INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES
(ICSID Case No. ARB(AF)/12/1)

(1) APOTEX HOLDINGS INC.

(2) APOTEX INC.

Claimants

v.

THE UNITED STATES OF AMERICA

Respondent

PROCEDURAL ORDER ON THE PARTICIPATION OF THE APPLICANT, BNM, AS A NON-DISPUTING PARTY

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

The Secretary to the Tribunal:
Eloïse M. Obadia

1. On 1 March 2013, the Tribunal informed the Study Center for Sustainable Finance that its application for leave to file a non-disputing party submission was denied. In its letter, the Tribunal indicated that detailed reasons for its decision would follow shortly. This procedural order sets out the Tribunal's reasons.

I. Procedural Background

2. As agreed at the First Session of the Tribunal held with the Disputing Parties on 24 July 2012 and as set out in paragraph 20.2 of the First Procedural Order dated 29 November 2012:

> 20.2 The Tribunal shall consider any application for permission to file a submission in this arbitration by an intending Amicus, in consultation with the Parties. Any Amicus application shall adhere to the requirements set forth in the recommendations of the FTC on non-disputing party participation, issued on 7 October 2003.

3. Different schedules for such applications were fixed in Section 14 of the First Procedural Order taking into account the possibility of the United States of America ("Respondent") raising jurisdictional objections and requesting bifurcation of the proceeding between jurisdiction and the merits. The Respondent having raised such objections and requested bifurcation in its Counter-Memorial of 14 December 2012, the Tribunal decided in its Procedural Order of 25 January 2013 to join the objections to jurisdiction filed by the Respondent to the merits. Accordingly, the schedule of paragraph 14.2.7 of the First Procedural Order applied:

> 14.2.7. If the Tribunal decides not to bifurcate and therefore to join the objections to jurisdiction to the merits ("scenario 1"), the schedule shall be as follows:
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> (i) The Claimants and Respondent shall file document requests by 8 February 2013 (1 week from decision on bifurcation). By this date, Canada and Mexico shall file submissions under NAFTA Article 1128, if any, and any intending Amicus shall file Amicus Applications for Leave to File;
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> (ii) The Claimants and Respondent shall make submissions, if any, on the Amicus Applications for Leave to File by 15 February 2013 (1 week from Amicus deadline);
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> (iii) The Claimants and Respondent shall submit a response and any objections to the document requests by 1 March 2013 (3 weeks from document requests);

(iv) The Tribunal shall decide on any Amicus Applications for Leave to File within two weeks from receiving submissions from the Claimants and Respondent, if any (that is, by 1 March 2013);

(v) The Claimants and Respondent shall submit any responses to objections to the document requests and produce any documents to which they do not object by 15 March 2013 (2 weeks from objections to document requests);

4. On 31 January 2013, by an announcement posted on the website of the International Centre for Settlement of Investment Disputes ("ICSID"), the Tribunal "invite[d] any person or entity that is not a Disputing Party in this arbitration proceeding or a Contracting Party to the NAFTA to make a written application for permission to file submissions as an *amicus curiae*" by 8 February 2013. The Tribunal indicated that the application and submission should adhere to the requirements set forth in the recommendations of the Free Trade Commission on non-disputing party participation dated 7 October 2003 (the "FTC Statement").

5. On 7 February 2013, the ICSID Secretariat received from the Applicant an "Application for Leave to File a Non-Disputing Party Submission" from the Study Center for Sustainable Finance of the Business Neatness Magnanimity BNM srl ("BNM"), dated 25 August 2011 ("BNM's Application"). In accordance with Section B(1) of the FTC Statement, BNM's Application was accompanied by a submission called "Statement of Non Disputing Party". Both documents were attached to an email of 7 February 2013 sent by the Director of the Study Center for Sustainable Finance. The Director wrote that "[t]his time BNM will not send any permission to file submission, but kindly request the tribunal to reconsider to admit former BNM submission reminding that NAFTA art. 1139G in the French and the Spanish versions lack an equivalent to the expression in the expectation in both languages there is no doubt that the intangible property has to been acquired or used with the purpose to obtain an economic benefit or other commercial purpose."

6. On 15 February 2013, Apotex Holdings Inc. and Apotex Inc. (collectively, "Apotex" or the "Claimants") filed observations on BNM's application requesting that the Tribunal deny it. In a letter of the same date, the Respondent indicated that it was taking no position on BNM's application.

7. For the sake of clarity, the Tribunal notes that there are two other NAFTA arbitral proceedings commenced by Apotex Inc. against the United States of America (being also the Respondent in this arbitration). Those proceedings are conducted under the UNCITRAL Rules and are administered by the International Centre for Settlement of Investment Disputes ("ICSID"). They are referred to as the *Apotex Inc. v. United States*, NAFTA/UNCITRAL proceedings. The Disputing Parties in this arbitration noted that BNM filed an application in the NAFTA/UNCITRAL proceedings on 25 August 2011, which was the subject of Procedural Order No. 2 on the Participation of a Non-Disputing Party rendered on 11 October 2011 by the tribunal in those other proceedings.

II. BNM'S Application

8. The Tribunal understands that BNM submitted in this arbitration materially the same application and statement that it had already submitted to the tribunal on 25 August 2011 in the *Apotex Inc. v. United States*, NAFTA/UNCITRAL proceedings. Accordingly, the Tribunal will quote the summary of BNM's application included in Procedural Order No. 2 issued in those NAFTA/UNCITRAL proceedings at paragraphs 8, 9, and 11:

> 8. BNM is a management consulting firm, which describes itself as a "*per profit non-governmental organisation*", incorporated on 20 July 2005 in Rome, Italy, with a "*significant presence in Mexico and several other countries in the world*". (Application para.1). It states that:
>
> > "BNM on one hand share interests of hundreds of securities firms, banks, and asset managers, on another hand, and as it first priority is sharing interests of last users of the goods, and services of the projects in which take part. BNM members include leading professionals from universities, investment banks, broker-dealers, and mutual funds companies. BNM's mission is to support a strong financial industry, investor opportunity, capital formation, job creation, and economic growth, while building not only trust and confidence in the financial markets, but also making a substantial difference in emerging and frontier countries as well as in poor areas in developed countries.
> >
> > BNM shareholders were donors and managers of trusts and foundations working in the South of world, since BNM incorporation, results show that the best way to help the poor is not through donations, but in helping them to get access to justice, credit, and information. All BNM work and venture capital is devoted to

> health, environment, safety and other scientific matters related to strategic sectors in the economy."
>
> (Application, page 1)
>
> 9. BNM's research and development arm, the Study Center for Sustainable Finance is said to be:
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> "… an interdisciplinary working group of scholars and leading professionals in the fields of law, finance and development, including engineers with scientific background. The Study Center for Sustainable Finance develops new creative ways to improve public and private sectors' ability to invest money more efficiently in public goods, particularly increasing the overall number of public and private funds available for health, food, education, infrastructure, energy, and services."
>
> (Application, page 1)
>
> […]
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> 11. In its Application, BNM confirms that it does not have any affiliation, direct or indirect, with any disputing party or any pharmaceutical company anywhere in the world. It also states that it has not received any financial or other assistance from any government, person or organization.

9. BNM further states that its interest is the development of "new financial alternative services to build a more ethical legal framework for the global pharmaceutical market."[1] To that effect, it considers the possibility of creating a "litigation venture capital fund" to finance intellectual property litigation.[2]

10. Finally, BNM specifies that its submission is intended to address "the scope of definition of 'investment' under Article 1139(g) NAFTA". More particularly, it seeks to determine "whether or not an expectation is an entitlement to an intangible asset, and if so, if the venture capital used by claimant is an 'investment' as defined and protected by Chapter XI."[3]

III. The Claimants' Observations

11. The Claimants note that BNM has submitted in this arbitration the exact same application and statement that was rejected by the tribunal in the other

[1] BNM's application, at para. 4.
[2] *Ibid*, p. 2.
[3] *Ibid* at para. 5.

NAFTA/UNCITRAL proceedings. The Claimants further state that "[b]ecause BNM has made the same application here, Apotex also relies here on the submissions it made in 2011 opposing BNM's application." The Claimants conclude that BNM's application is without any merit for the same reasons discussed in Apotex's 2011 submissions and Procedural Order No. 2 of the other tribunal.[4]

12. Since the Claimants rely on the observations filed on 8 September 2011 in the context of the other Apotex case, and their contents were summarized by the tribunal of the NAFTA/UNCITRAL proceedings in its Procedural Order No. 2, this Tribunal will here refer to that summary, at paragraphs 12 and 13:

> 12. In its Response, Apotex objects to BNM's submission on the grounds that the Applicant has failed to satisfy the standards determined in the FTC Statement.
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> 13. According to Apotex:
>
> a) BNM has not demonstrated that it would assist the Tribunal in the determination of factual or legal issues relating to this Arbitration, as it does not appear to have any knowledge or insight about any of the issues that are at the heart of the proceedings (see Response, paras. 5-9);
>
> b) BNM does not address matters within the scope of the dispute; nor does it have a significant interest in the Arbitration. In Apotex's words:
>
> > "Applicant has *no recognizable interest in* NAFTA, *no recognizable interest in* Apotex's NAFTA claims, and *no recognizable interest in* the federal court cases that serve as the basis for Apotex's claims" (Response, para. 17);
>
> c) BNM does not seek to support the public's interest, as the:
>
> > "Applicant's sole apparent interest in this Arbitration lies in advancing its own *private* interests in opening a litigation venture capital fund and making a profit for its investors—which could explain why Applicant failed to address this factor altogether"
> > (Response, para. 20).
>
> d) BMN has mischaracterised Apotex's arguments, such that granting BNM the opportunity to file a submission would not only disrupt the proceedings, but also force the Disputing Parties and the Tribunal to address misstatements and thereby unduly burden, if not unfairly prejudice, Apotex (Response, paras. 22-24).

[4] Apotex produced these documents on 15 February 2013 as CLA-477(2) and CLA-476(2) respectively.

13. In their observations of 15 February 2013 in this arbitration, the Claimants further note that BNM's application is here even more misplaced than it was in the other arbitrations because it does not address the facts and arguments advanced in this arbitration. The Claimants give the following striking example: contrary to BNM's Application, "Apotex has never asserted in this arbitration that legal services constitute an investment under the NAFTA."

14. The Claimants reiterates their conclusion that accepting BNM's application would be disruptive and distracting to this arbitration; and it would unduly burden, if not unfairly prejudice, the Claimants.

IV. The Tribunal's Decision

15. Pursuant to Articles 1120(1)(b) and 1120(2) and as confirmed in the First Procedural Order, these arbitration proceedings are to be conducted in accordance with the ICSID Arbitration (Additional Facility) Rules in force as of April 2006 ("Arbitration (AF) Rules"), except to the extent that these rules are modified by Section B of NAFTA Chapter 11.

16. Article 41(3) of the Arbitration (AF) Rules allows the Tribunal to accept submissions by non-disputing parties based on certain criteria. However, the Disputing Parties and the Tribunal chose to apply the FTC Statement both to potential non-disputing parties and to the Tribunal's ruling. The First Procedural Order provides that:

> 20.2 […] Any Amicus application shall adhere to the requirements set forth in the recommendations of the FTC on non-disputing party participation, issued on 7 October 2003.
>
> […]
>
> 20.4 The Tribunal shall issue a ruling on any Amicus application for leave to file a submission, taking into account the recommendations of the FTC on non-disputing party participation.

17. The Tribunal considers that this choice does not contradict the wording of Article 41(3) of the Arbitration (AF) Rules. This wording provides the following:

> (3) After consulting both parties, the Tribunal may allow a person or entity that is not a party to the dispute (in this Article called the "non-disputing party") to file a written submission with the Tribunal regarding a matter within the scope of the dispute. In determining whether to allow such a filing, the Tribunal shall consider, among other things, the extent to which:
>
> (a) the non-disputing party submission would assist the Tribunal in the determination of a factual or legal issue related to the proceeding by bringing a perspective, particular knowledge or insight that is different from that of the disputing parties;
>
> (b) the non-disputing party submission would address a matter within the scope of the dispute;
>
> (c) the non-disputing party has a significant interest in the proceeding.
>
> The Tribunal shall ensure that the non-disputing party submission does not disrupt the proceeding or unduly burden or unfairly prejudice either party, and that both parties are given an opportunity to present their observations on the non-disputing party submission.

18. Article 41(3) does not contain an exhaustive list of criteria, as it provides that the Tribunal shall consider those stated "among other things". Therefore this Tribunal is free to address "other things" for the purpose of arriving at its decision. In addition, all the criteria contained in Article 41(3) are also re-stated in Sections B(6), (7) and (8) of the FTC Statement. These provisions read as follows:

> 6. In determining whether to grant leave to file a non-disputing party submission, the Tribunal will consider, among other things, the extent to which:
>
> > (a) the non-disputing party submission would assist the Tribunal in the determination of a factual or legal issue related to the arbitration by bringing a perspective, particular knowledge or insight that is different from that of the disputing parties;
> >
> > (b) the non-disputing party submission would address matters within the scope of the dispute;
> >
> > (c) the non-disputing party has a significant interest in the arbitration; and
> >
> > (d) there is a public interest in the subject-matter of the arbitration.
>
> 7. The Tribunal will ensure that:
>
> > (a) any non-disputing party submission avoids disrupting the proceedings; and
> >
> > (b) neither disputing party is unduly burdened or unfairly prejudiced by such submissions.
>
> 8. The Tribunal will render a decision on whether to grant leave to file a non-disputing party submission. If leave to file a non-disputing party submission is granted, the Tribunal will set an appropriate date by which the disputing parties may respond in writing to the non-disputing party submission. By that date, non-disputing NAFTA Parties may, pursuant to Article 1128, address any issues of interpretation of the Agreement presented in the non-disputing party submission.

19. Therefore the application of the FTC Statement by the Tribunal in this arbitration complies with Article 41(3) of the Arbitration (AF) Rules.

20. The question to be examined by the Tribunal is whether the Applicant, BNM, meets the criteria under Sections B(6) and (7) of the FTC Statement. The Tribunal notes first that BNM is not a national of a Party to the NAFTA but claims to have a significant presence in the territory of a Party (Mexico) as required by Section B(1) of the FTC Statement. BNM does not substantiate its allegation but the Tribunal considers that no determination is needed on this first question in view of the Tribunal's reasoning below.

21. The Tribunal considers that BNM does not meet all of the requirements of Sections B(6) and (7) of the FTC Statement, for the following reasons.

Assistance to the Tribunal

22. This criterion is contained in Section B(6)(a) of the FTC Statement:

> (a) the non-disputing party submission would assist the Tribunal in the determination of a factual or legal issue related to the arbitration by bringing a perspective, particular knowledge or insight that is different from that of the disputing parties;

23. Likes the tribunal in the other Apotex proceedings, this Tribunal has considered whether BNM could provide a materially different perspective or insight in regard to the issues in this arbitration, on the basis of either substantive knowledge or relevant expertise or experience, that extend beyond or differ from that of the Disputing Parties themselves.[5]

24. Even if the requirement of a different expertise, experience or perspective from that of the Disputing Parties is construed very broadly, the Tribunal agrees with the Claimants' assessment that BNM does not have any special knowledge or relevant expertise or experience with the food and drug laws of the United States, or any other aspect of the United States legal and judicial system, or with NAFTA itself, which would provide to

[5] Procedural Order No. 2 dated 11 October 2011, *Apotex Inc. v. United States*, NAFTA/UNCITRAL proceedings, para. 21.

the Tribunal with a material perspective or insight that is different from that of the Disputing Parties.[6]

25. This assessment is corroborated by the fact that BNM filed in this arbitration the exact same application and submission as in the *Apotex Inc. v. United States*, NAFTA/UNCITRAL proceedings, while the issues are quite different. Even though Apotex Inc., for the UNCITRAL proceedings, and Apotex Holdings Inc. and Apotex Inc. for this arbitration, rely on Article 1139 of the NAFTA, the context and the claims are materially different and manifestly would have called for different submissions from BNM.

26. The Disputing Parties have already fully briefed the Tribunal in their memorials in this arbitration on the definition of investment and of the meaning and scope of Article 1139(g) of the NAFTA in particular, which BNM intends to address in its submission. Accordingly, the Tribunal concludes that BNM's submission would not be of any assistance to the Tribunal in this arbitration. In addition, as explained below, BNM's submission would not address matters within the scope of the dispute.

Addressing Matters Within the Scope of the Dispute

27. This criterion is intended to avoid the unnatural broadening of the scope of the Disputing Parties' dispute by non-disputing parties, as set out in Section B(6)(b) of the FTC Statement:

> (b) the non-disputing party submission would address matters within the scope of the dispute;

28. BNM states in its application of 25 August 2011[7] and in its cover email message of 7 February 2013 that the issue to be addressed in its submission is the scope of the definition of "investment" under Article 1139(g) of the NAFTA. The Tribunal understands that BNM intends particularly to address the question whether pending or

[6] Apotex's 2011 submissions, para. 5 and Procedural Order No. 2 dated 11 October 2011, *Apotex Inc. v. United States*, NAFTA/UNCITRAL proceedings, para. 23.
[7] BNM's Application, para. 5.

tentatively-approved Abbreviated New Drug Applications ("ANDAs") constitute "investments" under Article 1139 of the NAFTA.

29. By letter of 7 February 2013, the Claimants indicated to this Tribunal that they no longer claim damages for the loss of the opportunity to launch new products during the Import Alert. As a consequence, the Claimants state that "because pending ANDAs in this case were exclusively relevant to the claim for hindered launch damages, the question of whether pending or tentatively-approved ANDAs constitute investments is no longer presented here."

30. In these circumstances, the Tribunal determines that BNM's proposed submission addresses a non-issue outside the scope of the Disputing Parties' dispute.

Significant Interest in the Arbitration

31. This criterion is contained in Section B(6)(c) of the FTC Statement:

> (c) the non-disputing party has a significant interest in the arbitration;

32. As stated in Procedural Order No. 2 issued in the UNCITRAL proceedings at paragraphs 27 and 28:

> 27. […] In paragraph 4 of its Application, BNM identifies its interest in this matter as follows: "*Develop new financial alternative services in order to build a more ethical legal framework for the global pharmaceutical market*". It further states that "*BNM is considering the pros and cons of opening a 'litigation venture capital fund' in which the biotechnology, telecommunications, mining and energy sector may benefit.*" (Application, para. 4).
>
> 28. The Applicant has not defined any significant interest in this arbitration. It has not explained how the rights or principles it may represent or defend might be directly or indirectly affected by the specific jurisdictional issue on which it intends to make submissions, or indeed by the outcome of the overall proceedings. The fact that the Applicant is "*considering*" opening a venture capital fund does not amount to a concrete interest as contemplated by the FTC Statement. It is, at best, an aspiration, that has not in fact vested in any way at this juncture. The Tribunal therefore concludes that BNM has failed to satisfy this criterion.

33. The Tribunal considers that while BNM seems to have a general interest in the Tribunal adopting interpretations of NAFTA that support its apparent interest in narrowing the

scope of drug manufacturers' intellectual property protection, BNM has not demonstrated its *significant* interest. This Tribunal therefore concurs with and adopts the other tribunal's conclusion.

The Public Interest in the Subject Matter of this Arbitration

34. This is the last requirement of Section B(6) of the FTC Statement:

> (d) there is a public interest in the subject-matter of the arbitration.

35. The Tribunal considers that the subject-matter of an arbitration proceeding is to be considered of public interest when the decisions to be issued in that arbitration are likely to affect individuals or entities beyond the Disputing Parties.

36. It is not at all clear from BNM's application which public interest it has identified in this arbitration's subject-matter. Even if it could be inferred that BNM refers to the impact of a decision on the interpretation of Article 1139(g) of the NAFTA on the pharmaceutical industry at large, as explained above that question is now moot. In any event, the Tribunal determines that BNM has also not met this requirement.

Avoiding Disruption, Burden and Prejudice to the Disputing Parties

37. In view of the Tribunal's decisions above, it would be materially disruptive and would unduly burden the Disputing Parties to grant permission to BNM to file a non-disputing party submission in this arbitration, given especially the fact that BNM's application does not address the relevant facts and arguments advanced in this arbitration.

V. The Tribunal's Order

38. For the above reasons, the Tribunal does not grant to the Study Center for Sustainable Finance of the Business Neatness Magnanimity BNM srl permission to file a non-disputing party submission in this arbitration.

Date: 4 March 2013

Signed for the Tribunal:

V.V. Veeder (President of the Tribunal)