

**IN THE ARBITRATION UNDER
CHAPTER 11 OF THE
NORTH AMERICAN FREE TRADE AGREEMENT
AND THE
UNCITRAL ARBITRATION RULES (1976)**

BETWEEN:

APOTEX INC.

Claimant,

- AND -

THE GOVERNMENT OF THE UNITED STATES OF AMERICA

Respondent.

**CLAIMANT APOTEX INC.'S REJOINDER MEMORIAL ON
RESPONDENT'S REPLY ON OBJECTIONS TO JURISDICTION**

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1. In accordance with Procedural Order No. 1, entered on December 16, 2010, Claimant Apotex Inc. hereby respectfully submits its Rejoinder Memorial On Respondent's Reply On Objections To Jurisdiction.

I. INTRODUCTION.

2. In its efforts to prematurely dismiss Apotex's NAFTA claims on jurisdictional grounds, Respondent mischaracterizes the nature of Apotex's investments in its U.S. ANDAs, misrepresents the finality requirements under international law, and misapplies its timeliness and finality arguments to the facts underlying Apotex's Pravastatin Claim. The Tribunal can and should dismiss each jurisdictional challenge in its entirety.

3. As explained herein, the arguments advanced by Respondent fail to refute that Apotex is an "investor" that has made certain "investments" in the United States under Article 1139. Apotex invested significant resources into developing, formulating and compiling separate ANDAs for its generic sertraline and pravastatin products, and submitted those ANDAs to the FDA, in order to market the underlying ANDA products in the United States. These ANDAs amount to Apotex "property," which are to be "used for the purpose of economic benefit," and thus qualify as "investments" under Article 1139(g).¹

4. Respondent argues that Apotex does not have full property rights in its ANDAs because, at the time of Respondent's respective breaches, Apotex's ANDAs were only "tentatively approved" and subject to ongoing governmental oversight. As explained in detail below, the approval status and ongoing regulation of Apotex's ANDAs is irrelevant to the issue of whether such ANDAs constitute the "property" of Apotex. Apotex's investment in its

¹ NAFTA, art. 1139 at "investment" sub(g).

ANDAs, and its property rights therein, are actualized the moment such ANDAs are filed with FDA.

5. Respondent's argument, moreover, lacks all legitimacy given the fact that the sole reason Apotex was only eligible for tentative approval (as opposed to final approval) was *because Respondent had breached its obligations under NAFTA*. Respondent cannot use its own breach to avoid jurisdiction over Apotex's claims.

6. Respondent also argues that Apotex's interests arising from the commitment of capital and other resources in the United States, including the purchase of ingredients from U.S. suppliers, the designation of a U.S. agent, and the expenditure of legal fees in connection with filing and maintaining its ANDAs, also fail to qualify as investments under Article 1139(h).² Instead, according to Respondent, such capital commitments are merely "commercial contracts for the sale of goods or services" that fall under Article 1139(i).³ Respondent's arguments, once again, mischaracterize Apotex's position. Apotex's investment interests lie in its ANDAs, not merely in claims for money arising from its supply contracts or relationships with its U.S. agent or U.S. attorneys. Thus Article 1139(i) does not apply.

7. Respondent's challenges to Apotex's Pravastatin Claim on timeliness and finality grounds fair no better. Respondent concedes that certain court decisions with respect to Apotex's Pravastatin Claim (namely, at least the June 6, 2006 decision of the United States Court of Appeals for the District of Columbia and the August 17, 2006 denial of rehearing *en banc* by that same court) occurred within the three-year limitations period. Further, Respondent does not dispute that the sole issue underlying both of those judicial decisions was whether the FDA's April 11, 2006 administrative ruling refusing to find that Apotex's declaratory judgment action

² *Id.* at "investment" sub(h).

³ *Id.* at "investment" sub(i).

resulted in a court decision sufficient to trigger Teva's 180-day exclusivity period was unlawful under United States law. Given these uncontested facts, Respondent's timeliness argument must be rejected because FDA's decision is part of one single, continuous action, which must be considered for the Tribunal to effectively resolve Apotex's Pravastatin Claim on the merits.

8. Finally, Respondent's arguments that the judicial actions challenged in Apotex's Pravastatin Claim were not sufficiently "final" to impart State responsibility under NAFTA are based on an improper interpretation of the "finality" doctrine, which essentially vitiates the "obviously futile" exception that applies to Apotex's claim.

9. Because none of Respondent's arguments has merit, the Tribunal must dismiss Respondent's jurisdictional challenge and move forward with adjudicating Apotex's arbitration claims on their merits.

II. APOTEX IS AN INVESTOR THAT MADE INVESTMENTS PURSUANT TO NAFTA ARTICLE 1139.

10. Article 1139 of NAFTA defines "investment" as follows:

investment means:

* * *

(g) real estate or other *property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes*; and

(h) *interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, such as under*

(i) *contracts involving the presence of an investor's property in the territory of the Party, including turnkey or construction contracts, or concessions, or*

(ii) *contracts where remuneration depends substantially on the production, revenues or profits of an enterprise[.]*⁴

⁴ *Id.* at "investment" (emphasis added).

11. As Respondent previously has acknowledged, the term “investment” must be construed broadly.⁵ Similarly, others have observed that “[t]he definition of ‘investment’ that is protected under Chapter 11 is much broader than the real property rights and specific interests in property that are protected under the Takings Clause” in the United States.⁶

12. Invoking these inclusive interpretations here, Apotex’s ANDAs and ANDA-related interests unquestionably qualify as investments under both Article 1139(g) and Article 1139(h).

A. APOTEX HAS STANDING UNDER ARTICLE 1139(g).

13. The main thrust of Respondent’s initial argument appears to be that Apotex cannot satisfy the definition of “investment” under Article 1139(g) because Apotex’s ANDAs were merely “tentatively approved” when the breaches occurred, as opposed to being “finally approved.” Specifically, according to Respondent, Apotex “has not established under Article 1139(g) that, on the date its claims arose, its ANDAs were property acquired or used. Instead, those ANDAs were *tentatively approved* applications”⁷ Respondent’s distinctions between tentatively approved ANDAs and finally approved ANDAs are distinctions without a difference.

14. Regardless of whether an ANDA is “tentatively approved,” “finally approved,” or is still under substantive review by the FDA, the ANDA is the exclusive “property” of the

⁵ NORTH AMERICAN FREE TRADE AGREEMENT, IMPLEMENTATION ACT, STATEMENT OF ADMINISTRATIVE ACTION, H.R. Doc. No. 103-159, Vol. 1, 103d Cong. 1st Sess., at 140 (1993) (“‘Investment’ is broadly defined in Article 1139, and both existing and future investments are covered.”) [R82].

⁶ See, e.g., Matthew C. Porterfield, *International Expropriation Rules and Federalism*, 23 STAN. ENVTL. L. J. 3, 6 (2004). [C86].

⁷ Reply on Objections to Jurisdiction of Respondent United States of America ¶ 16 (Oct. 17, 2011) (emphasis in original) (hereinafter “U.S. Reply M.O.J.”).

ANDA applicant that has been acquired for, and/or is expected to be used for, the purpose of economic benefit or other business purposes.

15. Indeed, an ANDA meets the Article 1139(g) definition of investment at the very moment it is submitted to FDA. FDA regulations explicitly state that, once filed in the United States with the FDA, only the “applicant may transfer *ownership* of its application.”⁸ In other words, FDA readily admits that an ANDA applicant owns its ANDA, and that the property rights in such ANDA may only be transferred by the applicant itself.

16. Respondent’s argument, moreover, fails to account for the critical fact that, *but for* Respondent’s breach of its legal obligations, Apotex would have been granted *final*, not tentative, approval because no other impediments to approval existed at that time.

17. According to Respondent, “FDA grants ‘tentative approval’ to an ANDA when all scientific and procedural conditions for approval have been met, but FDA cannot finally approve an ANDA until various other barriers to approval no longer apply.”⁹ In FDA’s own words:

*If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.*¹⁰

18. Apotex’s own tentative approval letters for its pravastatin and sertraline ANDAs, moreover, acknowledge that Apotex had met the manufacturing quality, clinical safety and efficacy requirements necessary for ANDA approval in the United States, but that, due solely to

⁸ 21 C.F.R. § 314.72(a). [C71].

⁹ U.S. Reply M.O.J. ¶ 17.

¹⁰ Drugs@FDA glossary, “Tentative Approval” (emphasis added) [C77]; *see also* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) (codifying FDA’s long-standing definition) [C2].

unexpired periods of 180-day generic marketing exclusivity, FDA was prevented from granting Apotex final approval.¹¹

19. Apotex’s pravastatin and sertraline NAFTA claims stem directly from Apotex’s efforts to clear the approval blockade caused by the respective exclusivity periods. Apotex was unable to lift the blockades, however, *precisely because of the unlawful and improper actions of FDA and the United States federal courts, which Apotex has challenged via these actions.* Indeed, had the FDA and the United States federal courts fulfilled their obligations under NAFTA and international law, Apotex *would have obtained final approval without delay*, thereby eliminating the need for this NAFTA action altogether. Respondent can not now hide behind its own unlawful breach to deny Apotex jurisdiction over its NAFTA claims.

20. Moreover, even “tentatively approved” ANDAs and ANDAs that are still under review have value, to the extent such factor is relevant to the Tribunal’s “investment” analysis.¹² Indeed, companies regularly buy, sell, and calculate the estimated value of ANDAs that have not yet received approval.¹³

¹¹ See FDA Tentative Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) (Sept. 27, 2006) [R96]; FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, 40, and 80 mgs) (Apr. 25, 2006) [R99].

¹² See U.S. Reply M.O.J. ¶ 23.

¹³ See, e.g., *Zydus Acquires KV’s Generics Business*, World Generic Markets (August 5, 2011), available at 2011 WLNR 15529655 (“KV Pharmaceutical announced that it had entered into a definitive agreement to divest [the firm’s generics subsidiary] . . . to Zydus Pharmaceuticals USA for around US \$60 million in cash [T]he agreement included . . . existing and pipeline ANDAs The acquired ANDA pipeline comprises eight existing filings and five products under development”) [C81]; *Impax Laboratories at Jeffries & Co. Global SpecPharma & European Healthcare Conference – Final Transcript*, Fair Disclosure Wire (October 5, 2010) (Art Koch, Senior VP of Finance and CFO of Impax Laboratories, Inc. stating that “So for 2010 on a budget of \$41 million, about the same as the prior year, we expect to file 8 to 10 new ANDA’s A key aspect of our business is our pipeline. We have 96 products in the pipeline. 63 in the lab and 33 already pending [ANDAs filed with FDA]”) [C78]; *Q3 2007 Abraxis BioScience Earnings Conference Call – Final Transcript*, Fair Disclosure Wire (November 8, 2007) (Tom Silberg, Chairman of APP, Abraxis Bioscience stating that “[W]e continue to fuel our development pipeline. We have over 60 product candidates in current stages of development and currently have 29 ANDA’s pending with the FDA, including tentative approvals. Present market value of

21. As an extension of Respondent’s baseless “tentative approval” argument, Respondent argues that Apotex has no property interests in its sertraline and pravastatin ANDAs for the further reason that they “were subject to change on the basis of new information that may come to FDA’s attention,” and because even finally approved ANDAs can “be revoked for numerous public health and policy reasons under U.S. law without giving rise to compensation.”¹⁴ Again, these arguments offer much ado about nothing, and have no basis in law or fact.

22. To begin, while this is not the appropriate venue to address whether an ANDA may be revoked without giving rise to compensation—and certainly Respondent has offered no legal support for this proposition—even if this were true (Apotex takes no position on this point),¹⁵ it has no bearing on the issue of whether Apotex’s ANDAs constitute “property” for purposes of Article 1139(g). The law in the United States is clear that a party may enjoy property rights in something regardless of whether such party would be entitled to compensation

the pending ANDAs is over \$2.6 billion”) [C80]; *Impax Laboratories at JP Morgan HealthCare Conference – Final Transcript*, Fair Disclosure (January 11, 2011) (Larry Hsu, President, CEO, Impax Laboratories, stating that “In our generic division, we have 65 ANDAs approved, and currently market 43 of them. Our pipeline of opportunity remains strong with 36 pending at the FDA and 62 under development that will fuel our future growth. These 98 products in the pipeline currently have a U.S. brand and generic sales totaling over \$33 billion. This is a clear indication of the potential and the value we see in our generic business.”) [C79].

¹⁴ U.S. Reply M.O.J. ¶¶ 18, 20 (internal quotations omitted).

¹⁵ Respondent further cannot use Apotex’s prior omeprazole litigation proceedings in an attempt to raise some sort of quasi-estoppel theory. (See U.S. Reply M.O.J. ¶ 20 n.22). In the omeprazole litigation, FDA granted Apotex final approval of its omeprazole ANDA on October 6, 2003, and Apotex commenced marketing that drug product. *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 81 (D.D.C. 2007) [R115]. On June 14, 2007, a district court found that Apotex’s product infringed a patent, and because the pediatric exclusivity associated with that product did not expire until October 20, 2007, “FDA revoked final approval of [Apotex’s] ANDA until at least October 20, 2007.” *Id.* at 81-82. Again, however, the focus on FDA’s ability to revoke an ANDA misses the mark. Apotex’s property interests lie in its ANDAs, not in FDA’s approval of such ANDAs.

for a government taking of that property.¹⁶ Moreover, as noted above, “[t]he definition of ‘investment’ that is protected under Chapter 11 is much broader than the real property rights and specific interests in property that are protected under the Takings Clause” in the United States.¹⁷

23. Similarly, the fact that an ANDA—whether tentatively or finally approved—is subject to continuing governmental oversight and regulation to ensure patient health and safety is immaterial to whether or not the ANDA itself constitutes “property.” Any number of products are subject to continuing governmental oversight and/or product recalls—that does not mean that none can claim to be “property.” For the same reason, it simply is not relevant whether FDA retains the authority to revoke an ANDA applicant’s tentative or final approval. Apotex has property rights *in its ANDAs*, regardless of whether FDA’s *approval* of such ANDAs or the *products* that are the subjects of those ANDAs may be revoked or recalled. In other words, Apotex’s property rights arise from the ANDAs themselves—not from FDA’s “permission” to sell products pursuant to such ANDAs.

24. Respondent next criticizes Apotex’s reliance on Black’s Law Dictionary’s definition of “property.”¹⁸ Yet, tellingly, Respondent cites nothing in its place to show that reliance on this definition is improper—nor could it. Black’s Law Dictionary is an acceptable legal authority routinely cited by United States federal courts, including numerous courts that have relied specifically upon its definition of “property,” as well as other NAFTA Tribunals.¹⁹

¹⁶ See, e.g., *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001-1004 (1984) (whether manufacturer had a protectable property interest was a separate inquiry from whether a governmental taking of such property required compensation) [C75]; *Tri-Bio Labs., Inc. v. U.S.*, 836 F.2d 135, 139-141 (3d Cir. 1988) (same) [C76].

¹⁷ Matthew C. Porterfield, *International Expropriation Rules and Federalism*, 23 STAN. ENVTL. L. J. 3, 6 (2004). [C86].

¹⁸ U.S. Reply M.O.J. ¶ 21.

¹⁹ See, e.g., *Brobeck, Phleger & Harrison LLP v. Orrick, Herrington & Sutcliffe LLP*, 408 B.R. 318, 337 (Bankr. N.D. Cal. 2009) (“While the [United States] Bankruptcy Code does not define ‘property,’ Black’s

25. Respondent in fact relies on Black’s Law Dictionary itself, and points to the definition of “private property” to argue that Apotex does not enjoy property interests in its ANDAs because Apotex allegedly does not have “exclusive” or “absolute” rights to such ANDAs.²⁰ This argument appears to be little more than a regurgitation of Respondent’s “tentative approval” and “revocation” arguments, and thus is subject to the same fatal flaws discussed above.

26. For example, Respondent appears to argue that, because Apotex’s ANDAs are subject to continuing regulatory oversight, and because Apotex cannot sell its ANDA products until such ANDAs are approved by FDA, Apotex does not have “exclusive” ownership over its ANDAs. As explained above, irrespective of whether Apotex’s ANDAs are subject to continuing governmental oversight, or are subject to revocation or recall, Apotex still has a property interest in the underlying ANDA itself.

27. Moreover, Respondent’s “market-based notion of exclusivity” reveals a clear lack of understanding of what an ANDA is and is not. Far from what Respondent would have this Tribunal believe, “[a]ny manufacturer of [a] generic drug” can *not* simply “produce the same product” as a different manufacturer.²¹ Each ANDA contains proprietary information regarding its formulation, development, testing, and compliance with the overriding statutory and

Law Dictionary defines it as “[t]he right to possess, use and enjoy a determinate thing.”) [C72]; *Nat’l Sign & Signal v. Livingston*, 422 B.R. 645, 655 (W.D. Mich. 2009) (“When faced with the need for a definition of ‘property,’ Michigan courts have relied on Black’s Law Dictionary, where property is defined as ‘the right to possess, use and enjoy a determinate thing (either a tract of land or a chattel); the right of ownership.’” (citing several additional cases relying upon Black’s Law Dictionary’s definition of property)) [C74]; *John R. Sand & Gravel Co. v. U.S.*, 60 Fed. Cl. 230, 237 (Fed. Cl. 2004) (citing Black’s Law Dictionary 1232 (7th ed. 1999) for the definition of “property as ‘[t]he right to possess, use, and enjoy a determinate thing.’”) [C73]; *see also Grand River Enterprises Six Nations Ltd. v. United States*, NAFTA/UNCITRAL, Award ¶ 110 (Jan. 12, 2011) [R76].

²⁰ U.S. Reply M.O.J. ¶ 24.

²¹ U.S. Reply M.O.J. ¶ 25.

regulatory requirements. Thus, while competing generic companies may file ANDAs referencing the same brand-name drug product, each ANDA represents a separate investment, and each drug product subject to those ANDAs is considered a separate proprietary product subject to its own individual testing and compliance requirements, among other things.

28. Finally, Respondent argues that because much of Apotex's development costs "were incurred: (1) in Canada, and (2) to meet regulatory requirements to export a particular product for sale by others," the costs associated with Apotex's ANDAs "cannot constitute an investment under NAFTA."²² In support of this argument, Respondent cites the *Bayview Award* for the proposition that "NAFTA Chapter Eleven was not intended to provide substantive protections or rights of action to investors whose investments are wholly confined to their own national States, in circumstances where those investments may be affected by measures taken by another NAFTA State Party."²³ This additional argument fails at several levels.

29. *First*, Apotex's investments (*i.e.*, ANDAs) are not "*wholly confined to [Apotex's] own national State[]*." Far from it: (1) Apotex's ANDAs were filed and are maintained in the United States; (2) the sole purpose of an ANDA is to develop and market a product for the purpose of obtaining economic benefit in the United States; and (3) because Apotex has designated certain U.S. suppliers in its ANDAs, Apotex must manufacture its ANDA products with components obtained from the United States.

30. *Second*, in arguing that "[t]he mere regulation of Apotex's foreign products . . . cannot transform the costs incurred in developing those products into U.S. investments,"²⁴

²² U.S. Reply M.O.J. ¶ 27.

²³ U.S. Reply M.O.J. ¶¶ 28-29 (citing *Bayview Award* ¶ 103 [R69] (emphasis added) and *Grand River Award* ¶ 87 [R76]).

²⁴ U.S. Reply M.O.J. ¶ 29.

Respondent purposefully ignores the fact that Apotex's ANDAs seek approval to market the subject products *solely in the United States*. The *Grand River* Award relied upon by Respondents thus has little application here, as Claimants Grand River, Kenneth Hill and Jerry Montour sold products "only in Canada."²⁵

31. This Tribunal should thus find that, consistent with the *Bayview* Award, because Apotex, a Canadian company, has "ma[de] an investment that falls under the laws and the jurisdiction of the authorities of another NAFTA Party, it [should] be treated as a foreign investor under Chapter Eleven."²⁶

B. APOTEX HAS STANDING UNDER ARTICLE 1139(h).

32. Respondent further argues that Apotex's additional activities in the United States, namely the purchase of U.S. supplies, the designation of a U.S. agent and distributor, and incurring and paying U.S. legal fees, do not qualify as investments under Article 1139(h). Importantly, Respondent does not contest that these activities constitute the "commitment of capital or other resources [in the United States] to economic activity [in the United States]," but rather solely asserts that Apotex purportedly has "failed to identify what investment 'interests' arose from" these activities.²⁷ Nothing could be further from the truth.

33. As Apotex has repeatedly made clear, Apotex's investment "interests" lie in the submission, maintenance and utilization of its sertraline and pravastatin ANDAs and in achieving an economic benefit from the marketing and sale of the products subject to such ANDAs in the United States. Indeed, Respondent itself acknowledges that "Apotex's expenses

²⁵ *Grand River*, Award ¶ 97 [R76].

²⁶ *Bayview*, Award ¶ 102 [R69].

²⁷ U.S. Reply M.O.J. ¶ 35.

. . . relate to Apotex's . . . related ANDAs.”²⁸ Respondent should not now be allowed to argue that Apotex has kept those interests hidden, or even more disingenuously allege that Apotex's interests simply do not exist.

34. Respondent further argues that Apotex's purchase of inactive ingredients from suppliers based in the United States; designation of an authorized agent in the United States; and expenditure of legal fees and costs in the United States are merely “claims to money” arising from “commercial contracts for the sale of goods and services,” and therefore are expressly excluded from the definition of “investment” under Article 1139(i) for purposes of giving rise to a NAFTA claim. Respondent is wrong again.

35. Apotex is not asserting that it has made an investment for purposes of NAFTA based “solely” on monetary claims arising from its supply agreements, the relationship with its U.S. agent, or the payment of legal fees. Rather, Apotex's investment is, and always has been, its ANDAs (and its property and other interests in its ANDAs), which arise at least in part from Apotex's capital commitments in the United States. Thus, for at least this additional reason, Apotex has standing under Article 1139(h).

III. APOTEX'S PRAVASTATIN CLAIM WAS TIMELY SUBMITTED AND SATISFIED ANY FINALITY REQUIREMENTS.

36. In addition to its standing arguments, Respondent contends that, “regardless of whether Apotex qualifies as an ‘investor’ or its activities were ‘investments’ under the NAFTA, the Tribunal cannot hear Apotex's pravastatin claim challenging [the April 11, 2006] final ruling of the [FDA], as that claim is time-barred,” and further “the Tribunal cannot hear Apotex's challenge to the U.S. Courts' adjudication of Apotex's pravastatin claim, because Apotex failed

²⁸ U.S. Reply M.O.J. ¶ 35.

to obtain the judicial finality that is required before bringing an international claim.”²⁹ Neither argument holds water.

37. Respondent admits that the June 6, 2006 decision by the United States Court of Appeals for the District of Columbia Circuit and the August 17, 2006 denial of rehearing *en banc* by that same Court admittedly fall within the three-year period.³⁰ Respondent nevertheless appears to argue that the April 11, 2006 FDA administrative ruling at the heart of these decisions cannot be considered when evaluating Apotex’s Pravastatin Claim.³¹ Respondent’s attempts to separate the FDA’s administrative ruling from the court decisions interpreting the lawfulness of that ruling must fail.³² The FDA ruling is part of a single, continuous action that served to unlawfully delay Apotex’s final approval. Indeed, without the underlying administrative ruling, there would have been no judicial action. For this reason, in analyzing the judicial decisions related to Apotex’s Pravastatin Claim, the Tribunal must necessarily consider the underlying FDA decision that served as the underlying basis for those decisions.

38. Second, Respondent argues that, even though the judicial decisions challenged in Apotex’s Pravastatin Claim fall within the three-year limitations period, these decisions are nevertheless insufficient to hold it responsible under NAFTA because the decisions purportedly lack sufficient “finality.”³³ Respondent’s argument is grounded in an overly restrictive interpretation of the finality doctrine which effectively eliminates the “obviously futile” exception altogether. Applying the proper standard of finality, the Tribunal must find that Apotex had sufficiently exhausted its local remedies; that it would have been obviously futile for

²⁹ U.S. Reply M.O.J. ¶¶ 8-9.

³⁰ *See, e.g., id.* at ¶ 54.

³¹ *Id.* at ¶¶ 52-54.

³² *Id.* at ¶ 41.

³³ *Id.* at ¶¶ 10-11.

Apotex to pursue further judicial recourse; and that Apotex could not have obtained relief that was “effective and adequate” before the relevant 180-day exclusivity period expired.

A. THE TRIBUNAL MUST CONSIDER FDA’S ADMINISTRATIVE RULING IN REVIEWING APOTEX’S PRAVASTATIN CLAIM.

39. Apotex’s Pravastatin Claim is based on, *inter alia*, the unlawful, arbitrary and capricious ruling by FDA finding that the dismissal of Apotex’s declaratory judgment action against the patent owner failed to constitute a court decision trigger under the statute, and the subsequent actions by the D.C. District Court and the Court of Appeals for the D.C. Circuit in wrongfully denying Apotex’s federal court challenge to that ruling.³⁴ Notably, Respondent does *not* argue that a judicial decision by the United States federal courts is beyond the scope of NAFTA.³⁵ Moreover, Respondent does not dispute: (1) that the sole issue in the judicial proceedings that are the subject of Apotex’s Pravastatin Claim was the lawfulness of FDA’s administrative ruling; or (2) that the U.S. federal courts had the authority to reverse the FDA’s administrative ruling, find that the court decision trigger had occurred under the statute, and grant Apotex immediate final approval of its pravastatin ANDA. Further, Respondent fully acknowledges that the Court of Appeals decisions challenged as part of Apotex’s Pravastatin Claim were filed within the three-year limitations period.³⁶ Given these uncontested facts, this Tribunal plainly has jurisdiction to hear Apotex’s entire Pravastatin Claim on its merits.

³⁴ See Apotex Statement of Claims ¶¶ 107-08, 112-29.

³⁵ NAFTA, art. 1101. More specifically, Respondent appears to concede that a sufficiently final judicial action can be an “action” that is “maintained or adopted by the party” sufficient to vest this Tribunal with jurisdiction. Other Tribunals constituted under Chapter Eleven have reached the same conclusion. (*See, e.g., Loewen Group, Inc. v. United States*, NAFTA/ICSID Case No. ARB(AF)/98/3, Award on Jurisdiction, ¶¶ 32, 54, 60 (Jan. 5, 2001) [C85]; *Mondev Int’l Ltd. v. United States*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award ¶ 128 [R81] (evaluating allegations of breach based on U.S. court decisions).

³⁶ U.S. Reply M.O.J. ¶ 43 n. 55.

40. Pursuant to NAFTA Article 1116(2), “[a]n investor may not make a claim if more than three years have elapsed from the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage.” Importantly, this provision provides for a three-year limitation period from the time that the Claimant acquired *both* knowledge of breach and knowledge of loss or damage.³⁷ Further, nothing prevents this Tribunal from considering underlying facts related to a NAFTA claim that occurred prior to this three-year period. In fact, in the *Loewen* and *Glamis Gold* arbitrations held under NAFTA Chapter Eleven, Respondent argued that consideration of such underlying facts were perfectly acceptable.³⁸

41. Respondent argues that the challenged federal court decisions and underlying FDA decision were not part of one “single action” because FDA’s ruling was “administrative,” while the court decisions were “judicial.”³⁹ These are distinctions without a difference. The fact is, the *only* issue addressed in the court actions was whether FDA’s administrative action should be overturned. It would thus be wholly improper for this Tribunal to refuse to consider the underlying FDA administrative decision when reviewing Apotex’s claim on the merits.

³⁷ KINNEAR, BJORKLUND & HANNAFORD, INVESTMENT DISPUTES UNDER NAFTA: AN ANNOTATED GUIDE TO NAFTA CHAPTER 11 at 1116-36b (July 2009) (“The investor must, however, acquire knowledge of both the breach and the ensuing damage. The three-year limitation period presumably runs from the later of these events to occur in the event that the knowledge of both events is not simultaneous.”) [C65]; *see also* U.S. M.O.J. ¶ 32 n.63 (*citing* Vienna Convention on the Law of Treaties (“VCLT”), May 23, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679 (1969), art. 31 [R85]). While the United States is not a party to the VCLT, it has recognized since at least 1971 that the Convention is the “authoritative guide” to treaty law and practice. *See* Letter from Secretary of State Rogers to President Nixon Transmitting the Vienna Convention on the Law of Treaties, Oct. 18, 1971, *reprinted in* 65 DEP’T OF ST. BULL. 684, 685 (1971) [R77]).

³⁸ *See, e.g., Loewen Group, Inc. v. United States*, NAFTA/ICSID Case No. ARB(AF)/98/3,, Award ¶ 77 (June 26, 2003) [R78]; *Glamis Gold, Ltd. v. United States*, NAFTA/UNCITRAL, Procedural Order No. 2 ¶ 19 (May 31, 2005) (recognizing Respondent United States’ view that claimant, “of course, may refer to facts that predate [the three-year limitations period] as background for its claims”) [C62].

³⁹ U.S. Reply M.O.J. ¶ 41.

42. The Tribunal decisions cited by Respondent do not require a different result. For instance, in *Mondev*, the Tribunal was asked to consider whether certain events allegedly occurring prior to enactment of NAFTA could be the appropriate subject of a NAFTA claim.⁴⁰ The *Mondev* Tribunal held, “[t]he basic principle is that a State can only be internationally responsible for breach of a treaty obligation if the obligation is in force for that State at the time of the alleged breach.”⁴¹ Here, of course, this is not an issue; NAFTA was in effect throughout the course of the underlying factual proceedings. Moreover, in *Mondev*, the Tribunal observed that the Claimant there must have known that “not all its losses would be met by the [judicial] proceedings.”⁴² Not so, here. The U.S. federal courts had the authority to reverse the FDA’s unlawful decision and immediately approve Apotex’s pravastatin ANDA. And because Apotex took advantage of the local remedies available to it, FDA’s decision must be considered part of the same single, continuous action as the judicial actions reviewing it.

43. Respondent’s reliance on *Grand River* is equally misplaced. There, the Claimants challenged individual state laws that were enacted on several different dates. In addressing which of these challenged state laws fell within the three-year statutory period, the Tribunal held, *inter alia*, that the Claimants had not pled that each individual state’s enactment of the law was a separate breach and never supported such a claim with information regarding “the particular states and times where the products were sold to consumers.”⁴³ Here, in contrast, the FDA’s

⁴⁰ See, e.g., *Mondev*, Award ¶ 70 [R81]; see also *id.* at ¶ 73 (“As to these rights or interests, there was no continuing wrongful act in breach (or potentially in breach) of Article 1110 at the date NAFTA entered into force.”).

⁴¹ *Id.* at ¶ 68.

⁴² *Id.* at ¶ 87.

⁴³ *Grand River*, Decision on Jurisdiction ¶ 81 [R75].

April 11, 2006 decision is part of a single, continuous action that culminated at the federal appellate court level.

44. In the end, because Respondent admits that at least the June 6, 2006 Court of Appeals decision and the August 17, 2006 denial of rehearing *en banc* were submitted within the three-year limitations period, and further does not dispute that those decision are based entirely upon the April 11, 2006 FDA administrative ruling, this Tribunal must evaluate the full merits of Apotex's Pravastatin Claim.

B. APOTEX SUFFICIENTLY EXHAUSTED ITS LOCAL REMEDIES WITH RESPECT TO ITS PRAVASTATIN CLAIM TO SATISFY ANY FINALITY REQUIREMENT.

45. Finally, Respondent argues that the June 6, 2006 decision of the United States Court of Appeals for the District of Columbia and the subsequent August 17, 2006 denial of rehearing *en banc* did not satisfy the finality requirements necessary to impart State responsibility under NAFTA. Rather, according to Respondent, even after the D.C. Circuit denied Apotex's petition for rehearing *en banc* with only 67 days remaining in the 180-day exclusivity period for pravastatin, Apotex nevertheless was required to pursue one of two options: (1) seek *certiorari* from the U.S. Supreme Court, or (2) proceed to have its case heard on the merits in the district court.⁴⁴ By failing to do so, Respondent argues that the judicial acts on which Apotex's claim is based lack the requisite finality because both paths were "available" to Apotex. Respondent not only misrepresents what is required under the finality doctrine, but also how that doctrine properly applies to Apotex's facts here.

⁴⁴ U.S. Reply M.O.J. ¶¶ 61, 63.

46. Respondent concedes that a Claimant need not exhaust all local remedies if such action would be “obviously futile.”⁴⁵ Yet, Respondent’s overly restrictive interpretation of the finality doctrine effectively eliminates that exception altogether. Neither NAFTA nor international law permits this. As Apotex explained in its opening brief, neither of Respondent’s suggested courses of action would have allowed Apotex to obtain relief that was “effective and adequate” before the relevant 180-day exclusivity period expired on its own accord.⁴⁶ For that reason, once the D.C. Circuit denied Apotex’s petition for rehearing *en banc*, Respondent’s breach was sufficiently final for purposes of implicating State responsibility under Chapter Eleven of NAFTA.

47. According to Respondent, “[u]nder international law, the question of whether the failure to obtain judicial finality may be excused for ‘obvious futility’ turns on the unavailability of relief by a higher judicial authority, not on measuring the likelihood that the higher judicial authority would have granted the desired relief.”⁴⁷ And because, Respondent continues, Apotex could have petitioned the United States Supreme Court for certiorari or continued litigating its case before the district court, despite the fact that only 67 days remained in the exclusivity period, Apotex had an *available* local remedy that it failed to exhaust. This, quite simply, is not the law.

48. The “obvious futility” exception to the finality doctrine, by its plain and ordinary terms, cannot require Apotex to have undertaken obviously futile measures to preserve its NAFTA claim. The question therefore is not whether any further judicial recourse is merely “available,” but whether any such recourse would have offered Apotex an effective and adequate

⁴⁵ U.S. Reply M.O.J. ¶ 56.

⁴⁶ Apotex Counter-Mem. ¶¶ 90-96; *Loewen*, Award ¶ 168 [R78].

⁴⁷ U.S. Reply M.O.J. ¶ 10.

remedy under the circumstances.⁴⁸ Here, at the time that Apotex dismissed its case, because of the impending natural expiration of the 180-day exclusivity period, the clear answer to that question is “no.”

49. Respondent argues that “Apotex misunderstands the futility exception under international law, conflating the availability of a remedy with a prediction of the likelihood of obtaining preferred relief in a particular case.”⁴⁹ Not so. At no point has Apotex argued that it lacked a “reasonable prospect of success” or that success was “improbable.”⁵⁰ Apotex asserts, rather, that, at the time Apotex dismissed its litigation, even if it were eventually successful on the merits, any local remedy could not have effectively redressed its injuries. Respondent’s own authority recognizes that this is the critical issue in any proper finality analysis.

50. For example, Judge Aréchaga expressly acknowledges that, “even if there are remedies existing and available, the [judicial exhaustion] rule does not apply if these remedies are ‘obviously futile’ or ‘manifestly ineffective,’” and further that such circumstances would exist where there is “such unreasonable delay in the administration of the remedy that it becomes ineffective.”⁵¹ This is precisely the situation here where, due to the impending expiration of the 180-day exclusivity period—which Apotex does not control—there simply was no further avenue for Apotex to pursue in order to attain effective relief from the U.S. federal courts.

51. Professor Borchard similarly observes that the need to seek local remedies is “subject to the important condition that the local remedy sought is obtainable *and* is effective in

⁴⁸ See, e.g., *Loewen*, Award ¶ 168 [R78].

⁴⁹ U.S. Reply M.O.J. ¶ 59.

⁵⁰ *Id.*

⁵¹ Jiménez de Aréchaga, *International Law in the Past Third of a Century*, 159 RECUEIL DES COURS 294-95 (1978) [R132].

securing redress. If this condition is absent, it would be futile and an empty form to require the injured individual to resort to local remedies.”⁵²

52. And Dr. C. F. Amerasinghe agrees that, “[w]here it is clear that the resort to an appeal or reference to another court or tribunal would not be a source of adequate redress, the alien is excused from spending his money and time.”⁵³

53. Holding firm to its “mere availability” theory of finality, Respondent makes the unremarkable observation that the “United States Supreme Court has the power to hear cases that relate only to preliminary procedural issues and to issue stays.”⁵⁴ As noted above, however, it is not enough that further judicial recourse is merely available; the question is whether pursuing such recourse would have been obviously futile. Here, there is no question that it would have been.

54. Applying the proper recitation of the finality doctrine to the facts here, it is unrealistic to the point of absurdity to suggest that, with only 67 days left in Teva’s 180-day exclusivity period, the Supreme Court would not only grant a petition for certiorari, but could schedule argument and render an opinion before the exclusivity period expired. The average time between a grant of certiorari and the Supreme Court’s decision is approximately nine months—a fact Respondent does not dispute.⁵⁵ Moreover, the briefing schedule alone likely would have extended beyond the 180-day exclusivity period.⁵⁶

⁵² E. BORCHARD, *THE DIPLOMATIC PROTECTION OF CITIZENS ABROAD* 821-22 (1916) (emphasis added) [C84].

⁵³ C.F. AMERASINGHE, *LOCAL REMEDIES IN INTERNATIONAL LAW* 205 (2d ed. 2004) [C82]; *see also* RESTATEMENT (THIRD) FOREIGN RELATIONS LAW § 713 cmt. f (the failure to exhaust local remedies is excused if “such remedies are clearly sham or inadequate, or their application is unreasonably prolonged”) [C83].

⁵⁴ U.S. Reply M.O.J. ¶ 61.

⁵⁵ Apotex Counter-Mem. ¶ 94 n. 109.

⁵⁶ *Id.* at ¶ 94.

55. Nor is it any more reasonable to suggest that, had Apotex pressed forward with its case at the district court level, it could have obtained a favorable court decision before the issue became moot on October 23, 2006. At the time Apotex voluntarily dismissed its litigation on October 3, 2006, only 20 days remained in the 180-day exclusivity period. Apotex had no reasonable expectation that it could obtain a decision that would afford it effective relief before that date.⁵⁷

56. Taking Respondent's argument to its logical conclusion, had Apotex simply continued to litigate for those additional twenty days at the district court level, regardless of whether the court had provided Apotex with any effective relief whatsoever, Apotex's claims would have met the finality requirements under NAFTA. Yet, because Apotex voluntarily dismissed its action once it became obvious there was no possibility of obtaining effective relief, this Tribunal, according to Respondent, lacks jurisdiction to review Apotex's challenge to the U.S. courts' adjudication of Apotex's Pravastatin Claim. This is absurd. As noted above, "[w]here it is clear that the resort to an appeal or reference to another court or tribunal would not be a source of adequate redress, the alien is excused from spending his money and time."⁵⁸

57. Respondent's additional suggestion that Apotex is somehow at "fault" for the futility of any effective remedy has no factual or legal support and should be rejected out of hand. Apotex complied with all deadlines, and actively pursued its case. And, far from

⁵⁷ Respondent incredibly argues that even after the D.C. District Court and D.C. Circuit rejected Apotex's motion for expedited consideration and preliminary injunctive relief, Apotex should nevertheless have sought expedited consideration again from the district court. The law does not require Apotex to expend its resources in an unreasonable or irresponsible manner simply because it can.

⁵⁸ C.F. AMERASINGHE, LOCAL REMEDIES IN INTERNATIONAL LAW 205 (2d ed. 2004) [C82]; *see also* RESTATEMENT (THIRD) FOREIGN RELATIONS LAW § 713 cmt. f (the failure to exhaust local remedies is excused if "such remedies are clearly sham or inadequate, or their application is unreasonably prolonged") [C83].

intentionally waiving its right to a local remedy, like the Claimant in the *Ambatielos Case*, Apotex vigorously appealed its case until any such further action was obviously futile.⁵⁹

58. Finally, Respondent's arguments regarding the 80 mg strength of pravastatin are a red herring and reveal a substantial lack of understanding of the generic pharmaceutical market. The fact is, once Teva's exclusivity period had expired for all the other strengths, Apotex's ability to obtain any effective relief expired with it, as the damage to the generic pravastatin market had been done.

59. In the end, under a proper application of the finality doctrine to the facts here, this Tribunal has jurisdiction over the judicial actions challenged in Apotex's Pravastatin Claim, as pursuing the options suggested by Respondent would have been obviously futile and could not have provided Apotex with any effective relief before the 180-day exclusivity period expired on October 23, 2006.

IV. CONCLUSION AND RELIEF REQUESTED.

60. For the foregoing reasons, and those expressed in Apotex's Counter-Memorial, Claimant Apotex Inc. respectfully requests that the Tribunal dismiss Respondent's objections to jurisdiction; deny in its entirety the relief sought in Respondent's Memorial on Objections to Jurisdiction; proceed with the scheduling of briefing and a hearing on the merits of Apotex's arbitration claims; and award Apotex any further relief the Tribunal may deem appropriate, including but not limited to an award of costs and fees for defending against Respondent's jurisdictional objections.

⁵⁹ See U.S. Reply M.O.J. ¶ 62 n. 106.

Dated: December 16, 2011

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