011 SCC 1 (CanLII) [*Celgene*]; *ICN Pharmaceuticals, Inc. v Canada (Staff of the Patented Medicine Prices Review Board),* 1996 CanLII 4089 (FCA) [*ICN*].
[8] *Celgene, ibid* at para 25.
[9] *Celgene, ibid* at para 27.

also ensure consumer protection by creating a drug prices review board to monitor drug prices. . . .
. . .

I humbly submit that anybody who takes an objective view of what we are proposing will see that we have in place enormous checks and balances to ensure that consumer prices of drugs remain reasonable. They should look at what we will get by way of research and development, and at the jobs this will create.
. . .

Whatever costs might be associated with this legislation will be minimal. They will not hit the consumer. [Emphasis added.]

(*House of Commons Debates*, vol. I, 2nd Sess., 33rd Parl., November 20, 1986, at pp. 1369 and 1373)

When the *Patent Act* was further amended in 1993 (*Patent Act Amendment Act, 1992*, S.C. 1993, c. 2), the then Minister of Consumer and Corporate Affairs and Minister of State (Agriculture), the Hon. Pierre Blais, reiterated the Board's consumer protection mandate:

With Bill C-91, we also wanted to strengthen consumer protection, so that consumers can continue to obtain patented medicine at reasonable prices. I think that all Canadians are entitled to that.
. . .

. . . The board will thus be able to provide all Canadian consumers with even more effective price control. These new powers will authorize the board to order a reduction of prices it considers too high. . . .

. . . I am convinced that these new provisions will assure Canadian consumers, of reasonable prices, like those they have had since 1987.
(*House of Commons Debates*, vol. XII, 3rd Sess., 34th Parl., December 10, 1992, at pp. 14998 and 15001)
[Underlined emphasis added by Supreme Court of Canada]

27) In Board Staff's submission, this guidance from the Supreme Court of Canada cannot be accurately characterized as "loose" and "occasional". On the contrary, it is clear in its insistence that, in any interpretive task faced by the Board, including interpreting and applying section 85 to determine if the price of a patented medicine is excessive, the Board *must* consider its duty to protect consumers from excessive prices.

28) Furthermore, the Supreme Court of Canada in *Celgene* demonstrates that it is appropriate to have regard to the legislative history of the excessive pricing regime, including Parliamentary Debates. Hansard provides the context necessary to understand and apply the excessive pricing regime. It clarifies the intention of Parliament with regard to the interpretation and application of the Board's legislative framework. Thus, while it is true, as the FCA states in *Alexion*, that Hansard does not overwrite the express terms of legislation, Hansard remains an optimal tool to give effect to the will of Parliament when that will is not defined in the legislation itself (such as the absence of a definition for "excessive"). This, after all, is the ultimate goal of any statutory tribunal, including the Board: to give effect to the will of Parliament, as expressed in its home statute.

29) With respect to the prior Federal Court of Appeal decision in *ICN*, the Supreme Court of Canada in *Celgene* held that the Federal Court of Appeal correctly recognized that the "mischief" addressed by the excessive pricing regime in the *Patent Act* was to ensure that prices did not rise to "unacceptable levels". The Supreme Court of Canada in *Celgene* interpreted this as a recognition by the Federal Court of Appeal that the excessive pricing regime in the *Patent Act*, and the Board itself, are both intended to protect consumers.

30) In addition to the clear guidance of the Supreme Court of Canada in *Celgene* relating to *ICN,* the Federal Court of Appeal in *ICN* also directly addressed the Board's duty to protect consumers. When providing a legislative overview, the Federal Court of Appeal recognized that one of the objectives of the legislative

scheme was to make sure that Canadians have access to patented medicines which are reasonably priced, as set out at page 13 (cited to CanLII):

> The purpose of extending patent protection to medicines is to reward innovation and provide an incentive for pharmaceutical manufacturers to expend further resources in the research and development of new drugs. At the same time, it is believed that that objective must not overtake the need to ensure that Canadians have access to patented medicines which are reasonably priced. Two legislative frameworks for striking this balance have been pursued in Canada this century. The first in time involves a system of compulsory licensing. The second is a system of price regulation.

31) When reviewing the 1993 amendments in particular, the Federal Court of Appeal in *ICN* held that the protection of Canadian consumers was one of the features of the regime, as outlined at page 17 (cited to CanLII):

> The 1993 amendments to the Act and the enactment of the NOC Regulations affected the system in three major ways. The first two served to strengthen the position and rights of patentees. The third sought to protect the interests of Canadian consumers.

32) Finally, when determining the validity of the Board's determination as to whether an invention pertains to a medicine, the Federal Court of Appeal accepted that an interpretation should be given that would not permit pharmaceutical companies to avoid the Board's power to protect Canadian consumers from excessive pricing, as outlined at page 42 (cited to CanLII):

> Under the 1993 amendments to the Patent Act, the price review powers of the Board are intended to achieve the same result, with respect to the same spectrum of inventions. Thus, the broad interpretation of subsection 39(4) accepted by the courts is equally applicable to the present subsection 79(2). There is nothing to suggest that it is to be interpreted restrictively, as suggested by ICN. There need only be a slender thread of a connection between a patented invention and the medicine sold in Canada in order to satisfy the test for a nexus. The legislative reason for this is simple. Requiring a stronger nexus would provide a window of opportunity for pharmaceutical companies to avoid the jurisdiction of the Board, and would limit the ability of the Board to protect Canadian consumers from excessive pricing.

33) This interpretation is also consistent with the Federal Court of Appeal's decision in *Sandoz* (2015 FCA 249), where Chief Justice Noel held that an interpretation of the Board's enabling provisions that "focused on the persons in need of protection from [the mischief of excessive pricing], i.e. consumers" (para 67) was a "defensible interpretation of the Act". (para 66)

34) When interpreting the excessive pricing regime, the animating and paramount consideration of both the Supreme Court of Canada and the Federal Court of Appeal is to protect consumers from excessive prices of patented medicines.

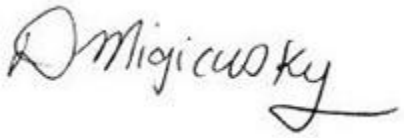
35) However, as noted at paragraph 50 of *Alexion,* it is true that the Board does not have a consumer protection mandate at large, in the sense that it can disregard the *Patent Act* (or assume powers not granted to it in the *Patent Act*), in order to protect consumers from excessive prices.

36) With this interpretation in mind, when referring to "abuse" at paragraph 49 of *Alexion,* the Federal Court of Appeal instructs the Board Panel to focus on "excessive" prices under section 85 of the *Patent Act* since, as *IMC* held (and which the Federal Court of Appeal in *Alexion* relied on), an "excessive" price is the abuse that the Board was created to address. Even so, the Federal Court of Appeal did not purport to define "excessive price" when it referred to "abuse", but rather specifically deferred to the expertise of the Panel to interpret and explain "excessive price" on the facts before it.

37) The Board has the statutory discretion to tailor its approach. Parliament did not establish a specific formula or single test for all cases: it entrusted the Board with an array of general factors in section 85 to consider and apply as the Board's expertise and experience sees fit, based on the facts and the law applicable in each case. In other words, case-by-case variability is inherent in the very text and structure of the excessive pricing regime: a Board Panel is intended by

Parliament to have maximum flexibility in determining what “excessive” means in any given set of circumstances.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 10th day of September 2021.



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