#### 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

RESPONDING EXPERT REPORT OF DR. JOEL HAY, PH.D. (Responding to Expert Report of Professor R. Schwindt)

### TABLE OF CONTENTS

Appen	ndix B:	Schedule to Financial Economic Analysis	B-1
Appen	ndix A:	Scope of Review	A-1
V.	Prof. Sch	windt's critique of the "Moderate Improvement Test" is Unsupported	8
IV.	Prof. Sch	windt's Critique of the MIPC Test is Baseless	6
		AP Price for Cystagon in Canada is not an appropriate mark	6
	A. PROC	YSBI and Cystagon are not Substitutes	3
III.	Prof. Schv	windt's Analysis of the TCC Test is Fundamentally Flawed	3
II.	Summary	of Opinion	1
I.	Mandate a	and Issues to be Addressed	1

I, Joel W. Hay, PhD, of the City of Los Angeles in the State of California in the United States of America, provide the following statement of evidence that I propose to present at the hearing of the above referenced proceeding:

#### I. MANDATE AND ISSUES TO BE ADDRESSED

1. I previously prepared a report dated September 9, 2019. Since that time, counsel for Horizon has provided me with the expert reports of Professor Richard Schwindt and Dr. Julian Midgley and has asked me to provide my comments. In this Report, I comment on the key areas of disagreement that I have with the Schwindt Report.

#### II. SUMMARY OF OPINION

2. **Prof. Schwindt's analysis of the TCC test is fundamentally flawed.** Prof. Schwindt's endorsement of the TCC test assumes that PROCYSBI and Cystagon are competitors and therefore close substitutes. This assumption is incorrect. Prof. Schwindt provides no justification or independent analysis to demonstrate that the two drugs are close substitutes. In fact, it is my understanding that the two drugs are highly differentiated.<sup>3</sup> In addition, Prof. Schwindt fails to recognize that Cystagon cannot be a comparator to PROCYSBI in Canada because it is not commercially sold in Canada; it is only available through Canada's Special Access Program (SAP).<sup>4</sup> The SAP price for Cystagon is not a "market" price and therefore does not provide a reasonable benchmark for the price of Cystagon. Further, the lack of alternative producers of immediate release cysteamine bitartrate suggests that the SAP price is too low to incentivize manufacturers to seek authorization to commercialize this drug in

<sup>&</sup>lt;sup>1</sup> I rely on the CV and Expert Witness Declaration attached to my September 2019 Report. A complete list of the additional information relied on in preparing this report is listed in Appendix A to this report.

To the extent I do not address an issue raised by Prof. Schwindt, my non-response should not be taken to mean that I agree or disagree with Prof. Schwindt on that issue.

Dr. Langman states that he views PROCYSBI as superior to Cystagon for numerous reasons and that he does not view them as close substitutes. [See, e.g., Langman Report, ¶30, 35-35, 97, 166.]

Prof. Schwindt refers to Cystagon's potential comparability to PROCYSBI, given that it is sold through the SAP, as a legal question as opposed to an economic question [Schwindt Report, p. 9]. However, the existence of comparables to PROCYSBI is, in part, an economic question: no other producers of cysteamine bitartrate have entered the market even though Cystagon has no market exclusivity or patent protection. See also paragraphs 16-18 of the Statement of Allegations of Board Staff.

Canada. Accordingly, Prof. Schwindt's endorsement of using the SAP price for Cystagon for the TCC test makes no economic sense.

- 3. **Prof. Schwindt's critique of the MIPC Test is baseless.** Prof. Schwindt assumes, without any evidence, that in markets where Cystagon is freely available, payors will be less sensitive to the price of PROCYSBI because the volume of purchases of PROCYSBI will be limited. This conclusion has no basis in fact. Prof. Schwindt proffered his opinion without any analysis of PROCYSBI's sales volumes or market share relative to Cystagon. Prof. Schwindt further assumes that data relating to the market price for PROCYSBI in comparator countries are somehow distorted, causing him to "have misgivings about the use of the MIPC test in the case of PROCYSBI." I disagree with this conclusion. The fact that PROCYSBI is priced at a substantial premium over Cystagon in international markets where both products are commercially sold is real world evidence that PROCYSBI is viewed as being of higher quality than (and substantially different from) Cystagon. This is common sense: if the premise is that PROCYSBI is no better than Cystagon, there would be no demand for the higher-priced drug.
- 4. **Prof. Schwindt's assertion that the Moderate Improvement Test overcompensates Horizon is unsupported.** Prof. Schwindt assumes that PROCYSBI represents a "moderate improvement" over Cystagon an assumption that is inconsistent with Dr. Langman's evidence. Relying on this assumption, Prof. Schwindt concludes that the price of PROCYSBI under the Moderate Improvement Test would somehow overcompensate Horizon. This conclusion is incorrect. At the price produced using the Moderate Improvement Test,

Dr. Langman's evidence is that PROCYSBI is at least a vast improvement over Cystagon. It is my understanding that the maximum non-excessive price for a new drug providing substantial improvement is the higher of: (a) the highest price among comparator drugs identified in the Therapeutic Class Comparison Test; and (b) the median international price from the Median International Price Comparison (MIPC) Test [See, e.g., Langman Report, ¶155; PMPRB Compendium, C.11.3 and C.8.5.]

<sup>&</sup>lt;sup>5</sup> Schwindt Report, p. 11.

Under this test, the price of a drug that is deemed to be a "moderate improvement" is the half-way point between the median international price based on the Median International Price Comparison test and the highest non-excessive price of the drug products with the same approved indication or use over which the new patented drug product represents a moderate therapeutic improvement based on the Therapeutic Class Comparison Test. Prof. Schwindt refers to this calculation as a midpoint formula [PMPRB Compendium, C.11.6 and C.8.7; Schwindt Report at p.14.]

Thus, Prof. Schwindt cannot credibly state that the price produced by the Moderate Improvement Test overcompensates Horizon. Indeed, Prof. Schwindt acknowledges that the market price must include "a normal return to entrepreneurial effort (i.e., profits)," and that "the appropriate price is one that both adequately rewards the patentee for the improvement (assuming there is an improvement) provided by the product and at the same time protects the public interest in not going beyond that."

## III. PROF. SCHWINDT'S ANALYSIS OF THE TCC TEST IS FUNDAMENTALLY FLAWED

5. I disagree with Prof. Schwindt's assertion that the TCC test is the appropriate test in this case. As explained below, Prof. Schwindt provides no evidence, justification, or independent analysis to support the assumptions that he relies on in coming to this conclusion.

#### A. PROCYSBI AND CYSTAGON ARE NOT SUBSTITUTES

- 6. Prof. Schwindt's endorsement of the TCC test is premised on the assumption that PROCYSBI and Cystagon are competitors and therefore close substitutes. I note, however, that Prof. Schwindt's opinion on the economic competition between Cystagon and PROCYSBI is not relevant to the TCC test. It is my understanding that the only applicable factors when defining a therapeutic class under section 85(1)(b) of the Act are: (i) "other medicines in the same therapeutic class" (i.e., determined based on clinical equivalence), which is entirely unrelated to the question of economic competition, and (ii) whether that medicine "ha[s] been sold in the relevant market." Cystagon is not a close substitute and is not a competitor. Nor has it been commercially sold in the relevant market (as discussed in section III(B), below).
- 7. But, even if economic competition were somehow relevant to the TCC test, Prof. Schwindt provides no economic justification, analysis, or independent support to demonstrate that Cystagon is a close competitor of, and thus close substitute for, PROCYSBI. Despite acknowledging that economists "have tools to deal with the identification and quantification of excessive prices," he fails to use any such tools. <sup>10</sup> Prof. Schwindt does not state the evidence.

3

<sup>&</sup>lt;sup>8</sup> Schwindt Report, pp. 2-3.

<sup>&</sup>lt;sup>9</sup> Schwindt Report, p. 15.

Schwindt Report, p. 2.

tests, or research approaches used to arrive at his conclusion that Cystagon and PROCYSBI are "close substitutes." He relies only on Board Staff's "view [of] Cystagon as a close substitute for PROCYSBI"<sup>11</sup> but does not analyze or refer to any data to support this claim.

- 8. Prof. Schwindt also refers to the financial reports of Horizon and Raptor, citing isolated statements which indicate that the two drugs compete in the U.S. market in a broad sense. But these statements do not suggest that the two drugs are close substitutes, <sup>12</sup> nor do they lead to the conclusion that Cystagon is a perfect substitute for PROCYSBI. Despite Prof. Schwindt's assertion that "[a] competitor provides a substitute product (or products)," <sup>13</sup> the existence of competition between two products is a necessary but far from sufficient condition for demonstrating close economic substitutability. <sup>14</sup>
- 9. The existence of competition between two products is not sufficient to demonstrate substitutability because even products that compete in some broad sense may be highly differentiated. One of the most important means through which companies differentiate their products is by providing different levels of quality, a strategy referred to as "vertical product differentiation." Vertical differentiation reduces the scope for price competition among products with the same end use, particularly when there are significant quality differences among such products. Moreover, the higher-quality products are typically priced substantially higher than the lower-quality products. These quality differences help explain why a Rolls

Schwindt Report, p. 8.

Schwindt Report, pp. 6-7. For example, Schwindt quotes a lengthy passage from Horizon's 2018 annual financial statements in which Horizon describes PROCYSBI in some detail, including key points of differentiation from Cystagon. From this lengthy passage, Prof. Schwindt isolates the statement that "Cystagon is PROCYSBI's primary competitor" (See Schwindt Report, pp. 5-6). He then purports to draw inferences about the clinical substitutability of, and degree of economic competition between, PROCYSBI and Cystagon from that statement.

<sup>13</sup> Schwindt Report, p. 16.

Schwindt Report, p. 5. For example, in the financial statement cited by Prof. Schwindt, Horizon notes that "PROCYSBI is differentiated by its ability to control cystine concentration continuously over twelve hours."

See, e.g., Gabszewicz, J.J. and Thisse, J.-F. (1979). Price Competition, Quality and Income Disparities. *Journal of Economic Theory*, 20, 340-359; Shaked, A. and Sutton J. (1982). Relaxing Price Competition Through Product Differentiation. *Review of Economic Studies*, 49, 3-13; Motta, M. (1993). Endogenous Quality Choice: Price vs. Quantity Competition. *Journal of Industrial Economics*, 41(2), 113-132.

Royce is more expensive than a Ford Fiesta, or why Laser Eye Surgery costs more than a pair of eyeglasses, despite each set of products having the same end use.

- 10. If left untreated, cystinosis inevitably results in kidney failure. Even when treated, cystinosis often ends in early death. Thus, if PROCYSBI were not available in Canada, physicians would have to apply through the SAP to enable their patients to access Cystagon, as it would be "unethical to withhold treatment for a group of patients who require it to prevent irreversible kidney damage." However, as a matter of economics, this does not mean that the two drug products are close substitutes. According to the expert opinion of Dr. Langman, "there is no comparison between the two drugs: PROCYSBI is simply superior." As a matter of economics, this implies that PROCYSBI is highly (vertically) differentiated from Cystagon (i.e., of substantially "higher quality") and that a substantial price premium over Cystagon is warranted. Indeed, the financial statements that Prof. Schwindt relies on to demonstrate substitutability also explain how PROCYSBI is differentiated from Cystagon.
- 11. Nevertheless, Prof. Schwindt appears to conclude that because Cystagon and PROCYSBI have a common end use (the treatment of cystinosis), the two drugs are competitors and therefore close substitutes that should be assigned the same price. But this conclusion is not supported. PROCYSBI is priced at a substantial premium over Cystagon in markets where both products are commercially available, which indicates that PROCYSBI is viewed as being of higher quality than (and thus substantially differentiated from) Cystagon. Moreover, the price of PROCYSBI in comparator countries provides probative evidence on the extent of differentiation between Cystagon and PROCYSBI. Because the comparator countries in which PROCYSBI is sold have also sold Cystagon for many years, the price of

Expert Report of Dr. Craig Langman, dated September 9, 2019 ("Langman Report"), ¶¶35-36.

Langman Report, ¶62.

<sup>&</sup>lt;sup>18</sup> Langman Report, ¶¶30, 97, 166.

In essence, Prof. Schwindt assumes that economic concepts that apply to perfectly competitive markets for homogeneous products (like wheat) are also applicable to the pricing of pharmaceuticals and rare disease drugs. As noted above, Prof. Schwindt wrongly assumes that PROCYSBI and Cystagon are perfect substitutes and therefore mandates a pricing scheme that provides no opportunity for Horizon to recover a reasonable return on its investment in bringing PROCYSBI to market. (see, e.g., Schwindt Report, pp.2-3.)

<sup>&</sup>lt;sup>20</sup> Schwindt Report, pp. 7-8, 10.

PROCYSBI in these comparator countries reflects the degree of substitutability between PROCYSBI and Cystagon.

## B. THE SAP PRICE FOR CYSTAGON IN CANADA IS NOT AN APPROPRIATE BENCHMARK

- 12. Prof. Schwindt further assumes that the price of Cystagon in Canada under the SAP is an appropriate benchmark for the price of PROCYSBI. I disagree with this assumption. Prof. Schwindt fails to appropriately account for the fact that Cystagon is not approved for sale in Canada; hence, it has not been commercially sold in the relevant market. Access only through the SAP means there is no operational market to define a meaningful price for the drug.
- 13. Moreover, although Board Staff asserts that the SAP price for Cystagon is approximately \$5,000 per year, recent reports indicate that Recordati Rare Diseases Inc. ("Recordati") plans to seek Canadian approval to launch Cystagon and is considering prices ranging from \$25,000 per year to one-third the price of PROCYSBI.<sup>21</sup> These facts indicate that the price of Cystagon under the SAP is far below a market price. Accordingly, even if Cystagon were clinically equivalent to PROCYSBI which I understand it is not the SAP price of Cystagon in Canada is not an appropriate benchmark for the price of PROCYSBI.

#### IV. PROF. SCHWINDT'S CRITIQUE OF THE MIPC TEST IS BASELESS

- 14. Prof. Schwindt claims that there is a "fundamental problem with respect to applying the MIPC test to the introductory price of Procysbi."<sup>22</sup> However, Prof. Schwindt's underlying analysis is speculative and is unsupported by any evidence.
- 15. According to Prof. Schwindt, fundamental differences between the market for cysteamine in Canada and in the comparator countries suggest that the use of the MIPC test is not appropriate in this case. Specifically, he argues that the availability of Cystagon in all reference countries would "condition the buyers' willingness to purchase Procysbi at the

<sup>&</sup>quot;Recordati to seek Canadian approval for kidney disease drug", Allison Martell, Reuters, April 16, 2010, available at https://www.reuters.com/article/us-recordati-canada-idUSKCN1RS1YP; "News and Updates", Canadian Association of Paediatric Nephrologists, available at https://www.capneph.ca/.

<sup>&</sup>lt;sup>22</sup> Schwindt Report, p. 10.

transaction price [... such that ...] in markets where Cystagon was freely available, payers would be less sensitive to the price of PROCYSBI because the volume of purchases of PROCYSBI would be very limited."<sup>23</sup> In other words, Prof. Schwindt asserts, without evidentiary support, that payors are willing to pay more for PROCYSBI in countries where Cystagon is available for sale because most patients will continue to rely on inexpensive Cystagon. He further asserts that the patients who switch to PROCYSBI will not impose significant costs on payors because their aggregate number will be small.

- 16. This argument is speculative. There are no data to support this claim, and Prof. Schwindt did not assess PROCYSBI's sales volumes and market share relative to Cystagon. His failure to perform this analysis is particularly noteworthy given that Board Staff possesses the precise sales data that he states do not publicly exist.<sup>24</sup> For this reason alone, it is my opinion that Prof. Schwindt's analysis is inadequate and fundamentally flawed. In any event, as stated in my September 2019 Report, I understand that PROCYSBI has most of the market share in the U.S. and Canada.
- 17. Prof. Schwindt further assumes that the price and other data for PROCYSBI in comparator countries is somehow distorted.<sup>25</sup> I disagree. It is my opinion that these market data provide valuable information on the extent of differentiation between PROCYSBI and Cystagon. As explained in my September 2019 Report, under the MIPC test, the price of PROCYSBI would be based on the median price at which the drug is sold in other countries. Indeed, Prof. Schwindt notes that each of the comparator countries that have approved PROCYSBI for sale have also sold Cystagon for many years. Thus, the price of PROCYSBI in those comparator countries reflects payors' willingness to pay based on the best interests of

As explained in my September 2019 Report,

Based on my review of Board Staff's Statement of Allegations, it appears that Board Staff's approach to calculating market shares is inappropriate because it includes countries in which Cystagon is sold but PROCYSBI is not approved for sale.

7

<sup>&</sup>lt;sup>23</sup> Schwindt Report, p. 10.

Only a redacted pdf-copy of the native dataset used by Board Staff has been provided by Board Staff to Horizon in this matter.

<sup>&</sup>lt;sup>25</sup> Schwindt Report, p. 10.

their patients. Put differently, the fact that PROCYSBI is priced at a substantial premium over Cystagon in international markets where both products are available provides real world evidence that PROCYSBI is viewed as being of higher quality than (and substantially different from) Cystagon. Indeed, Prof. Schwindt appears to agree with this point, noting that:

Comparison with the price charged for the new medicine in other jurisdictions provides the PMPRB with valuable information. First, the price charged in a market similar to Canada discloses the patentee's willingness to supply. Generally, willingness to supply suggests that the price is covering the patentee's costs which would include a competitive profit level.<sup>26</sup>

18. Finally, Prof. Schwindt suggests that the MIPC test is inappropriate because Cystagon is not available in Canada.<sup>27</sup> This suggestion is also unfounded. Nowhere in the test is it required that Canada have the same comparator drugs as other countries. Indeed, the median international price of PROCYSBI is closely aligned to its price in other jurisdictions. There may be some force to the argument if PROCYSBI were priced at a premium in Canada, but that is not the case.

# V. PROF. SCHWINDT'S CRITIQUE OF THE "MODERATE IMPROVEMENT TEST" IS UNSUPPORTED.

19. Prof. Schwindt asserts that the Moderate Improvement Test is inappropriate because it would overcompensate Horizon and "would result in a price 2,652% greater than" Cystagon.<sup>28</sup> While I agree that the moderate improvement test is inappropriate in this case (given Dr. Langman's evidence that PROCYSBI is at least a substantial improvement over Cystagon), I disagree with Prof. Schwindt's suggestion that the price produced by the Moderate Improvement Test would somehow overcompensate Horizon. The opposite is true.

Schwindt Report, p. 5.

<sup>&</sup>lt;sup>27</sup> Schwindt Report, p. 10. Here Prof. Schwindt states that "[t]he market for cysteamine is fundamentally different from Canada in this regard; there are two cysteamine products available abroad instead of just one."

<sup>&</sup>lt;sup>28</sup> Schwindt Report, p. 13.

- 20. As discussed in my September 2019 Report, from an economic perspective, Horizon must charge a price that covers the costs associated with developing and commercializing PROCYSBI (i.e., an enterically coated, delayed release formulation of cysteamine bitartrate), which, as I understand from Dr. Langman's evidence, has led to greatly improved patient outcomes. <sup>29</sup>
- 21. As shown in Figure 1, below, the moderate improvement test would set a maximum price for PROCYSBI of between \$0.2128 to \$0.2201 per mg, which represents a price reduction of between 47% and 49% of the current price of PROCYSBI.

**Figure 1: Moderate Improvement Test** 

Price in CAD\$ As At	Median International Price [A]	Purported Listing Price of Cystagon in Newfoundland and Labrador [B]	Midpoint [C] = ([A] + [B]) /2		
April 2017	\$0.4179		\$0.2128		
December 2017	\$0.4207 \$0.0077		\$0.2142		
June 2018	\$0.4289	ŞU.UU77	\$0.2183		
June 2019	\$0.4325		\$0.2201		

Sources: Statement of Allegations of Board Staff, ¶31; Horizon Pharma PLC, Form 2 - Block 5, January to June 2019; Patented Medicine Prices Review Board, Exchange Rates 2019, available at https://www.pmprbcepmb.gc.ca/view.asp?ccid=1426&lang=en; Response of Horizon Pharma, ¶56. Notes:

22. I have conducted an analysis of Horizon's returns from sales of PROCYSBI in Canada at the price reduction that would result from the Moderate Improvement Test.<sup>30</sup> As explained in detail below at paragraphs 22-24, the results show that, under a 47% price reduction—and using the prime business loan rate as an extremely conservative *lower bound* on Horizon's cost of capital—

\_

<sup>[</sup>A] The time series variation in the international prices of PROCYSBI is driven entirely by foreign exchange rate fluctuations. In particular, the price of PROCYSBI has remained constant.

<sup>[</sup>B] Price of Cystagon is based on the Allegation of Statement of Board Staff, which relies on a website listing from the Newfoundland and Labrador Department of Health and Welfare purportedly published in October 2017.

<sup>&</sup>lt;sup>29</sup> Schwindt Report, p. 16.

Appendix B provides the schedule supporting the analysis; it is the same financial model that was presented in my September 2019 Report.

23.	My Se	eptember 2	2019 Report	showed	that,	given	various	price	reductions	proposed	by
the P	PMPRB,										

However, as explained in my September 2019 Report, the cost of capital measures the opportunity cost of obtaining financing (via debt or equity) and is a critical cost that companies must take into account when deciding whether or not to undertake an investment. This is because carrying out R&D for pharmaceutical products is a long, complex and risky process, characterized by large up-front investment costs, the returns from which will not be realized until many years in the future, if ever. The cost of capital compensates investors for bearing this risk.

24. The standard approach in economics for taking the cost of capital into account when assessing the return from an investment project is through the use net present value ("NPV").<sup>32</sup> The NPV of an investment project is the cash flows expected to be generated by the project (including both revenues and costs), discounted at a rate that is equal to the company's cost of financing the investment.

25. N	My N	NPV	analysis	shows	that	the	price	reduction	required	under	the	Moderate
Improve	ment	Test	would									
										То	pei	rform this
analysis,	, I u	se th	e prime	busine	ss lo	an r	ate in	October	2016 (2.7	7%) as	an	extremely
conserva	ative	lowei	r bound	on Hor	izon'	s cos	st of c	apital in th	e month t	hat Ho	rizoı	n acquired
Raptor.33	<sup>3</sup> The	prin	ne busine	ss loan	rate	is the	e inter	est rate cha	arged to tl	ne mos	cre	dit-worthy
(i.e., leas	st risk	ky) bo	orrowers	for <u>sho</u>	rt-teri	n loa	ans by	chartered b	oanks in C	anada a	and h	nence does
not refle	ct the	risks	or long	time ho	rizon	asso	ciated	with Horiz	on's inves	stment i	n PR	ROCYSBI.

If my analysis had taken into account *any* cost of capital for Horizon, its losses would have been even greater.

Ross, S.A. *et al.*, (2005). Chapter 4: Financial Markets and Net Present Value: First Principles of Finance. *Corporate Finance, Seventh Canadian Edition*.

Bank of Canada, *Chartered Bank Administered Interest Rates – Prime Business*, available at https://www.bankofcanada.ca/wp-content/uploads/2010/09/selected\_historical\_v122495.pdf.

My NPV analyses show that even at this very conservative lower bound rate,
The cost of capital associated with
developing a rare disease drug like PROCYSBI would be significantly greater than the prime
business rate, and so Horizon's losses would be correspondingly larger.

- 26. Thus, Prof. Schwindt cannot credibly state that the price produced by the Moderate Improvement Test somehow overcompensates Horizon. Indeed, Prof. Schwindt acknowledges that the market price must include "a normal return to entrepreneurial effort (i.e., profits)," and that "the appropriate price is one that both adequately rewards the patentee for the improvement (assuming there is an improvement) provided by the product and at the same time protects the public interest in not going beyond that." <sup>35</sup>
- 27. My analysis shows that, like Board Staff's Same Medicine Comparison Test, Market Share Comparison Test, and Premium Comparison Test, the Moderate Improvement Test provides *de minimis* compensation for the significant therapeutic benefit offered by PROCYSBI and would leave Horizon
- 28. In any event, the fact that the Moderate Improvement Test results in a substantial premium over Cystagon is not a defensible critique. Prof. Schwindt provides no independent analysis to show that this premium is inappropriate. He simply speculates, without any evidence, that it is unlikely that the authors of the mid-point formula "envisaged a situation where the formula would allow a 2,652% premium for a moderate improvement." Not only is this criticism unsupported, but it is inappropriate for Prof. Schwindt to speculate on the views of the authors of the Adderall Hearing Panel and the revised Guidelines. Moreover, Prof.

11

<sup>&</sup>lt;sup>34</sup> Schwindt Report, pp. 2-3.

<sup>&</sup>lt;sup>35</sup> Schwindt Report, p. 15.

Schwindt Report, p. 14.

Schwindt's critique of the appropriate price premium is completely tautological; it is based entirely on the classification of PROCYSBI as a moderate improvement over Cystagon, when Dr. Langman's evidence indicates that PROCYSBI is at least a substantial improvement over Cystagon.<sup>37</sup>

29. Prof. Schwindt's report compares apples and oranges. PROCYSBI and Cystagon are not comparable to Adderall XR and Adderall because PROCYSBI and Cystagon are used to treat a rare and life-threatening disease and Adderall XR (and Adderall) are not. As explained in my September 2019 Report (see Section V), PROCYSBI is a drug for rare diseases and the economic considerations associated with developing such drugs are very different than those associated with developing a drug for treating broad populations (such as Adderall and Adderall XR). Accordingly, Prof. Schwindt's suggestion that the moderate improvement test somehow overcompensates Horizon is entirely unfounded.

Signed October 6, 2020

Joel W Hay

<sup>&</sup>lt;sup>37</sup> Langman Report, ¶¶30, 35-36, 62, 97, 166.

#### **Appendix A: Scope of Review**

In preparing this report, in addition to the information and documents set out in Appendix D of my September 2019 Report, I have reviewed and relied upon the information from documents and listed below:

#### A. Expert Reports

i. Expert Report of Professor R. Schwindt, dated September 6, 2019.

#### B. Publicly Available Information

- Bank of Canada, Chartered Bank Administered Interest Rates Prime Business, available at https://www.bankofcanada.ca/wp-content/uploads/ 2010/09/selected\_historical\_v122495.pdf.
- ii. Gabszewicz, J.J. and Thisse, J.-F. (1979). Price Competition, Quality and Income Disparities. *Journal of Economic Theory*, 20, 340-359.
- iii. Motta, M. (1993). Endogenous Quality Choice: Price vs. Quantity Competition. *Journal of Industrial Economics*, 41(2), 113-132.
- iv. Ross, S.A. *et al.*, (2005). Chapter 4: Financial Markets and Net Present Value: First Principles of Finance. *Corporate Finance, Seventh Canadian Edition*.
- v. Shaked, A. and Sutton J. (1982). Relaxing Price Competition Through Product Differentiation. *Review of Economic Studies*, 49, 3-13.

### **Appendix B: Schedule to Financial Economic Analysis**















