

(1) APOTEX HOLDINGS INC.

(2) APOTEX INC.

Claimants

v.

THE UNITED STATES OF AMERICA

Respondent

**PROCEDURAL ORDER ON THE PARTIES' RESPECTIVE
REQUESTS FOR DOCUMENT PRODUCTION**

The Tribunal:

J. William Rowley, Arbitrator;
John R. Crook, Arbitrator; and
V.V. Veeder, President.

The Secretary to the Tribunal:

Eloise M. Obadia

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(I) Introduction

(A) By Paragraphs 14 and 15 of the Tribunal's First Procedural Order dated 29 November 2012, the Parties agreed to refer their respective requests for document production, if disputed between the applicant and responding parties to such requests, to the decision of the Tribunal within these arbitration proceedings in accordance with the procedural timetable fixed by the First Procedural Order.

(B) By Paragraph 15.1 of the First Procedural Order, the Parties agreed that, in deciding such disputes, the Tribunal may take account of Articles 3 and 9 of the International Bar Association's Rules on the Taking of Evidence 2010 (the "IBA Rules") as an additional general guide to the exercise of its discretion under Article 41(2) of the ICSID Arbitration (Additional Facility) Rules forming part of the Parties' arbitration agreement.

(C) Pursuant to Paragraph 14.2.7(v) of the First Procedural Order, the Claimants and the Respondent submitted to the Tribunal on 15 March 2013 disputes under their respective Schedules for document production for decision by the Tribunal, such decision to be issued on 29 March 2013 in accordance with the procedural timetable fixed by Paragraph 14.2.7(vi) of the First Procedural Order.

(D) The Claimants' Schedule with its numbered requests is attached to this order marked "Appendix A"; and the Respondent's Schedule with its numbered requests is attached to this order marked "Appendix B".

(E) By letter dated 18 March 2013, the Claimants confirmed that no privileged document was responsive to the Respondent's requests numbered 3, 6, 7 and 14 in the Respondent's Schedule and that, accordingly, the Claimants were not withholding any document so requested by the Respondent on the ground of privilege (or otherwise).

(F) By letter dated 20 March 2013, the Respondent made further submissions relating to (i) alleged inaccuracies in the Claimants' representations of the Parties' understandings regarding the Claimants' requests for document production (as recorded in the Claimants' Schedule); and (ii) alleged inaccuracies in the Claimants' representations of the Parties' discussions regarding the "deliberative process privilege" invoked by the Respondent (as also recorded in the Claimants' Schedule).

(G) By email message dated 21 March 2013, the Claimants objected to the Respondent's unsolicited further submissions of 20 March 2013.

(H) By email message dated 21 March 2013, the Tribunal's president invited (but did not order) the Claimants to respond 'de bene esse' to the Respondent's further unsolicited submissions as soon as possible, but not later than 22 March 2013 (such invitation being later confirmed and here so recorded by the Tribunal as a whole).

(I) By letter and email message dated 22 and 24 March 2013, pursuant to the Tribunal's invitation of 21 March 2013, the Claimants made submissions responding to the two items raised in the Respondent's letter dated 20 March 2013.

(J) Having considered the Parties' respective Schedules, the Claimants' letter dated 18 March 2013 and (as explained below) the Parties' correspondence dated 20, 22 and 24 March 2013, the Tribunal makes the following procedural order in regard to the Parties' respective requests for document production in these arbitration proceedings.

(II) The Claimants' Requests for Document Production to be made by the Respondent

(The references below relate to the 103 separate requests listed in the Claimants' Schedule, attached hereto as Appendix A. The notations "*" and "+" are explained later below).

1. 1(a)*: The Tribunal understands that the Respondent will produce the documentation here requested. It shall do so.

1(b)*: The Tribunal understands that the Respondent will produce the documentation here requested, subject to redactions to protect identifying information. It shall do so. (The Tribunal understands that the Claimants do not oppose the Respondent's response to this sub-request).

1(c)*: The Tribunal understands that the Respondent will produce documentation explaining abbreviations and acronyms (in addition to the web-site identified by the Respondent), as here requested. It shall do so. (The Tribunal understands that the Claimants do not oppose the Respondent's response to this sub-request).

1(d)*: The Tribunal understands that the Respondent will produce a list and brief definitions, as here requested. It shall do so. (The Tribunal understands that the Claimants do not oppose the Respondent's response to this sub-request).

2. 2(a)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested (beyond R-20), subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

2(b)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

2(c)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

2(d)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

2(e)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

2(f)*: The Tribunal notes the Respondent's consent to produce certain documentation, as identified to the Claimants and recorded in column six to their Schedule. It shall do so. Save as aforesaid, the Tribunal rejects this request (as further explained by the Claimants in column six of their Schedule) because the requested documentation is insufficiently identified and also insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules).

2(g)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege (beyond C-34, R-25 and R-26). It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

2(h)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

2(i): The Tribunal rejects this request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules).

2(j): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

2(k)*: The Tribunal notes the Respondent's consent to produce certain documentation as identified to the Claimants and recorded in column six to their Schedule. It shall do so. Save as aforesaid, the Tribunal rejects this request (as further explained by the Claimants in column six of their Schedule) because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

2(l): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Article 3(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

2(m): The Tribunal rejects this request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules).

2(n): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Article 3(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

2(o)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

3. The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

4. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

5. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6. 6(a)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6(b)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6(c)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6(d)*+:The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6(e)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6(f): The Tribunal rejects this request because the requested documentation is insufficiently identified and also insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules).

6(g)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6(h)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

6(i): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

6(j)*+: The Tribunal accepts this request and orders production of the requested documentation (excepting R-46 and C-138 already in the Claimants' possession), subject to privilege. As to such privilege, the Tribunal refers to Paragraph L below.

6(k): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

6(l): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

6(m): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

6(n): The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

6(o)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

7. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
8. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
9. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
10. The Tribunal rejects this request because the requested documentation is insufficiently identified and insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules) and also insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).
11. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
12. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
13. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
14. *+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

- 15. *+:** The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
- 16. *+:** The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
- 17.** The Tribunal rejects this request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).
- 18. *+:** The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
- 19. *+:** The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
- 20. *+:** The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
- 21. *+:** The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.
- 22. 22(a)+:** The Tribunal notes the Respondent's objection based on privilege. As to such privilege, the Tribunal refers to Paragraph L below.
- 22(b)+: The Tribunal notes the Respondent's objection based on privilege. As to such privilege, the Tribunal refers to Paragraph L below.

23. 23(a)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

23(b)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

23(c)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

23(d)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

23(e)+: The Tribunal notes the Respondent's objection based on privilege to this sub-request. As to such privilege, the Tribunal refers to Paragraph L below.

23(f)+: The Tribunal notes the Respondent's objection based on privilege to this sub-request. As to such privilege, the Tribunal refers to Paragraph L below.

23(g): The Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Article 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

23(h)+: The Tribunal notes the Respondent's objection based on privilege to this sub-request. As to such privilege, the Tribunal refers to Paragraph L below.

23(i)+: The Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Article 3(c)(i) of the IBA Rules).

24. 24(a)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

24(b)*: The Tribunal understands that the Respondent will produce certain documentation here requested (as clarified by the Claimants in the sixth column to their Schedule), as identified to the Claimants and recorded in column six to their Schedule. It shall do so.

24(c)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

24(d)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

24(e)+: The Tribunal notes the Respondent's objection based on privilege to this sub-request. As to such privilege, the Tribunal refers to Paragraph L below.

24(f)+: The Tribunal notes the Respondent's objection based on privilege to this sub-request. As to such privilege, the Tribunal refers to Paragraph L below.

24(g)*: The Tribunal understands that the Respondent will produce certain documentation here requested (as clarified by the Claimants in the sixth column to their Schedule), as identified to the Claimants and recorded in column six to their Schedule. It shall do so.

24(h)+: The Tribunal notes the Respondent's objection based on privilege to this sub-request. As to such privilege, the Tribunal refers to Paragraph L below.

24(i): The Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9((2)(c) and 9(2)(g) of the IBA Rules).

25. *+: The Tribunal notes the limitation made by the Claimants to this request to certain electronic and searchable documentation (with search terms) in the sixth column to the Claimants' Schedule. The Tribunal understands that the Respondent will produce such further responsive documentation, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

26. 26(a)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

26(b)*+:

The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

27. The Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

28. 28(a)*+: The Tribunal understands that the Respondent will produce any further responsive documentation here requested, subject to relevance, materiality and privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below.

28(b): The Tribunal understands that the Claimants have withdrawn this sub-request: see the sixth column to their Schedule.

29. *+: The Tribunal notes that this request (as limited by the Claimants in the sixth column to their Schedule) is the subject of the Parties' letters dated 20 and 22 March 2013, from which the Tribunal understands that the Respondent is willing to produce non-privileged communications between the FDA and Health Canada concerning Health Canada's May-June 2011 inspection. It shall do so. As to privilege, the Tribunal refers to Paragraph L below. Save as aforesaid, the Tribunal rejects this request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules), insufficiently identified and insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules) and

insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules).

30. *+: The Tribunal notes that the Claimants withdrew that part of this sub-request relating to “Taro”: see the sixth column to the Claimants’ Schedule. The Tribunal understands that the Respondent will produce certain responsive documentation here requested as regards “Ranbaxy”, subject to privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below. The Tribunal notes that this request is the subject of the Parties’ letters dated 20 and 22 March 2013, from which the Tribunal understands that this responsive documentation will comprise, according to the Respondent, non-privileged Form 483s, EIRs (Establishment Inspection Reports) and final agency actions (in the form of warning letters and a letter concerning the FDA’s “application integrity policy”).

31. 31(a)+: The Tribunal notes the Claimants’ limitation to this sub-request in column six of their Schedule. The Tribunal also notes the Respondent’s objection to this sub-request (as limited) based on privilege (including the FDA’s new policy on redactions). As to such privilege (or like impediment), the Tribunal refers to Paragraph L below. (The Tribunal notes that this sub-request is the subject of the Parties’ letters dated 20 and 22 March 2013).

31(b)+: The Tribunal notes the Claimants’ limitation to this sub-request in column six of their Schedule. The Tribunal also notes the Respondent’s objection based on privilege to this sub-request (as limited). As to such privilege, the Tribunal refers to Paragraph L below. (The Tribunal notes that this sub-request is the subject of the Parties’ letters dated 20 and 22 March 2013).

32. 32(a)*: The Tribunal understands that the Respondent will produce a redacted Form 483 as here (*inter alia*) requested with respect to an inspection of the Sandoz/Novartis facility in 2011. It shall do so. The Tribunal notes that this sub-request is the subject of the Parties’ letters dated 20 and 22 March 2013, from which the Tribunal understands that the redaction and non-production of other documentation, according to the Respondent, is required owing to an “ongoing investigation”. Save as aforesaid, this sub-request is rejected because the production of the redacted and other material is currently subject to legal impediment (Article 9(2)(b) of the IBA Rules).

32(b): The Tribunal rejects this sub-request (as further explained by the Claimants in column six of their Schedule) because the requested documentation is insufficiently identified and also insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules). (The Tribunal notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013).

33. 33(a)*: The Tribunal understands that the Respondent will produce any Form 483s and EIRs (redacted), as well as any final agency determinations forming part of this sub-request relating to Teva's facilities in Irvine and Jerusalem. It shall do so. Save as aforesaid, the Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules) and also because it is insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules). (The Tribunal notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013).

33(b): Save as regards overlapping production ordered under sub-request 33(a) above, the Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules) and also because it is insufficiently described identified and insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules). (The Tribunal notes that this sub-request is also the subject of the Parties' letters dated 20 and 22 March 2013).

34. 34(a)*+: The Tribunal understands that the Respondent will produce Form 483s and EIRs (redacted), as well as any final agency determinations forming part of this sub-request relating to Ranbaxy's facility in India, subject to privilege. It shall do so. As to privilege, the Tribunal refers to Paragraph L below. Save as aforesaid, the Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules) and also because it is insufficiently identified and insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules). (The Tribunal notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013).

34(b)*+: Save as regards overlapping production order under sub-request 34(a) above and certain documentation which the Respondent has agreed to produce (see below), the Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules) and also because it is insufficiently identified and insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules). The Tribunal notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013, from which the Tribunal understands that the documentation which the Respondent has agreed to produce shall comprise Form 483s and any non-privileged EIRs and final agency actions (e.g. letters). As to privilege, the Tribunal refers to Paragraph L below.

35. 35(a): The Tribunal rejects this sub-request (as limited by the Claimants in the sixth column of their Schedule) because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules). The Tribunal also notes that this sub-request (likewise the following sub-request) is the subject of the Parties' letters dated 20 and 22 March 2013), from which the Tribunal understands and accepts that the redaction and non-production of certain documentation relating to the Sandoz/Norvatis facilities, according to the Respondent, is required owing to an "ongoing investigation" and its production therefore subject to legal impediment (Article 9(2)(b) of the IBA Rules).

35(b): The Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be relevant and material (Articles 3(3)(b) and 9(2)(a) of the IBA Rules). (The Tribunal notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013).

36. 36(a)*: The Tribunal notes that the Claimants limited this sub-request to Form 483s and an update to a list of foreign and domestic inspections previously received from the FDA (as also the following sub-requests 36(b) to (d) below): see the sixth column to the Claimants' Schedule. As regards this sub-request 36(a), the Tribunal understands that the Respondent has agreed to produce certain redacted documentation. It shall do so. The Tribunal notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013, from which it understands that this documentation shall comprise a redacted Form 483 with respect to an inspection of the Sandoz/Novartis facility in 2011 and that

the redaction and non-production of other documentation, according to the Respondent, is required owing to an “ongoing investigation”. Save as aforesaid, this sub-request is rejected by the Tribunal because the production of the redacted and other material is currently subject to legal impediment (Article 9(2)(b) of the IBA Rules).

36(b)*: The Tribunal notes that the Claimants likewise limited this sub-request to Forms 483s and an update to a list of foreign and domestic inspections previously received from the FDA: see the sixth column to the Claimants’ Schedule. The Tribunal understands that the Respondent has agreed to produce certain documentation. It shall do so. The Tribunal notes that this sub-request is the subject of the Parties’ letters dated 20 and 22 March 2013, from which the Tribunal understands that this documentation shall comprise Form 483s and any non-privileged EIRs and final agency actions (e.g. letters).

36(c)*: The Tribunal notes that the Claimants likewise limited this sub-request to Forms 483s and an update to a list of foreign and domestic inspections previously received from the FDA: see the sixth column to the Claimants’ Schedule. The Tribunal understands that the Respondent has agreed to produce certain documentation. It shall do so. The Tribunal notes that this sub-request is the subject of the Parties’ letters dated 20 and 22 March 2013, from which the Tribunal understands that this documentation shall comprise Form 483s and any non-privileged EIRs and final agency actions (e.g. letters).

36(d)*: The Tribunal notes that the Claimants limited this sub-request to Forms 483s and an update to a list of foreign and domestic inspections previously received from the FDA: see the sixth column to the Claimants’ Schedule. The Tribunal understands that the Respondent has agreed to produce certain documentation. It shall do so. The Tribunal notes that this sub-request is the subject of the Parties’ letters dated 20 and 22 March 2013, from which the Tribunal understands that this documentation shall comprise Form 483s and any non-privileged EIRs and final agency actions (e.g. letters).

37. 37(a): The Tribunal rejects this sub-request (regarding Teva, as further explained by the Claimants in column six of their Schedule) because the requested documentation is insufficiently identified and also insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules) and because the requested documentation is insufficiently shown to be reasonably necessary and its production

reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules). The Tribunal also notes that this sub-request (likewise the following sub-request) is the subject of the Parties' letters dated 20 and 22 March 2013), from which the Tribunal understands that the non-production of documentation, according to the Respondent, is also required owing to the FDA's new policy on redacting information concerning third-party drug products.

37(b): The Tribunal rejects this sub-request (regarding Sandoz/Novartis, as also explained by the Claimants in column six of their Schedule) because the requested documentation is insufficiently identified and also insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules) and because the requested documentation is insufficiently shown to be reasonably necessary and its production reasonably proportionate (Articles 3(3)(c)(i), 9(2)(c) and 9(2)(g) of the IBA Rules). (The Tribunal notes that this sub-request is also the subject of the Parties' letters dated 20 and 22 March 2013: see above).

38. 38(a): The Tribunal understands that no current dispute exists as regards this sub-request (as limited by the Claimants in column six of their Schedule), with the Claimants indicating that they do not currently request this further documentation from the Respondent (albeit reserving the right to request additional documentation at a future date). Accordingly, the Tribunal makes no order as regards this sub-request. (The Tribunal notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013).

38(b): The Tribunal understands that no current dispute exists as regards this sub-request (as likewise limited), with the Claimants indicating that they do not currently request this further documentation from the Respondent (albeit reserving the right to request additional documentation at a future date). Accordingly, the Tribunal makes no order as regards this sub-request. (The Tribunal notes that this sub-request is also the subject of the Parties' letters dated 20 and 22 March 2013).

38(c): The Tribunal understands that no current dispute exists as regards this sub-request (as likewise limited), with the Claimants indicating that they do not currently request further documentation from the Respondent (albeit reserving the right to request

additional documentation at a future date). Accordingly, the Tribunal makes no order as regards this sub-request. (The Tribunal also notes that this sub-request is the subject of the Parties' letters dated 20 and 22 March 2013).

- 39.** The Tribunal notes that the Respondent states that no documents exist responsive to this request and that, in these circumstances, the Respondent does not oppose the Respondent's response to this sub-request. Accordingly, the Tribunal makes no order as regards this sub-request.
- 40.*:** The Tribunal notes that the Claimants limited this request to manuals, guidelines and instructions: see the sixth column to the Claimants' Schedule. The Tribunal understands that the Respondent has agreed to produce such documentation. It shall do so.
- 41.** The Tribunal notes that the Claimants have withdrawn this request: see the sixth column to the Claimants' Schedule. Accordingly, the Tribunal makes no order as regards this sub-request.
- 42.** The Tribunal notes that the Claimants have withdrawn this request: see the sixth column to the Claimants' Schedule. Accordingly, the Tribunal makes no order as regards this sub-request.

(III) The Respondent's Requests for Document Production to be made by the Claimants

(The references below relate to the 14 numbered requests listed in the Respondent's Schedule, attached hereto as Appendix B. The notations "*" and "+" are explained later below).

1. *: The Tribunal understands that the Claimants are willing to produce this complete (unredacted) document of 1 April 2006 subject to the approval of Barr Laboratories Inc or, if such approval is not (or not yet) available, subject to an order to do so by the Tribunal. In the circumstances, the Tribunal orders its production on a confidential basis between the Parties, subject to: (i) any redaction of any confidential business or proprietary information irrelevant and immaterial to the Parties' dispute in this arbitration; and (ii) protection of the document under the Confidentiality Order made in these proceedings to be confirmed between the Parties or, in default of such confirmation, to be decided by the Tribunal.
2. *: The Tribunal understands that the Claimants will produce documentation here requested, as identified in the fifth column to the Respondent's Schedule. They shall do so.
3. *: The Tribunal understands that the Claimants will produce any further responsive documentation here requested, subject to its existence (in the Claimants' possession). They shall do so. As to attorney-client and other privileges, the Tribunal notes the Claimants' statement that they are not currently aware of any responsive documents that would be required to be withheld on the ground of any privilege: see the fifth column to the Respondent's Schedule. The Tribunal also notes the Claimants' statement in their letter dated 18 March 2013 confirming that no privileged document exists and that no document is being withheld from production on the ground of privilege (or otherwise) in response to this request.
4. The Tribunal notes the Respondent's clarification of this request, now described as any "Contact Reports" or "any other similar documents" which the Claimants received from Health Canada's inspection of September to November 2009: see the sixth column to the Respondent's Schedule. The Tribunal notes the Claimants' response that, insofar as they are aware, no such "Contact Reports" were received by the Claimants and that the

Respondent's original phrase "equivalent" is vague. The Tribunal rejects this request because the requested documentation, as to "Contact Reports", is not sufficiently shown to be in the possession of the Claimants (Article 3(3)(c) of the IBA Rules) and, as to "equivalent" or "any other similar documents", is insufficiently identified and also insufficiently described as a narrow and specific category of documentation (Article 3(3)(a) of the IBA Rules).

5. *+: The Tribunal understands that the Claimants will produce any further responsive documentation here requested, subject to its existence (in the Claimants' possession) and privilege. They shall do so. As to the attorney-client and other privileges invoked by the Claimants, the Tribunal notes the Claimants' statement that they are not currently aware of any responsive documents that would be required to be withheld on the ground of any privilege: see the fifth column to the Respondent's Schedule. If and to the extent that such privilege were to be invoked by the Claimants, the Tribunal refers to Paragraph N below.

6. *: The Tribunal understands that the Claimants will produce any further responsive documentation here requested, subject to its existence. They shall do so. As to attorney-client and other privileges, the Tribunal notes the Claimants' statement that they are not currently aware of any responsive documents that would be required to be withheld on the ground of any privilege: see the fifth column to the Respondent's Schedule. The Tribunal also notes the Claimants' statement in their letter dated 18 March 2013 confirming that no privileged document exists and that no document is being withheld from production on the ground of privilege (or otherwise) in response to this request.

7. *: The Tribunal understands that the Claimants will produce any further responsive documentation here requested, subject to its existence (in the Claimants' possession). They shall do so. As to attorney-client and other privileges, the Tribunal notes the Claimants' statement that they are not currently aware of any responsive documents that would be required to be withheld on the ground of any privilege: see the fifth column to the Respondent's Schedule. The Tribunal also notes the Claimants' statement in their letter dated 18 March 2013 confirming that no privileged document exists and that no document is being withheld from production on the ground of privilege (or otherwise) in response to this request.

8. *: The Tribunal understands that the Claimants will produce any responsive documentation here requested: see the fifth column to the Respondent's Schedule. They shall do so.
9. *+: The Tribunal understands that the Claimants will produce any further responsive documentation here requested not already in the Respondent's possession, subject to its existence (in the Claimants' possession) and privilege: see the fifth column to the Respondent's Schedule. They shall do so. As to the attorney-client and other privileges invoked by the Claimants, the Tribunal refers to Paragraph N below.
10. *+: The Tribunal understands that the Claimants will produce any further responsive documentation here requested not already in the Respondent's possession, subject to its existence and privilege: see the fifth column to the Respondent's Schedule. They shall do so. As to the attorney-client and other privileges invoked by the Claimants, the Tribunal refers to Paragraph N below.
11. *: The Tribunal accepts this request and orders the production of the requested documentation.
12. *: The Tribunal understands that the Claimants will produce documentation here requested, as identified in the fifth column to the Respondent's Schedule. They shall do so.
13. The Tribunal notes and accepts the Claimants' statement that no documents responsive to this request exist. The Tribunal accordingly makes no order as regards this request.
14. * The Tribunal understands that the Claimants will produce any further responsive documentation here requested not already in the Respondent's possession, subject to its existence (in the Claimants' possession): see the fifth column to the Respondent's Schedule. They shall do so. The Tribunal notes the Claimants' statement in their letter dated 18 March 2013 confirming that no privileged document exists and that no document is being withheld from production on the ground of privilege (or otherwise) in response to this request.

(IV) Conclusion and Summary

(K) In the exercise of its powers under Article 41(2) of the ICSID Additional Facility Rules, the Tribunal orders the production of the documentation identified above against the numbered requests (marked “*” above) listed from the Claimants’ Schedule and the Respondent’s Schedule respectively, subject to (where expressly noted) relevance, materiality and privilege - as further explained below. Pursuant to Paragraph 14.2.7(vii) of the First Procedural Order, the Claimants and the Respondent as the responding parties shall produce such documents to the applicant parties as soon as practicable, but no later than 19 April 2013. The responding parties are requested to produce any documentation as and when that documentation becomes available for production and not to delay production until all documentation becomes available for production.

(L) As regards the privilege or privileges (or like impediments) invoked or to be invoked by the Respondent (including deliberative process privilege) as a ground for not producing any responsive documentation here ordered by the Tribunal “subject to privilege” (marked “+” in Part II above), the Respondent shall prepare a privilege log identifying, by reference to any ordered document or (if not an identified document) any narrow and specific category of documentation, the particular privilege invoked by the Respondent barring such production in these proceedings and the particular reasons for such bar in relation to such document or documentation. The Tribunal intends that the Claimants shall have an opportunity to respond in writing to such privilege log, with the Respondent afforded a brief opportunity to reply to such response, also in writing.

(M) In preparing these further submissions, the Parties are requested to bear in mind that the Tribunal has already received their extensive legal submissions regarding deliberative process privilege set out in the Claimants’ Schedule and the Parties’ letters dated 20 and 22 March 2013.

(N) As regards the privilege or privileges invoked or to be invoked by the Claimants (including attorney-client privilege, attorney work-product doctrine or like impediments) as a ground for not producing any responsive documentation here ordered by the Tribunal “subject to privilege” (marked “+” in Part III above), the Claimants shall prepare a privilege log identifying, by reference to any ordered document or (if not an identified document) any narrow and specific category of documentation, the particular privilege invoked by the

Claimants barring such production in these proceedings and the particular reasons for such bar in relation to such document or documentation. The Tribunal intends that the Respondent shall have an opportunity to respond in writing to such privilege log, with the Claimants afforded a brief opportunity to reply to such response, also in writing.

(O) For the time being, the Parties should assume that the Tribunal is minded not to take into account deliberative process privilege, attorney-client privilege, attorney work-product doctrine privilege (or any other privilege or like impediment) as a matter of any applicable law or rules of law, but rather as one or more factors falling within Article 9(2) of the IBA Rules. The Tribunal has here taken no decision regarding any waiver of privilege by either the Claimants or the Respondent. Such issues should be addressed in the Parties' respective further submissions.

(P) As regards the application of the tests for "relevance" and "materiality" under Articles 3(3)(b) and 9(2)(a) of the IBA Rules, the Tribunal notes the sharp controversy between the Parties, as recorded particularly in the Claimants' Schedule. No tribunal can itself apply these tests to all disputed documentation, particularly when (as here) such documentation must extend over many thousands of pages; but even with a much more limited exercise, a tribunal should not ordinarily receive materials from one party in the absence of the adverse party; and, of course, an applicant party cannot check for itself whether the responding party has properly applied these tests to any document unless that document is already produced to the applicant party. In these circumstances, the Tribunal considers that the tests under Articles 3 and 9 of the IBA Rules are to be applied necessarily by the responding party, by its legal representatives acting in good faith and in accordance with the highest professional standards. In that sense, the application of these tests is "self-judging"; but it is a 'judgment' for which the responding party and its legal representatives are accountable to the Tribunal, with the usual sanctions for non-compliance (including the drawing of adverse inferences at any stage of the arbitration). Applied to the present case, in regard to the documentation ordered to be produced above "subject to relevance [and] materiality", the Tribunal orders the Claimants and Respondent respectively (as appropriate) to certify in writing that the tests for such relevance and materiality under Articles 3(3)(b) and 9(2)(a) of the IBA Rules have been applied to any documentation not produced on such grounds, with the names of the legal representatives responsible for that determination identified in such certification.

(Q) Given the urgency and strict timetable imposed by the First Procedural Order in regard to document production, the Parties are requested to consult amongst themselves with a view to agreeing a timetable for the exchange of these privilege logs, further submissions and certifications as soon as possible, but no later than 19 April 2013; or, if no such agreement is reached, the Parties are ordered to make their separate proposals to the Tribunal no later than 22 April 2013.

(R) Subject to further consultation with the Parties following the Tribunal's receipt of the privilege logs and such further submissions, the Tribunal may decide to appoint an independent and impartial referee to review disputed documentation withheld on the ground of any privilege, pursuant to the procedure suggested by Article 3(8) of the IBA Rules.

(S) As is evident above, the Tribunal has made use of part of the Parties' correspondence dated 20, 22 and 24 March 2013, which are all admitted into the file. Nonetheless, the Respondent's unsolicited letter dated 20 March 2013 should not be taken as establishing any precedent for this arbitration's procedure. In other circumstances, a party should apply for permission from the Tribunal in a timely manner before making such a belated, substantial and unscheduled submission, thereby affording the adverse party or parties an opportunity to be heard on such an application and without risking adverse affects on the procedural timetable fixed by procedural orders.

(T) The Tribunal notes that the Parties' requests for document production and, more particularly, their disputes over such requests, are both more extensive and intensive that was originally envisaged, certainly by the Tribunal. It is therefore possible that further disputes may arise as to the implementation of this procedural order. In that event, the Parties are requested to comply as far as possible with this order and not to delay production owing to an unrelated dispute which the Parties and the Tribunal may seek to re-address at a later date. Moreover, this procedural order is not intended to preclude an appropriate application by either side for further document production, albeit subject to compliance with the IBA Rules, particularly Article 3(3)(a) of the IBA Rules.

Dated 29 March 2013

Signed for the Tribunal:

[Signed]

V.V. Veeder (President of the Tribunal)