



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**

REASONS FOR DECISION

(Case Conference Regarding Hearing Format)

1. On October 8, 2020, the panel (the “**Panel**”) of the Patented Medicine Prices Review Board (the “**Board**”) seized with this proceeding held a Case Conference to address the format of the hearing scheduled to commence on November 23, 2020 (the “**Hearing**”).
2. At the Case Conference, counsel for the Respondent, Board Staff and the Province of British Columbia each had the opportunity to make oral submissions regarding their proposed format for the Hearing.
3. The Panel has carefully considered the correspondence and oral submissions of the parties and, for the reasons set out below, concluded that this Hearing will proceed by videoconference.

A. BACKGROUND

4. In light of the health and safety concerns raised by the COVID-19 pandemic, the parties requested this Case Conference to address the format of the upcoming Hearing.
5. The Hearing will determine the merits of a proceeding commenced by Board Staff, in which it alleges that the Respondent is selling the medicine Cysteamine

Bitartrate under the trade name Procysbi at a price that is excessive under section 83 of the *Patent Act*¹.

6. Board Staff submits that as much of the Hearing as practically possible should be conducted in person while maintaining adherence to the health and safety protocols. Board Staff also recognizes that some of the witnesses and counsel may be prevented from attending the Hearing in person and agrees that it would be appropriate for such persons to attend virtually. In Board Staff's submission, this hybrid in-person/virtual format for the Hearing maintains "the benefits of an in-person argument by counsel and witness testimony, while accommodating the involvement of those counsel and witnesses that may choose to appear remotely".² Board Staff submits that the benefits of conducting portions of the Hearing in person include that it will improve efficiency, and make it easier for: (i) counsel to adduce evidence and refer to documents; (ii) the Panel to assess a witness's credibility; (iii) counsel to make arguments and to communicate with the Panel; and (iv) the public to observe the Hearing.

7. During oral argument, Board Staff indicated that its counsel and most of its witnesses (excluding, potentially, two expert witnesses) are able to appear in person and wish to do so provided the appropriate health and safety measures are in place.

8. The Respondent objects to the hybrid Hearing format proposed by Board Staff and submits that the entirety of the Hearing should be conducted virtually because of the challenges, restrictions and uncertainty associated with the COVID-19 pandemic.

9. The Respondent submits that the hybrid format proposed by Board Staff is structurally unfair because the party who appears in person will enjoy the benefits of an in-person Hearing, while the party who appears virtually will be disadvantaged by the consequences of using videoconference technology. Accordingly, the Respondent

¹ R.S.C. 1985, c.P-4.

² Hearing Transcript (October 8, 2020), at p. 4, lines 17-22.

submits that all parties should appear by videoconference to ensure that the Hearing is conducted on a “level playing field”.³

10. The Respondent’s submission is supported by the Province of British Columbia, which indicated its preference to attend the Hearing by videoconference.

B. HEARING FORMAT

11. The key issue before this Panel is whether it should order a hybrid in-person/virtual Hearing over the objections of the Respondent and British Columbia, in circumstances where Board Staff has indicated that it intends to appear in person and the Respondent and British Columbia have indicated their intention to appear virtually due to the health and safety concerns and associated restrictions caused by the COVID-19 pandemic.

12. For the following reasons, the Panel has concluded that a hybrid Hearing format is not appropriate in these circumstances. To ensure the fair and expeditious conduct of this Hearing, all counsel and witnesses must appear by videoconference.

(i) Jurisdiction

13. As a preliminary matter, the Panel notes that the Board has jurisdiction to decide whether this Hearing will proceed in person, virtually or through some combination of the two. Both the *Patent Act*⁴ and the *Patented Medicine Prices Review Board Rules*⁵ grant the Board broad discretion to issue any directions necessary to ensure the fair and expeditious conduct of a proceeding.

(ii) Fairness

14. It is well-accepted that there are a number of benefits associated with in-person hearings, including those benefits raised in Board Staff’s oral submissions (summarized

³ Hearing Transcript (October 8, 2020), at p. 19, lines 14-21.

⁴ R.S.C. 1985, c.P-4, s. 97(1).

⁵ SOR/12-247, s. 5(2).

in paragraph 6 above). As a result, a party who presents its case in person will enjoy certain benefits that are not afforded to parties who appear virtually by videoconference.

15. Board Staff submits that no parties would be prejudiced by a hybrid in-person/virtual Hearing because all parties would be given the option to elect to participate in person, and accordingly would have the opportunity to enjoy the benefits of participating in person if they so choose.

16. The ability to choose, however, does not ensure fairness to the parties. Board Staff's proposal requires parties to make an impossible choice between putting the most effective and persuasive case forward before the Board (*i.e.*, by choosing to appear in person) or ensuring the health and safety of their counsel and witnesses (*i.e.*, by choosing to appear virtually). This is a particularly challenging decision for the Respondent to make in circumstances where several of its witnesses are subject to travel and quarantine restrictions and the party who commenced the proceeding has already made it clear that, if given the choice, it would attend the Hearing in person.

17. To adopt Board Staff's hybrid proposal in these circumstances would effectively reward those parties who are willing to attend the Hearing in person despite the pandemic, and penalize those parties who are not comfortable attending or are unable to attend the Hearing in person for health and safety reasons. No party should feel the need to risk their health and safety in order to have a fair hearing before the Board.

18. Accordingly, in the circumstances of this case, fairness dictates that the entirety of the Hearing shall be conducted virtually. All parties and witnesses shall appear virtually by videoconference. This will ensure that all parties have the same opportunity to participate and be heard on a level playing field. To quote Justice E.M. Morgan: "whatever the strengths and frailties of a virtual hearing, everyone is in the same position".⁶

⁶ [Miller v. FSD Pharma, Inc.](#), 2020 ONSC 3291 at para. 10. See also [Arconti v. Smith](#), 2020 ONSC 2782 at para. 32.

(iii) Efficiency & Public Access

19. In addition to promoting a fair Hearing, an entirely virtual Hearing will avoid the risks of delay and inefficiency associated with holding all or a portion of the Hearing in person during the COVID-19 pandemic. There are at least three reasons for this.

20. First, proceeding entirely by videoconference will assure the parties that this Hearing will commence as scheduled and will not be disrupted or delayed by any further potential restrictions on travel and public gatherings during the COVID-19 pandemic.

21. Second, proceeding entirely by videoconference will reduce the risk of an adjournment in the unfortunate circumstance that counsel, a witness, a Panel Member or a member of the public who attends the Hearing in person tests positive for COVID-19.

22. Third, proceeding entirely by videoconference will ensure that parties, counsel, witnesses and the public⁷ can participate in, and observe, the Hearing from the safety and comfort of their own homes or offices, while avoiding the time, cost and health risks associated with travelling to Ottawa for the Hearing.

23. The above-noted factors outweigh any risk of inefficiency due to the use of videoconference technology. In any event, even if the Panel adopted the hybrid Hearing method proposed by Board Staff – such risks of “logistical delays related to [the use of] technology”⁸ would still exist given that at least some of the parties would appear by videoconference.

C. DISPOSITION

24. For the foregoing reasons, the Panel hereby makes the following orders:

- (a) The Hearing shall proceed virtually. All parties, witnesses, counsel and the Panel shall appear by videoconference.

⁷ Paragraphs 7 and 9 of the draft Virtual Hearing Protocol attached as Schedule “A” to this Decision sets out a procedure that would enable members of the public to observe a live stream of the virtual Hearing.

⁸ Hearing Transcript (October 8, 2020), at p. 6, lines 5-11.

- (b) The parties shall review the Panel's draft Virtual Hearing Protocol attached to this Decision as Schedule "A", and file any comments on the draft Virtual Hearing Protocol with the Board no later than October 26, 2020.
- (c) The parties shall confer and jointly file with the Board a schedule for the virtual appearance of witnesses no later than November 9, 2020. This schedule must include:
 - (i) the name of each witness;
 - (ii) the email address and phone number that the Secretariat can use to contact each witness in the event that technical issues arise during the virtual Hearing;
 - (iii) the date and time that the witness will appear for examination-in-chief;
 - (iv) the date and time that the witness will appear to be cross-examined; and
 - (v) the expected duration of the examination-in-chief and cross-examination of each witness (understanding that the Panel's expectation is that no examination-in-chief should exceed 90 minutes).

25. For greater certainty, nothing in this Decision precludes members of each counsel team from being physically present in the same room while appearing before the Panel by videoconference. At this time, the Panel Members plan to be physically present with their counsel in Toronto, with appropriate health and safety measures in place.

Dated at Ottawa, this 20th day of October, 2020.

Signed on behalf of the Panel by
Carolyn Kobernick

Panel Members

Carolyn Kobernick
Mitchell Levine

Counsel for Board Staff

David Migicovsky
Christopher Morris
Courtney March
Timothy Jolly

Counsel for the Respondent

Sheila Block
Andrew Shaughnessy
Stacey Reisman

Counsel for the Province of British Columbia

Sharna Kraitberg

Counsel for the Panel

Sandra Forbes
Megan Percy

**SCHEDULE “A”
DRAFT VIRTUAL HEARING PROTOCOL**

The following Protocol shall govern the conduct of the virtual hearing, which is scheduled to commence on November 23, 2020 (the “**Hearing**”).

A. Videoconference Platform

1. The Hearing will take place using the Zoom platform.
2. The Zoom platform will provide real-time connection between the panel (the “**Panel**”) of the Patented Medicine Prices Review Board (the “**Board**”) seized with this proceeding, and all counsel and other representatives of the parties who intend to participate in the Hearing (“**Participants**”).
3. The Zoom Hearing will be moderated by Neesons (the “**Zoom Moderator**”).

B. Recording the Hearing

4. The Hearing will be transcribed by a court reporter.
5. No other recording of any part of the Hearing (including audio, video, photos, screen captures etc.) may be made unless authorized in advance by the Panel.

C. Registering to Participate In, or Observe, the Virtual Hearing

6. By 4:00 p.m. two business days in advance of the Hearing (*i.e.*, Thursday, November 19, 2020), counsel for each of the parties must send an email to the Secretariat (riaz.awadia@pmprb-cepmb.gc.ca) registering all of the members of their counsel team and representatives of the party who intend to participate in the Hearing. This registration email must include the following information for each Participant:
 - (i) name;
 - (ii) title (*e.g.*, counsel for Board Staff, CEO of Respondent, etc.);
 - (iii) email address; and
 - (iv) phone number.
7. By 4:00 p.m. two business days in advance of the Hearing (*i.e.*, Thursday, November 19, 2020), members of the public who wish to observe the Hearing (“**Observers**”) must send

an email to the Secretariat (riaz.awadia@pmprb-cepmb.gc.ca) setting out the Observer's name, email address and phone number.

8. The Secretariat will provide all registered Participants with a Zoom invitation by email. Participants are prohibited from forwarding or otherwise sharing the Zoom invitation.
9. The Secretariat will provide all registered Observers with a YouTube link by email. Observers are prohibited from forwarding or otherwise sharing this YouTube link. All Observers will be able to view a livestream of the Hearing, but not participate in the Hearing. The Panel and counsel will not hear or see the Observers.

D. Document Management

10. Documents for this Hearing will be managed using Sync.com.
11. Prior to the start of the Hearing, the Secretariat will provide all counsel with a unique link to a storage space on Sync.com that shall only be used in connection with this Hearing. Counsel are prohibited from forwarding or otherwise sharing this unique Sync.com link.
12. In accordance with this Panel's Direction dated April 7, 2020, all materials shall be filed with the Board electronically. Effective immediately upon receipt of the Sync.com link, all materials shall be filed with the Board electronically by:
 - (i) uploading the document to the appropriate sub-folder on Sync.com (see paragraph 13 below); and
 - (ii) sending an email to the Secretariat (riaz.awadia@pmprb-cepmb.gc.ca) that:
 - a. clearly states the title of the document that was filed; and
 - b. includes a hyperlink to the location of the document on Sync.com.
13. The Sync.com storage space shall contain a separate sub-folder for material filed by each party. Each sub-folder will be labelled with the filing party's name only. Parties may only upload material to their own sub-folder and shall not alter any material uploaded by any other party.
14. Documents for this Hearing shall be filed with the Board in accordance with the following guidelines:

- (i) all documents shall be in searchable PDF format (*i.e.*, the documents shall be scanned to text using Optical Character Recognition technology);
 - (ii) all PDF briefs that contain multiple documents shall be bookmarked into different tabs. Each tab should be named in a manner that briefly describes the contents of the tab;
 - (iii) any pagination of document briefs shall align with the PDF page number of the brief; and
 - (iv) document titles shall clearly indicate the document date, name of the filing party, and the contents of the document (*e.g.*, “2020.11.06 – Board Staff – Will-Say of Doe, J.”).
15. During the Hearing, counsel may direct the Panel to certain documents or authorities by either:
- (i) using Zoom’s screen-sharing function; or
 - (ii) asking the Panel to open a copy of the document on their own screens.
16. During the Hearing, counsel shall refer to documents consistently and clearly for the record (even if they are sharing the document using Zoom’s screen-sharing function). Counsel shall always refer to:
- (i) the document name;
 - (ii) the tab number (if applicable); and
 - (iii) the page number of the PDF (as opposed to the paper copy page number).
17. The parties shall cooperate in the timely preparation of an electronic joint brief of documents (“**JBD**”) to facilitate the management of documentary evidence. Any JBD shall be prepared well in advance of the Hearing, and shall be filed with the Board no later than November 18, 2020 in accordance with the Panel’s Scheduling Order dated September 8, 2020.
18. Counsel shall also file with the Board a condensed electronic brief containing only excerpts of documents, transcripts and authorities which they intend to rely on during oral arguments. This brief shall be filed with the Board no later than 4:00 p.m. on March 9, 2021.

E. Participation of Witnesses

(i) General

19. Prior to the start of the Hearing, the Secretariat will send each witness a Zoom invitation by email. The email will also note the specific date and time at which the witness is scheduled to testify.
20. Witnesses should only join the Zoom meeting at the time that they are scheduled to testify, unless otherwise instructed by the Panel.
21. Upon joining the Zoom meeting, the witness will be placed in a virtual waiting room by the Zoom Moderator until the Panel is ready to hear their testimony.
22. Witnesses will be asked by an official of the Registry of the Tribunal to confirm their identity. Once the identity of the witness has been verified, an official of the Secretariat of the Board will administer an oath or affirmation. If a witness wishes to take an oath, counsel must notify the Secretariat at least two business days prior to the start of the Hearing and the witness must attend the Hearing with a copy of the religious book of their choice.

(ii) Protocol for Witness Testimony

23. The applicable Rules of Professional Conduct and the *PMPRB Rules of Practice and Procedure* should be referred to and adhered to in all dealings with witnesses participating in the Hearing.
24. In addition, the following protocol applies to witnesses while they are giving evidence, and counsel shall specifically advise each witness of this protocol:
 - (i) While the witness is giving evidence, they should always keep their camera and microphone on, unless the Panel instructs otherwise.
 - (ii) While the witness is giving evidence, the camera should be positioned so that the Panel and Participants can clearly see the witness, particularly their whole face and their hands if possible.
 - (iii) While the witness is giving evidence, the witness shall not refer to or rely on a script or any notes.
 - (iv) While the witness is giving evidence, the witness shall not review any documents or access any electronic resources, other than:

- a. those documents put to them during their examinations;
 - b. such documents as they may ask and be permitted to review; and
 - c. in the case of expert witnesses, their own expert reports and other expert reports in this proceeding, provided that any such reports they review during their testimony do not contain any notes or annotations made by the witness or anyone else.
- (v) Witnesses are not permitted to testify with others present at their physical location, without the prior approval of the Panel.
 - (vi) If a witness intends to participate in the virtual Hearing from the same remote location as (*i.e.*, in the presence of) counsel to a party, counsel shall so advise the parties well in advance of the Hearing. Any party who objects in this regard shall promptly advise the Panel.
 - (vii) Witnesses cannot be assisted by others during their testimony, and shall not communicate with anyone outside the virtual hearing room during their testimony.

(iii) Documents Put to Witnesses

- 25. Any documents to be presented to a witness during an oral examination shall be filed with the Board using a password protected zip-folder at least twenty-four (24) hours prior to the examination.
- 26. The format of the documents must comply with the requirements set out in paragraph 14 above, with the exception that they shall be named as follows: "Witness Last Name, Witness First Initial – Document Number.pdf" (*e.g.*, "Doe, J. – 22").
- 27. The Secretariat shall not disclose the password for the password protected zip-folder to the Participants until immediately prior to the start of the examination, or cross-examination, as applicable.
- 28. When putting a document to a witness counsel may:
 - (i) use Zoom's screen-sharing function; or
 - (ii) ask the Panel and the witness to open a copy of the document on their own screens.
- 29. During the Hearing, counsel shall refer to documents consistently and clearly for the record by following the procedure set out in paragraph 16 above.

30. Counsel shall clearly state for the record when a document is to be marked as an exhibit. All exhibits will be marked by the Zoom Moderator.

F. Preparing for the Hearing

31. Well in advance of the Hearing, counsel shall ensure that all Participants and witnesses:
- (i) prepare their computer, screens, microphone, camera and phone to ensure that they are functioning properly;
 - (ii) have the necessary software installed to use Zoom and Sync.com;
 - (iii) address any security restrictions on their systems that may prevent access to Zoom and Sync.com, and make reasonable efforts to adapt their systems to ensure access to Zoom and Sync.com;
 - (iv) familiarize themselves with Zoom and Sync.com;
 - (v) test their internet connection ahead of time at least once, and preferably twice, from the places where they will participate in the virtual hearing; and
 - (vi) have the necessary software installed to open and view PDFs.
32. Parties will be contacted by the Secretariat in advance of the Hearing to schedule a test run. During the test run, the Participants, witnesses, and Zoom Moderator can test their devices and internet connection.

G. Hearing Etiquette

(i) Timeliness

33. The Board expects Participants and witnesses to appear on time and may decide to proceed regardless of their failure to do so.
34. Participants should join the Zoom meeting (via the link provided by the Secretariat) approximately 30 minutes before the Hearing is scheduled to begin. During this time, Participants should speak to each other to determine if there are any audio/visual/connection issues. However, Participants should not have discussions about the case at this time. If Participants wish to discuss the case, they should use a confidential means of communication (see paragraphs 42-43 below).
35. As described above, witnesses should only join the Zoom meeting at their scheduled start times.

36. Counsel shall file with the Board all documents and authorities to be referenced during the Hearing in accordance with the deadlines set out in this Protocol and the Panel's Scheduling Order dated September 8, 2020. In exceptional circumstances, the Board may consider requests to refer to documents or authorities during the Hearing that were not filed with the Board in accordance with those deadlines.

(ii) Professionalism

37. Virtual hearings remain hearings of the Board. Professional etiquette shall be maintained. In particular:
- (i) the Panel and counsel should be addressed as if they were in a physical hearing room;
 - (ii) unless directed otherwise by the Panel, it is not necessary to stand when the Panel joins the Hearing or when addressing the Panel. In lieu of bowing, participants may nod or bow their heads when the Panel enters the videoconference;
 - (iii) all Participants and witnesses should dress as if they were attending the Hearing in person;
 - (iv) Participants and witnesses should connect to Zoom from devices that are placed on a stable surface. Movement requires more bandwidth and reduces both video and audio quality;
 - (v) Participants and witnesses should ensure that any background visible on the screen (including any artificial digital background) is appropriate for the Hearing;
 - (vi) reasonable steps should be taken to reduce the risk of interruptions during the Hearing;
 - (vii) Participants and witnesses should minimize background noise. Using a headset with a microphone is recommended;
 - (viii) Participants and witnesses should close all applications and mute all notifications on their computer, phone and any other devices that are not needed for the Hearing;
 - (ix) Participants and witnesses should not move away from the screen or turn off their cameras during the Hearing without permission from the Panel;
 - (x) the usual restrictions on eating and drinking in a hearing room apply;
 - (xi) Participants and witnesses should look at the camera (not the screen) when they are speaking, if possible;

- (xii) Participants and witnesses should ensure that they are adequately lit to allow their face to be seen, and be mindful that they always have a camera on them even when they are not speaking;
- (xiii) Participants and witnesses should ensure that their display name properly reflects their first and last name;
- (xiv) Participants and witnesses shall only speak one at a time and should remember to pause and speak slowly and clearly, especially where there is any audio/video lag;
- (xv) unless addressing the Panel, or otherwise requested to speak, all Participants should have their microphones muted; and
- (xvi) counsel should not use Zoom's screen-sharing function without first obtaining the permission of the Panel.

(iii) Objections

38. Unless the Panel directs otherwise, where counsel wishes to raise an objection, the objecting counsel shall indicate such objection by physically raising their hand or otherwise verbalizing the objection.

(iv) Civility, Cooperation & Collaboration

39. Virtual hearings require civility, professionalism, cooperation, communication and collaboration between parties and counsel, both before and during the Hearing. The Board expects all Participants to adapt and cooperate in good faith in the preparation and conduct of this virtual Hearing to achieve the most fair and expeditious conduct of the proceeding. Participants shall not take unfair advantage of the fact that the Hearing is being held remotely.

H. Confidentiality

40. During the Hearing, counsel and witnesses shall endeavor to avoid discussing or displaying confidential information. To the extent possible, counsel shall provide pinpoint citation references to any confidential information without disclosing its content or displaying it.
41. In the event that the Panel must hear evidence or submissions that are governed by the Confidentiality Protocol issued by this Panel on October 29, 2019, counsel will advise the Panel before they start a confidential portion of the Hearing so that the Panel may

request that the Zoom Moderator set up a separate, *in camera*, Zoom breakout room for the Board and any appropriate person who is entitled to see the confidential information.

I. Communication Between Hearing Participants

- 42. Participants shall not use the chat function on the Zoom platform.
- 43. Prior to the start of the Hearing, counsel shall consider a way to communicate with their clients during the Hearing in a manner that ensures confidentiality.

J. Technical Issues Arising During the Hearing

- 44. Prior to the Hearing, all Participants, witnesses and Observers shall be made aware of the Zoom Moderator's email address and telephone number. In the event that an individual encounters technical difficulties (including if they are disconnected during the Hearing), they shall contact the Zoom Moderator.
- 45. In the event of unforeseen technological issues during the Hearing, the Board may temporarily adjourn the Hearing to address those issues in an attempt to resume the Hearing as quickly as possible. Participants and witnesses should be prepared to proceed by teleconference should the issues prevent the Hearing from proceeding further by videoconference.