

**IN THE ARBITRATION  
UNDER CHAPTER ELEVEN OF THE NAFTA  
AND THE ICSID ARBITRATION (ADDITIONAL FACILITY) RULES**

**BETWEEN:**

**APOTEX HOLDINGS INC. AND APOTEX INC.,**

*Claimants,*

*– and –*

**THE GOVERNMENT OF THE UNITED STATES OF AMERICA,**

*Respondent.*

**ICSID Case No. ARB(AF)/12/1**

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**AMENDED CONFIDENTIALITY AGREEMENT AND ORDER**

October 24, 2013

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**ARBITRAL TRIBUNAL:**

V. V. Veeder, QC (President)  
J. William Rowley, QC  
John R. Crook

1. The disputing parties in this arbitration have agreed that certain of the materials in this arbitration are confidential, non-public documents or information, and are therefore to be protected from disclosure pursuant to this Agreement and Order.
2. For the purposes of this Agreement and Order:
  - a. “disputing party” means, in the case of the Claimants, Apotex Holdings Inc. (Canada), Apotex Inc. (Canada), and Apotex Corp. (United States), and their successors and assigns (“Apotex”), and in the case of the Respondent, the Government of the United States of America;
  - b. “Centre” means the International Centre for Settlement of Investment Disputes;
  - c. “confidential information” means any information designated by a disputing party as confidential. A disputing party may designate as confidential, and protect from disclosure:
    - i. any confidential commercial or financial information, including information meeting the definition in 21 C.F.R. § 20.61(b); or
    - ii. any trade secret information meeting the definition in 21 C.F.R. § 20.61(a);
    - iii. any other sensitive non-public information that (a) as of the date of production, has been subject to strict internal controls limiting its dissemination by the disputing party and (b) if improperly disclosed, is likely to cause the disputing party or another person substantial harm; or
    - iv. any information that could otherwise be protected from disclosure by legislation, including, but not limited to, as amended, the *Freedom of Information Act*, 5 U.S.C. § 552, the *Trade Secrets Act*, 18 U.S.C. § 1905 or the *Food, Drug and Cosmetic Act*, 21 U.S.C. § 331(j).
3. If a disputing party believes that any part of any document it provides in this arbitration reflects confidential information, it shall clearly mark the specific information for which protection is claimed. If a disputing party believes that any part of any document submitted by another disputing party contains confidential information, that party shall, within thirty days of its submission to the Tribunal, provide a copy of that document in which the specific information for which protection is claimed is clearly marked.
4. Confidential information shall not be disclosed to any third party, except in accordance with the terms of this Agreement and Order or with the prior written consent of the disputing party that claimed confidentiality with respect to the information.

5. Except as otherwise provided in this Agreement and Order, information and materials containing confidential information may be used only in these proceedings and may be disclosed only for such purposes to and among:
  - a. legal counsel to a disputing party whose involvement in the preparation or conduct of this proceeding is reasonably considered by the disputing party to be necessary;
  - b. officials or employees of a disputing party to whom disclosure is reasonably considered by a disputing party to be necessary for the preparation or conduct of this proceeding;
  - c. independent experts or consultants retained or consulted by a disputing party in connection with this proceeding;
  - d. witnesses reasonably expected by a disputing party to offer evidence in this proceeding and only to the extent that the information is relevant to their expected testimony; or
  - e. members of the Tribunal, persons employed by member of the Tribunal to work on this arbitration, translators and interpreters retained by the parties and Tribunal and representatives of the Centre.
6. All persons receiving material in this proceeding containing confidential information shall be bound by this Agreement and Order. Each disputing party shall have the obligation of notifying all persons receiving such material of the obligations under this Agreement and Order. The Tribunal and the Centre shall maintain such material in conditions that ensure the protection of confidential information.
7. It shall be the responsibility of the disputing party wishing to disclose material containing confidential information to any person pursuant to paragraphs 5(c) or (d) to ensure that such person executes a Non-Party Consent to Be Bound by Confidentiality Agreement and Order in the form attached as Appendix "A" before gaining access to any such material. Each disputing party shall maintain copies of such Non-Party Consent Agreements and shall make such copies available to the other disputing party upon order of the Tribunal or upon the termination of this arbitration.
8. A disputing party may submit to the Tribunal its objections relating to the designation of information as confidential and/or redaction of information asserted to be confidential pursuant to paragraph 3 of this Agreement and Order. The Tribunal will rule on such objections on the basis of submissions by the disputing parties and in accordance with the terms of this Agreement and Order.
9. The acceptance by one disputing party of the designation of another disputing party of information as confidential shall not constitute an admission or concession, permit any inference, or create a presumption that any such designation is in fact required by this Agreement and Order.
10. Any request to the Government of the United States of America for documents, or the production of documents in other proceedings, under the *Freedom of Information Act* or as otherwise required by federal or state law,

including documents produced to the United States in these proceedings, shall be governed by the relevant legislation.

11. This Agreement and Order shall not be construed as an agreement to produce or supply any document or information or as a waiver of any right to object to the production of any document or information, or as a waiver of any claim of privilege with regard to production of any document or information.
12. No party shall file any confidential material covered by the terms of this Agreement and Order in any Court without first bringing this Agreement and Order to the attention of the Court and seeking directions concerning the filing of such material in a manner that protects its confidentiality.
13. As provided in the “Access to documents” section of the 31 July 2001 Note of Interpretation of the NAFTA Free Trade Commission, either disputing party may disclose to the public all documents submitted to, or issued by the Tribunal, subject to the redaction of confidential or otherwise protected information.
14. Neither party shall disclose any document, including awards or orders of the Tribunal, until the other party has had forty-five days to identify and redact confidential information from such material.
15. The obligations created by this Agreement and Order shall survive the termination of these proceedings. Disputes between the parties which arise out of or relate to this Agreement and Order after the termination of these proceedings shall be subject to the laws of the United States.
16. Within 120 days from the date when a disputing party may enforce a final award in these proceedings in accordance with NAFTA Article 1136(3), each disputing party shall destroy any confidential information designated as such and supplied by the opposing disputing party or parties. Legal counsel for each party shall be entitled to retain copies of any documents that have been admitted into evidence in this arbitration and that contain or refer to confidential information, provided that such documents remain subject to this Agreement and Order.
17. Upon consultation with the parties and for good cause, the Tribunal may at any time amend this Confidentiality Agreement and Order.

#### **Addendum**

- 5 bis. If a disputing party believes that any part of any document constituting confidential information produced in this arbitration reflects highly sensitive information, and that the disputing party or a third person would be greatly prejudiced by the document’s disclosure to the other party, it shall clearly mark the specific information for which protection is claimed as “CONFIDENTIAL – TRIBUNAL AND ATTORNEYS’ EYES ONLY.” Such documents may be viewed only by:
  - a. members of the Tribunal, persons employed by members of the Tribunal to work on this arbitration, translators and interpreters retained by the Tribunal and representatives of the Centre;

- b. legal counsel to a disputing party, as identified in paragraph 7.1 of the Tribunal’s First Procedural Order dated 29 November 2012, as well as counsel of the producing party;
- c. officials, employees, and witnesses of the producing party who received the document prior to the commencement of the arbitration; and
- d. independent experts or consultants of the disputing parties.

For clarity, such documents may not under any circumstances be provided to, or viewed by, officials, employees, or witnesses of the recipient disputing party other than legal counsel to that party, as defined in 5 bis.

- 6 bis. Should the party producing a document designated “CONFIDENTIAL – TRIBUNAL AND ATTORNEYS’ EYES ONLY” wish to submit that document to the Tribunal as an exhibit to a submission, it shall notify the non-submitting party 30 calendar days in advance of that submission. The non-submitting party may challenge the “CONFIDENTIAL – TRIBUNAL AND ATTORNEYS’ EYES ONLY” designation within five days of such notice, after which the submitting party shall have four days to respond, and the non-submitting party shall have three days to reply. The Tribunal shall endeavor to rule on any challenge on the basis of the parties’ submissions in one week.

Should the non-submitting party choose not to challenge the designation of “CONFIDENTIAL – TRIBUNAL AND ATTORNEYS’ EYES ONLY,” or should the Tribunal rule that the document shall remain so designated, the document shall be clearly marked “CONFIDENTIAL – TRIBUNAL AND ATTORNEYS’ EYES ONLY” in the submission to the Tribunal. Neither disputing party shall quote from any such document in their submissions. Should either disputing party wish thereafter to show or refer to any such document during a hearing, the party shall inform the Tribunal, so that the Tribunal may take appropriate safeguards to ensure that only persons referred to in 5 bis are present. Public access to the hearing shall be suspended in accordance with Procedural Order No. 1 ¶ 19.2 for the duration of the discussion of the documents. Any transcripts of the hearing shall be redacted to obscure the discussion of the document subject to this paragraph, to ensure that the requirements of paragraph 5 bis are maintained.

Should the Tribunal rule that the document should not be designated “CONFIDENTIAL – TRIBUNAL AND ATTORNEYS’ EYES ONLY,” the submitting party retains the right to rely on a redacted version of the document previously produced by the submitting party as confidential information. Should the submitting party rely on the redacted version, the parties may not reference any information that has been redacted, and the parties will maintain the unredacted version as “CONFIDENTIAL – TRIBUNAL AND ATTORNEYS’ EYES ONLY.”

FOR THE CLAIMANTS:

FOR THE RESPONDENT:

By: [Signed]

By: [Signed]

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FOR THE TRIBUNAL:

By: [Signed]

V. V. Veeder, QC (President)

**APPENDIX “A”**

IN THE ARBITRATION UNDER CHAPTER ELEVEN  
OF THE NORTH AMERICAN FREE TRADE AGREEMENT  
AND THE ICSID ARBITRATION (ADDITIONAL FACILITY) RULES  
BETWEEN

APOTEX HOLDINGS INC. AND APOTEX INC.,

*Claimants,*

*-and-*

UNITED STATES OF AMERICA,

*Respondent.*

Case No. ARB(AF)/12/1

**NON-PARTY CONSENT TO BE BOUND BY  
CONFIDENTIALITY AGREEMENT AND ORDER**

1. IN CONSIDERATION of being provided with materials in connection with the arbitration between Apotex Holdings Inc. and Apotex Inc. and the Government of the United States of America over which claims for confidentiality have been advanced (“confidential information”), I hereby agree to maintain the confidentiality of such material. It shall not be copied or disclosed to any other person nor shall the material so obtained be used by me for any purposes other than in connection with this proceeding.
2. I acknowledge that I am aware of the Confidentiality Agreement and Order that has been made in the arbitration, a copy of which is attached to this Consent, and agree to be bound by it.

Dated: \_\_\_\_\_  
*(Print Name)*

\_\_\_\_\_  
*(Signature)*