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

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I. Board Staff's Onus

1) The written submissions of Horizon in respect of the decision in *Alexion Pharmaceuticals Inc. v Attorney General of Canada* ("*Alexion*") are premised on a mischaracterization of Board Staff's onus and the plain wording of the *Patent Act*.

2) Horizon suggests that, in discharging its onus in any proceeding before the Patented Medicine Prices Review Board (the "Board" or the "Panel"), Board Staff is required to separately "establish" that a patentee "abused its patent monopoly". However, reading *Alexion* in this way runs contrary to the plain wording of section 85 of the *Patent Act*, which does not include "patent abuse" as a factor that the Panel must consider. Indeed, "patent abuse" is not found anywhere in the excessive pricing framework (sections 79 to 103 of the *Patent Act*). Rather, according to section 85, all that needs to be established is that the price is excessive, and this finding is based solely on the factors enumerated in section 85, which was confirmed as the appropriate test for excessiveness by the Federal Court of Appeal in *Alexion* at paragraph 40.

3) There is also no support for Horizon's position in the established jurisprudence. In *ICN Pharmaceuticals, Inc. v Canada (Staff of the Patented Medicine Prices Review Board) (CA)*, [1997] 1 FC 32 ("*ICN*"), the Federal Court of Appeal held that a patent's "potential for a deterrent effect, irrespective of its actual or prospective effect on market power, is the basis of the Board's jurisdiction." Similarly, in *Canada (Attorney General) v Sandoz Canada Inc.*, 2015 FCA 249, the Federal Court of Appeal held as follows, at paragraph 38:

> Nor does the wording of the Act require proof of a monopoly. This makes sense, given that a factual monopoly, though relevant to competition law, is irrelevant to the legislative purpose, which is to limit the negative effects that result from the statutory monopoly resulting from the grant of a patent (Attorney General's ratiopharm memorandum of fact and law at para. 67). That the Board is in no practical position to assess the market power of a

given party supports the view that it was reasonable for the Board not to view the existence of a monopoly in fact as a condition precedent for engaging the Board's jurisdiction (Attorney General's ratiopharm memorandum of fact and law at para. 71, citing *ICN*, inter alia).

4) The sequential and hierarchal relationship between sections 85(1) and 85(2) of the *Patent Act* also makes it clear that a Panel can reach a determination as to whether a medicine has been sold at an excessive price based solely on the factors contained in section 85(1) and **without** considering the costs of making and marketing the medicine. The Federal Court of Appeal in *Alexion* confirmed this at paragraphs 46 and 47 of its decision. Therefore, Horizon's argument that the Board cannot determine whether the price of Procysbi is excessive "without considering how economic . . . forces inform the pricing of an ultra-rare disease drug" is wrong and contrary to *Alexion*.[1]

5) Board Staff submits that it is therefore obviously erroneous and contrary to the plain wording of the *Patent Act* and *Alexion* to read sections 85(1) and 85(2) of the *Patent Act* in a manner which would compel a Panel to consider evidence of the costs of making and marketing a medicine, including under the guise of the undefined term -"patent abuse"- under section 85(1).

II. The Guidelines are Non-binding

6) The Guidelines are non-binding, as set out in section 96(4) of the *Patent Act* and as recognized in *Alexion* at paragraphs 38-39. Therefore, it would be a legal error for the Panel to treat the Guidelines as determinative where they do not properly implement section 85 in a given set of circumstances. For the reasons outlined in Board Staff's Statement of Allegations, Written Submissions, and oral argument, Procysbi is just such a case.

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[1] The term "economic forces" as used by Horizon is synonymous with "the costs of making and marketing". It is clear from paragraphs 46-47 of *Alexion* that the Panel would fall into error in taking into consideration "economic forces" in its section 85(1) analysis.

7) Moreover, in addition to being non-binding, the Guidelines were never written to apply to a Panel. They do not purport to address how panels will apply the *Patent Act*. Rather, the Guidelines were written for, and apply only to, Board Staff and patentees as a general administrative triage framework.

III. Reasonable versus Excessive Prices

8) Though Horizon argues at paragraphs 10 and 11 of its submissions that Board Staff was improperly focused on setting a reasonable price for Procysbi, this mischaracterizes Board Staff's position.

9) Board Staff agrees that the Board only sets maximum (ceiling) prices by determining the price at which the sale of a patented medicine would be excessive, and that therefore the focus of the Panel must always be on the excessiveness of the price. It is (and always has been) the position of Board Staff that the price of Procysbi is excessive, in view of section 85(1) of the *Patent Act*.

10) Finally, Horizon's accusation that Board Staff pursued a reasonable price, rather than an excessive price, is ultimately irrelevant. Even if this were true, the decision of whether a patented medicine is priced excessively falls to the Panel, not to Board Staff, and the task of the Panel remains the same as ever: to determine whether the evidence, argument, and law before it are sufficient to establish that the section 85(1) factors have been satisfied, and if not, whether the section 85(2) factors have been satisfied.

11) However, for the purpose of correcting the record, when Mr. Kellison testified that Board Staff was of the view "that the tests that are laid out in those guidelines didn't generate what we'd consider to be reasonable results, given the facts of this particular case," the reasonable results to which he was referring were not a reasonable price per se, but rather a reasonable application of the section 85 factors. This becomes abundantly clear when the

entirety of his testimony is read as a whole and in context, rather than a couple selective quotes. Below is one example where he clarifies his meaning:

> "In this case, using the tests that there are, and as we articulated to Horizon very early on, we were of the view that maybe there needed to be some other formulation of the factors in the Act to come out with a result that we felt was meaningful in this case. This was one opportunity to do that." [Emphasis added.][2]

To similar effect, see also Transcript Vol 3 (Kellison) at 561, lines 12-23; and Transcript Vol 3 (Kellison) at 560, lines 9-25; and at 561, lines 1-2.

IV. *Alexion* is Not Analogous to this Case

12) The factual underpinnings of *Alexion* and this case are not analogous. In particular, and unlike the factual situation in *Alexion*, the Panel in this case has a comparator to consider: Cystagon. Cystagon is a treatment that has been utilized effectively for decades to manage the very same condition as Procysbi (nephropathic cystinosis) and uses the very same single active medicinal ingredient as Procysbi (cysteamine bitartrate), albeit in an immediate-release format. Indeed, Cystagon continues to be widely used as an effective treatment for nephropathic cystinosis, both in Canada and worldwide, for a fraction of the cost of Procysbi. As a result, unlike in *Alexion*, the Panel has substantial clinical studies and expert evidence about the similarity of the two drugs (both forms of cysteamine bitartrate). Moreover, this Panel has considerable evidence related to all of the applicable factors listed in section 85(1) of the *Patent Act*, including the domestic and international prices for cysteamine bitartrate (Procysbi and Cystagon). Therefore, It is submitted that the Panel has ample evidence to make a determination in this case based on the factors listed in section 85(1) of the *Patent Act*.

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[2] Transcript Vol 3 (Kellison) at 576, lines 12-18.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 17th day of September 2021.

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