IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN

- x
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APOTEX, INC., :
:
Claimant/Investor, :
:
and :
:
UNITED STATES OF AMERICA, :
:
Respondent/Party. : AMENDED
:
- x Volume 1

FIRST SESSION OF THE ARBITRAL TRIBUNAL

Wednesday, February 15, 2012

The World Bank
1818 H Street, N.W.
Conference Room 4-800
Washington, D.C.

The hearing in the above-entitled matter came on, pursuant to notice, at 9:04 a.m. before:

MR. TOBY T. LANDAU, Q.C., President

MR. CLIFFORD M. DAVIDSON, Arbitrator

HON. FERN M. SMITH, Arbitrator

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Also Present:

MS. AURÉLIA ANTONIETTI,
Secretary to the Tribunal

Court Reporter:

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Registered Diplomate Reporter (RDR)
Certified Realtime Reporter (CRR)
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MS. JOANNA HOLGUIN

On behalf of the Government of Canada:

MS. FATIMA NAKHUDA

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C O N T E N T S

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P R O C E E D I N G S

PRESIDENT LANDAU: Good morning, ladies and gentlemen. Welcome to the hearing on preliminary issues in the two arbitrations commenced under Chapter Eleven of NAFTA and the UNCITRAL Arbitration Rules in the case of Apotex and the Government of the United States of America.

If I can start with introductions before we get to the substance of the day, as you know, I'm Toby Landau. To my left is Judge Fern Smith. To my right is Clifford Davidson, and to my further right is the Secretary to the Tribunal, Ms. Aurélia Antonietti.

And can I start, perhaps, although I've got a List of Attendees with each side introducing who is here today.

MR. RAKOCZY: Yes, thank you, Mr. Landau. William Rakoczy, on behalf of the Claimant Apotex, Inc., and with me is my partner, Lara FitzSimmons, and my colleague Bob Teigen.

PRESIDENT LANDAU: Thank you very much.

And for the Respondent.

MS. McLEOD: Mary McLeod, the Principal

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09:05:57 Deputy Legal Adviser for the U.S. Department of State on behalf of Respondent.

With me are Jeff Kovar, Jeremy Sharpe, Patrick Pearsall, David Bigge, and Neale Bergman. Oh, I'm sorry, and also Abbey Lounsberry.

PRESIDENT LANDAU: Thank you. Thank you very much.

Let's just quickly recap on the agreed format for this week's hearing. We have--we're starting just a little bit late, but the timing is as agreed that there will be, first of all, a presentation of the Respondent's case, which will be for about three and a half hours with a 15-minute break, which we'll take around about 10:45 or thereabouts, whenever it's convenient. We then break for lunch, 12:45 to 1:45. We then have Claimant's presentation for three and a half hours from 1:45 with a 15-minute break which we'll take mid-afternoon around half past 3:00 or so. And then we have a period from half past 5:00 to 5:45 for remaining Tribunal questions or any other issues to be considered for closing.

We then break for the day and start again

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09:07:01 tomorrow at nine with about an hour and a quarter each side for closing arguments, Respondent, followed by Claimant, a break, and then any remaining questions after that.

Are there any preliminary issues that either side would like to raise before we get into the submissions?

As for the Claimants?

MR. RAKOCZY: None for Claimants.

PRESIDENT LANDAU: And for the Respondent?

MS. McLEOD: None for the Respondent.

PRESIDENT LANDAU: Thank you very much. I understand that because this is being broadcast there is an issue as to possible confidentiality of some materials and that that has already been agreed that there will be a break to the feed when a confidential issue is coming up, and then the feed will be joined again thereafter.

Is that right?

MR. RAKOCZY: That's our understanding.

PRESIDENT LANDAU: Very good.

Then, before we start, there are just a few

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09:07:57 questions that I have which I would like to raise at the outset and give both sides an opportunity to think about. I'm not asking for a response straightaway, but a response before we close sometime tomorrow.

We have set this hearing up as a jurisdiction hearing, and both sides have presented submissions framed on issues of jurisdiction. Under the UNCITRAL Rules, that would indicate a procedure under Article 21, leading to a determination on jurisdiction, and that is certainly the way that the prayers for relief on both sides have been structured; i.e., the question being whether or not we, as a Tribunal, have jurisdiction.

The three issues that appear live now are, firstly, of course, the definition of "investment" and "investor" under the NAFTA. Secondly, there is a question of a possible time bar for one of the drugs in question, one of the claims. And, thirdly, there is a question of finality, the application of a rule of finality on the processing claim.

The first of those issues, I think, uncontroversially can be called a "jurisdiction

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09:09:19 issue." My question, however, is whether issues two and three properly characterized are actually jurisdiction issues. And let me explain that. The second issue is a question of a possible time bar. Depending on how one characterizes that, that could be seen as a merits question. The question may not be does this Tribunal have the ability to rule upon this issue at all or these claims at all, but rather whether or not there is a tenable claim. And the question that's put by the Respondent is, or the answer that's put by the Respondent is that there is no claim because it is time-barred, and that might be properly characterized as not an issue of jurisdiction, but an answer on the merits of the claim.

If that's right, that doesn't change the arguments. It doesn't change our ability to rule, but it does change the actual nature of the inquiry that we are embarking on and the frame of an award. That wouldn't be under Article 21 of the UNCITRAL Rules. It would be an award on a preliminary issue being a merits issue.

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09:10:31 And that, of course, may also have an impact if our Award under the UNCITRAL Rules and under the law of New York might be then taken before any subsequent forum to be questioned. There will be an issue as to what the nature of the determination is, whether it's a jurisdiction determination or a merits determination.

So, that is the question I'm raising on issue two.

There's also the distinction as a matter of international law between jurisdiction and admissibility which has not yet been articulated or addressed in either side's submissions. So the first question is will be is it jurisdictional merits; and, if it's jurisdiction, is it jurisdiction or admissibility?

The third issue, the question of judicial finality is a bit more complicated, but my question is the same. Is that actually a question of jurisdiction or is it something else? Is it merits?

And if you just bear with me one moment to explain this so that my query is clear and you have

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09:11:35 time afterwards to think about it, when one talks about a rule of judicial finality, there are two different types of rule. One is procedural and one is substantive. There is a procedural rule as to a requirement to exhaust local remedies before coming to an international tribunal, and there is an argument that has no application under NAFTA, that there is no procedural requirement generally to exhaust local remedies. Of course, there may be different views on that, but that may be the prevailing view.

Distinct from that, however, is a substantive requirement to reach judicial finality which is an ingredient of a cause of action itself when you're questioning judicial conduct, and that seems to be the focus of both sides' submissions in this case. That is, if you are questioning judicial conduct, then in order to perfect your cause of action, you have to get to the highest court to reach that finality. That analytically is totally different from a procedural requirement to exhaust remedies. It's an ingredient in the cause of action.

If that's right--all this is for the sake of

09:12:56 argument--if that is right, then it is jurisdictional, or are we back in the same territory that actually is on the merits. It's a question of whether the cause of action has been established or whether a requirement is missing? And again, that would take us back to the same question, are we under 21 of the UNCITRAL Rules? Is this a jurisdiction award, or is it an award on preliminary issues?

And my last point on this is that equally on that point there is a question, if it is jurisdiction, might it not be better characterized as admissibility; i.e., the claim is not yet ripe rather than this Tribunal has no jurisdiction to actually rule upon this at all, ever. Can I just ask for now, are those questions clear? I'm not asking for an answer at the moment.

MR. RAKOCZY: Clear.

PRESIDENT LANDAU: So, again, it doesn't affect our task. It rather is the framework for our decision.

With that, we can begin.

The other thing I should say is that we have

09:14:01 received with thanks and read all written submissions, so your respective presentations can begin from that starting point. We're very grateful to both sides for the work that's been put in, and you can assume that what you have given us has been read.

So, unless there are any other issues, then we will begin with Respondent's presentation. Thank you.

OPENING STATEMENT BY COUNSEL FOR RESPONDENT

MS. McLEOD: Good morning, Mr. President, Mr. Davidson, and Judge Smith. I am Mary McLeod, the Principal Deputy Legal Adviser at the United States Department of State. The Legal Adviser, Harold Koh, was looking forward to attending today's hearing and opening the United States's presentation. Unfortunately, yesterday, the Secretary of State asked him to travel to Egypt to address some very sensitive issues, and he had to leave last night.

On Harold's behalf, I'm honored to appear before you today for the Respondent, the United States of America. As the State Department's senior career lawyer, I'm pleased to introduce both the United

09:15:13 States's key jurisdictional arguments, and the team from our Office of International Claims and Investment Disputes that will present these arguments to you.

My presence at this public hearing today underscores the U.S. Government's commitment to binding and transparent international dispute resolution under international agreements such as the NAFTA. These agreements play a vital role in the overall legal framework designed by the Governments of Mexico, Canada, and the United States both to ensure the international protection of foreign investors and their investments and to preserve the three governments' ability to regulate in the public interest to protect health and safety. Our joint commitments enshrined in the NAFTA is fully shared by our partner governments who also appear before Chapter Eleven tribunals such as this one.

Members of the Tribunal, thank you for your hard work and commitment to this public process. The United States will do its part to fully and fairly to present our case and to respond forthrightly to your questions. In turn, we ask that you as arbitrators

09:16:26 solemnly adhere to the terms of the NAFTA and decide the case before you based solely on the facts, your jurisdiction, and the law as specified in that agreement.

My colleagues will address the United States's jurisdictional objections in greater detail and answer your questions, but let me preview their remarks by outlining the big picture behind this case and highlighting what we believe to be the crucial issues before you.

At bottom, this case is simple. It is about a company, Apotex Inc., a Canadian manufacturer of generic drugs that never had an investment in the United States, that lost no property rights through adverse U.S. Government action, that brought its NAFTA claims late, and that failed to exhaust its domestic judicial remedies. Even so, Apotex now seeks not less than $16 million in damages for alleged violations of NAFTA Chapter Eleven.

In doing so, Apotex raises somewhat usual claims concerning two different generic drugs. Sertraline, the generic version of Zoloft, a drug

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developed by Pfizer that is used to treat depression, obsessive-compulsive disorder, panic attack, and post-traumatic stress disorder, and Pravastatin, the generic version of Pravachol, a drug developed by Bristol-Meyers Squibb that is commonly used for lowering cholesterol and preventing cardiovascular disease.

Apotex's claims are unusual in two ways. First, those claims are not so much about how the U.S. Government has treated Apotex as they are about Apotex's failure to deprive other companies of an exclusive marketing period for their generic drug products. Under certain circumstances, U.S. law offers generic drug makers like Apotex 180 days of market exclusivity as an incentive to bring their products quickly to market and to challenge weak patents protecting branded drugs. But in this case, Apotex does not allege that the United States Government, which it claims expropriated its property, ever denied it permission to sell its generics Sertraline and Pravastatin drugs in the United States. Nor does it claim that it was the first company to

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make an application for these two drugs or that it was ever entitled to 180 days of market exclusivity for them.

Instead--and this is the first unusual point about this case--this case involves Apotex's unsuccessful attempts through litigation to deprive the 180 days of market exclusivity to those other companies that did first challenge the patents. Such litigation was standard practice in the generic pharmaceutical industry where companies often use litigation to try to trigger 180 days of market exclusivity and to time their entry into the market.

Apotex played its hand and now finds itself unhappy with the result. Its real complaint is that its own tactics were unsuccessful.

The second thing that makes Apotex's case unusual is that it seeks rulings from this Tribunal on the application of U.S. law. These claims assert that the U.S. Food and Drug Administration and U.S. federal courts in New York and Washington all egregiously misapplied U.S. law. Apotex, thus, comes here claiming three violations of international law that

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arise from this misapplications of U.S. law. It alleges that decisions of the FDA and U.S. courts were first, discriminatory in violation of NAFTA Article 1102; second, a violation of the minimum standard of treatment required by customary international law in violation of Article 1105; and, third, an unlawful expropriation of Apotex's property in violation of NAFTA Article 1110.

In the presentations that follow, we will give you more background on those NAFTA provisions and explain why the legal claims are baseless.

But for present purposes, what Apotex emphasizes are its claims that the FDA and federal courts in New York and Washington made "blatant legal errors" in interpreting and applying what Apotex freely admits was a complex body of U.S. law. Apotex states, "The general statutory framework governing the review and approval of Apotex's generic drug products is confusing and dense, and each of Apotex's claims involves very different and complicated sets of underlying facts and law."

But what precisely were those alleged blatant

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legal errors? In its Sertraline Claim, Apotex alleges that U.S. courts applied the wrong constitutional test in deciding whether Apotex had standing to bring a declaratory judgment action in Federal Court to declare a patent invalid. Under U.S. law, Federal courts are courts of limited subject matter jurisdiction which may only hear cases that involve genuine cases or controversies under Article 3 of the U.S. Constitution.

In literally hundreds of declaratory judgment cases over several decades, federal courts have found such cases or controversies to exist where a plaintiff can demonstrate under the common law a "reasonable apprehension of suit." At the time U.S. courts were addressing Apotex's Sertraline Case, the Federal Court referred to the reasonable apprehension of suit standard as the traditional test for standing in such cases. Despite this precedent, Apotex nonetheless contends that by applying the traditional test to Apotex's Sertraline Claim, federal courts committed a blatant legal error that violated the NAFTA.

Apotex makes much of the fact that over a

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09:22:13 year after Apotex was denied standing to bring its own claim, the U.S. Supreme Court, in a footnote in another case, cast doubt about application of the "reasonable apprehension" test. But what Apotex is basically arguing is that the Supreme Court's suggestion of modifications in the common law, years after Apotex's own case, somehow establishes a violation of international law in that earlier case.

But the ordinary evolution of the common law does not give rise to post hoc violations of domestic law or international law. If every change to the common law could give rise to international law violations, it would freeze the normal development of the law by courts or unduly burden the international investment dispute system with arguments that ordinary common law adjudication violated international law.

Apotex's Pravastatin Claim is equally baseless. The applicable statute provides that a generic drug company's 180-day market exclusivity period may be triggered by a decision of a court holding the patent which is the subject of the certification to be invalid or not infringed. Apotex

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09:23:25 alleges that this test is satisfied by a stipulated order of dismissal reflecting the litigating Parties' agreement not to litigate a patent infringement dispute.

But on its face that does not meet the statutory test. FDA, the Expert Agency charged with construing the statute, has interpreted this law as requiring an actual decision of a court holding the relevant patent to be invalid or not infringed, not merely a stipulated dismissal order reflecting the litigating Parties' agreement not to litigate the patent infringement issue.

The U.S. Court found FDA's interpretation reasonable and within its discretion, yet Apotex now claims that the FDA's decision and subsequent U.S. court decisions regarding the so-called "court decision trigger," were so blatantly wrong so as to violate not just domestic law, but also the NAFTA.

If this case were to proceed to the merits, the United States would demonstrate that these claims are baseless and seek an award of additional costs, but, Mr. President, Members of the Tribunal, as our

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09:24:32 pleadings have shown and as we will further demonstrate today, this case should not proceed to the merits because for three simple reasons. Apotex has failed even to establish the Tribunal's jurisdiction over its claims.

First, Apotex has no investment in the United States. A claim cannot be heard unless the claimant first is an Investor and second has made an investment. Apotex fails on both accounts. It has not established that it is an Investor or that it made, was making, or sought to make an investment in the United States. It thus cannot claim of NAFTA's investment chapter for either its Sertraline or its Pravastatin Claims.

Second, Apotex is time-barred. Under Article 1116(2) of the NAFTA, even an acknowledged 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." Despite this plain language, Apotex challenges a final measure taken by

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09:25:43 the FDA more than three years before Apotex brought its claim. Apotex cannot now try to move forward the date of this measure for purposes of avoiding time bar by linking it to subsequent court proceedings.

Third, Apotex failed to obtain finality for its Pravastatin Claim. Despite its current claim that the Court decisions were so riddled with errors as to violate international law, Apotex chose at that time not to seek Supreme Court review. The United States cannot be held responsible for alleged violations of the NAFTA in international law by its courts for nonfinal judicial acts.

In short, our position is clear and simple. With respect to either claim, Apotex had no investment protected by NAFTA Chapter Eleven; and for the Pravastatin Claim, it was late in challenging the FDA Decision, and it did not properly exhaust its domestic judicial appeals before burdening this Tribunal with its claim.

These facts, we submit, are fatal to Apotex's claim that this Tribunal has jurisdiction to hear the underlying charges of discrimination, expropriation,

09:26:54 and substandard treatment and relieve this Tribunal of the burden of hearing the charges on the merits.

In the remaining time, let me look with you in more detail at the three jurisdictional questions presented to this Tribunal.

First, is an application to approve the sale of Canadian goods in the United States an "investment in the territory of the United States"?

Second, when you're late filing your NAFTA challenge to a regulatory measure, can you avoid the limitations period by pointing to subsequent domestic court proceedings?

And, third, can you decline to seek Supreme Court review for what you claim to be blatant legal errors and nevertheless claim that you have exhausted your judicial domestic remedies?

To each of these important questions, we submit, the answer is no.

The first question concerns Apotex's claim that it is an Investor with an investment in the United States, but significantly, Apotex does not allege that it owns any real property, operations, or

09:27:57 subsidiaries in the United States. To the contrary, Apotex admits that it does not reside or have a place of business in the United States. Everyone agrees that Apotex develops, tests, manufactures, and labels its generic drugs in Canada entirely outside of the United States.

Apotex does not even allege that it prepared its abbreviated New Drug Applications, or ANDAs, in the United States. Apotex concedes that the ANDAs were prepared in Canada.

So what contacts with the United States does Apotex allege? Only three: The hiring of U.S. litigation counsel, the designation of a U.S. agent and distributor, and, like many foreign manufacturers who are not investors, the purchase of some raw materials in the United States that it shipped back to Canada for use in manufacturing there. Yet, hiring local counsel, designating an agent, and buying raw materials for export does not an investment make.

Nor, critically, does Apotex allege that its ANDAs had been either finally approved or denied at the time of the alleged breaches which, as you recall,

09:29:10 were related to Apotex's failure to extinguish other manufacturers' exclusive marketing periods. Nevertheless, Apotex now claims that at the moment it filed its applications with the FDA, it made an investment in the territory of the United States. According to Apotex, its applications themselves constitute investments under NAFTA Article 1139(g) because they are, "real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes."

Yet, even on a plain reading of this provision, Apotex's argument makes no sense for two reasons. First, Apotex's ANDAs are applications not property. They are not and are not claimed to be intellectual property, concessions, or other sorts of intangible property interests often protected by domestic law and international investment agreements.

Second, for purposes of the plain language of Article 1139(g), Apotex did not have any property acquired or used for economic benefit in the United States. All Apotex had was pending abbreviated new

09:30:25 drug applications which required it to provide to the FDA data regarding the safety and effectiveness of its projects and to ensure that the Canadian manufacturing facilities complied with technical and safety requirements. A pending abbreviated New Drug Application is not property acquired or used for economic benefit in the United States.

Apotex bases its entire case for jurisdiction on the argument that if the Tribunal consults a legal dictionary, it will find a very broad definition of "property," and it notes that a Party may enjoy property rights under U.S. law regardless of whether it can claim compensation for a Government taking of those rights. Apotex further observes that even nonfinal ANDAs are transferable to other Applicants.

But surely the test under Article 1139(g) is not simply whether a thing creates some interest for which someone might pay money, however contingent and replicable that interest might be. The issue is not whether an interest has greater than zero Market Value. Rather, the question is whether the Claimant has established that it has a property interest

protected by law against wrongful interference and whether that property interest has the characteristics of an investment.

We all understand intuitively that mere applications are by themselves not property or investments. Apotex has not established that the NAFTA intended to protect as an investment applications for regulatory approval that still required Government action for their intended use, and they could be lawfully revoked without the payment of compensation.

Significantly, Apotex support its sweeping interpretation of the word "property" with citations from a dictionary, not from either the relevant texts of the NAFTA or from customary international law. Nor does it find support in other texts, such as the NAFTA Statement of Administrative Action submitted to Congress, in the statements or notes of interpretation of the NAFTA Free Trade Commission, or in the pleadings or other statements of the United States, Canada, or Mexico.

At the end of the day, Apotex has simply put

no evidence before this Tribunal to support its far-reaching interpretation of investment under NAFTA Article 1139.

Mr. President and Members of the Tribunal, the dollar value of this case may appear low when compared to many other NAFTA Chapter Eleven cases, but the jurisdictional issues at stake in this arbitration are exceptionally important. The United States and its NAFTA partners did not consent to allow exporters to bring any and all trade disputes to investment arbitration. They did not intend for every mistaken market decision or unlucky business bet to constitute unlawful Government interference or expropriation redressable through NAFTA arbitration.

Rather, a principal object and purpose of NAFTA Chapter Eleven is to increase investment opportunities in the territory of the NAFTA Parties. The NAFTA Parties simply were not willing to give everyone engaging in cross-border trade the right to seek money damages when challenging measures affecting the sale of those goods. Chapter Eleven specifically affords investors, not exporters, that right, and only

when challenging measures affecting their foreign investments. If a company could invest simply by selling across national borders or if a Canadian exporter could transform itself into an Investor with an investment in the United States simply by complying with U.S. regulatory requirements necessary for the sale of its products, it would radically transform and expand the scope of NAFTA's investment chapter beyond intelligible limits. The United States and its NAFTA partners did not consent to such as far-reaching scheme, and this Tribunal should not accept it by interpretation.

It is hornbook law that an agreement governing sales of goods from one country into another does not, by itself, represent an investment in the territory of the foreign country. Sales and export entail a much less substantial engagement between the transnational business and the foreign country from which it hopes to reap profits. Contrary to Apotex's allegations, simply applying to sell its Canadian-manufactured generic drugs in the United States did not suddenly transform Apotex into an

Investor with an investment in the United States as those terms are defined in the NAFTA. Because Apotex does not fit the most basic features of an investor with an investment entitled to bring a claim under Chapter Eleven, its claims should be dismissed in their entirety for lack of jurisdiction.

Standing alone, this argument is sufficient to divest this Tribunal of jurisdiction over both of Apotex's claims. But even if this Tribunal were to disagree or to assume for the sake of argument that Apotex was somehow an Investor with an investment, this Tribunal still lacks jurisdiction over Apotex's Pravastatin Claim for two additional reasons.

First, Apotex cannot write the three-year limitations period out of the NAFTA. Article 1116(2) of the NAFTA clearly states that, "An 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."

Here, Apotex acquired knowledge of the

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09:36:02 alleged breach and loss arising from the FDA measure in April 2006, which was more than three years before it finally brought its Pravastatin Claim in June 2009. Thus, Apotex's Pravastatin Claim is plainly time-barred. Yet, Apotex now seeks to toll the claim by arguing that the FDA measure was not a discrete administrative action at all, but rather part of a single continuous differentiated action over a number of months by the administrative agencies and courts.

Like previous NAFTA Tribunals, this Tribunal should reject this argument. The NAFTA does not allow a Party through the mere filing of a court action to toll the limitations period prescribed by the Treaty for a challenge to a discrete and final regulatory measure. By its own terms, the relevant starting date for Article 1116(2) of the NAFTA is when the Party first learned of the alleged breach and loss, either actually or constructively, not when it chose to file suit in domestic court or to abandon that suit.

Were the rule otherwise, a Party could elastically stretch NAFTA's limitations period through the mere contrivance of filing a NAFTA claim within

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09:37:13 three years of challenging a regulatory measure in court. In its most recent filing, Apotex appears to recognize this fact, noting that, "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."

To the extent that Apotex's arguing that the FDA measure cannot be considered a discrete violation of the NAFTA that may be considered as a background fact, we agree; but given that Apotex claims that the FDA letter decision is a discrete measure that violates the NAFTA, its claim clearly is time-barred.

Finally, even if the Tribunal did not treat the Pravastatin Claim as time-barred, that claim still cannot proceed to the merits. As I have already noted, Apotex failed to obtain the judicial finality required to challenge any court acts under the NAFTA. The courts only denied Apotex's preliminary injunctive relief. Apotex never pursued its claim on the merits

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09:38:24 and ultimately dismissed most of those claims with prejudice.

Under the customary international law of diplomatic protection, it's familiar ground that an alien is required to exhaust all available local remedies before its claim can be espoused by its State of nationality and heard by an international court or tribunal. NAFTA Chapter Eleven revises that rule by generally allowing foreign investors to bring their claims directly to arbitration, but only once there is a final Government measure affecting them. NAFTA Article 1121, in fact, requires a disputing investor to waive its right to bring or continue domestic court proceedings as a condition to claiming under NAFTA Chapter Eleven.

But where the investor challenges the domestic court proceedings themselves as separate violation of NAFTA Chapter Eleven, it must first attempt all available appeals and obtain judicial finality. There are two principal reasons for requiring finality in the context of judicial actions.

First, courts are different from other

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09:39:29 government actors. If a government is alleged to have breached an investor's right under an international investment agreement, it can usually take action directly to remedy the alleged breach and thereby prevent an international wrong. But if a court is alleged to have breached an Investor's rights under an international investment agreement, the investor itself must take action within that court system to prevent the judicial act from becoming an actual breach.

Second, claims against courts differ from claims against other Government actors. A claim that a State that has allowed its courts to commit international violations is not an attack on a single court decision. It is an attack on the State's entire judicial system. So, an Investor cannot attack the fairness of a nation's judicial system in international arbitration unless it first affords that judicial system full opportunity to correct the decision that is said to put the State in breach of its international law obligations.

As the Loewen Tribunal put it, the reason

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that Claimants must obtain finality for judicial acts before bringing a claim under the NAFTA is to afford the State the opportunity of redressing through its legal system the inchoate breach of international law occasioned by the lower court decision. Were the rule otherwise, Claimants could bring their claims before a NAFTA tribunal without ever obtaining finality for their judicial acts. Once they lost at any level, they could bypass appellate courts where they thought they were likely to keep losing and instead bring lower court decisions or even jury awards directly to international arbitration.

They could prematurely elevate domestic disputes that could be resolved through domestic legal systems in to international claims. For obvious reasons, the NAFTA Parties did not consent to this and could not accept this when it designed this Tribunal's jurisdictional roles.

Ironically, Apotex seems to understand the finality requirement. Apotex concedes that it cannot challenge nonfinal acts of U.S. courts under Articles 1102, 1105, and 1110 of the NAFTA unless

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further recourse would have been "obviously futile." Indeed, with respect to Apotex's Sertraline Claim, Apotex satisfied the finality requirement because it sought certiorari from the United States's highest court, the Supreme Court.

But with respect to its Pravastatin Claim, by contrast, Apotex just plainly failed to obtain judicial finality. Apotex admits that it did not seek certiorari from the Supreme Court after the U.S. Court of Appeals for the D.C. Circuit denied Apotex's request for en banc review. Apotex that admits such relief was legally available and that it could have sought that relief, but concedes that it chose not to.

Apotex explains that oversight by arguing that it would have been absurd to seek that relief because the Supreme Court would not have been able to grant relief in a time frame consistent with Apotex's litigation strategy. Later today my colleague, Mr. Patrick Pearsall, will explain in detail why that is not true, either legally or factually.

But the critical issue for the Tribunal is this. Apotex has alleged that two U.S. courts, the

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U.S. District Court for the District of Columbia and the U.S. Court of Appeals for the D.C. Circuit, applied U.S. law so egregiously as to put United States in breach of its legal obligations was under the NAFTA, including the minimum standard of treatment required of all nations by customary international law.

Apotex further claims that these courts themselves unlawfully and blatantly discriminated against Apotex, expropriated Apotex's investments, and denied Apotex justice. Yet, even while claiming that these judicial errors were blatant, at the same time Apotex claims that it would have been obviously futile to have sought further review at the U.S. Supreme Court of these blatant legal errors.

Members of the Tribunal, I cannot tell you that the U.S. Supreme Court would have granted certiorari on an expedited basis to review these decisions. What I can tell you, though, is that the U.S. Supreme Court was available to hear and remedy the allegedly unlawful acts that now form the basis of this NAFTA Chapter Eleven claim, and to do it on an

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expedited basis, if necessary. Supreme Court Rule 10 says, a petition for a writ of certiorari will be granted only for compelling reasons, including whether a United States Court of Appeals has entered a decision in conflict with the decision of another United States Court of Appeals on the same important matter; has decided an important Federal question in a way that conflicts with a decision by a state court of last resort, or has so far departed from the acceptable and usual course of judicial proceedings, or sanctioned such a departure by a lower court, as to call for an exercise of this court's supervisory power, or decided an important Federal question in a way that conflicts with relevant decisions of the Supreme Court."

Apotex simply cannot have it both ways. On the one hand, it says that the judicial errors with respect to its Pravastatin claim were so egregious and blatant as to rise to the level of NAFTA violations. Yet, on the other hand, Apotex chose not to give the U.S. Supreme Court the opportunity even to consider the question because it reasoned that it would have

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been obviously futile to do so.

This Tribunal, as you know, does not sit as a supranational Court of Appeals, nor is it this Tribunal's job to correct legal errors that should have been brought to higher national courts. The NAFTA Parties have not charged this Tribunal with deciding whether U.S. courts correctly interpreted and applied U.S. law, nor is this Tribunal charged with investigating on a case-by-case basis whether a nation's highest court would have or should have given the Claimant the particular relief it seeks if that court had been given the opportunity to do so.

International tribunals are neither well equipped for that task nor called upon to exercise that domestic legal responsibility.

It is not the job of this Tribunal to assert jurisdiction simply because a Claimant engages in forum shopping. Apotex defeats its own case when it both alleges that U.S. federal courts committed egregious and blatant violations of U.S. law that put the United States in breach of its international law obligations and acknowledges that it could have put

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these allegations to the U.S. Supreme Court for review on an expedited basis, but failed to do so. How can it be that U.S. courts made such obvious legal errors that this Tribunal must fix them, while at the same time it would have been obviously futile for Apotex to have sought review of for these obvious legal errors before U.S. domestic courts. You should decline to consider the nonfinal judicial acts at issue here and dismiss Apotex's Pravastatin Claim in its entirety.

That, in a nutshell, is the U.S. Government's case. Mr. President and Members of the Tribunal, none of Apotex's claims are properly before this Tribunal, and we ask that you dismiss them and Award the United States its costs of arbitration.

With that, let me now introduce our team, who will make detailed presentations to support each and every element of the case that I've just described.

I would ask the Tribunal first call on Assistant Legal Adviser Jeffrey Kovar, who will provide you with a road map through the elements of our case, discussing each of the NAFTA provisions you will be asked to interpret. He will be followed by

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Attorney-Adviser David Bigge who will describe Apotex's alleged investments in this arbitration, its ANDA applications. And then by our investment arbitration chief, Jeremy Sharpe, who will discuss Apotex's failure to establish that those ANDAs constitute investments under Article 1135 of the NAFTA.

Next, Mr. Kovar will lead you through the Court proceedings of the Pravastatin Claim.

Then Attorney-Adviser Neale Bergman will show how Apotex cannot circumvent NAFTA's three-year limitations period through its subsequent judicial challenges.

Finally, Attorney-Adviser Patrick Pearsall will show how Apotex fails utterly to demonstrate that seeking Supreme Court review was obviously futile.

In closing, Mr. President, Mr. Davidson, Judge Smith, we very much look forward to presenting our case to you. Our legal team has prepared most diligently and thoroughly for this very important hearing. As lawyers for the United States of America, we will demonstrate why Claimant's case cannot stand.

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Mr. President and Members of the Tribunal, we thank you for your most careful attention.

PRESIDENT LANDAU: Thank you very much.

Mr. Kovar.

MR. KOVAR: Thank you very much, Mr. President and Members of the Tribunal.

I'd like today to give you a little bit of background on the NAFTA and a road map of sorts for our arguments. As Mary McLeod has noted, the intention of the Governments of Mexico, Canada, and the United States in Chapter Eleven of the NAFTA was to encourage foreign investment. The governments did this by committing to certain obligations with respect to the treatment of foreign investment and by providing Investors with the option of binding international arbitration for the resolution of disputes concerning alleged breaches of those obligations.

To date, about a dozen claims have been brought to arbitration against each of the three NAFTA Parties.

NAFTA's Investment Chapter contains two

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sections. Section A is entitled "Investment," and it sets out the substantive obligations agreed to by the treaty Parties in Articles 1101 through 1114, while Section B, which is titled "Settlement of disputes between a Party and an Investor of another Party," sets out in Articles 1115 through 1139 the dispute-settlement procedures pursuant to which foreign Investors can submit investment claims to arbitration.

Under Section A, Apotex claims the United States has violated three substantive obligations. First, they point to one of the two nondiscrimination obligations called national treatment in Article 1102. Under this obligation, treatment accorded to investors of another Party must be no less favorable than the treatment accorded in like circumstances to domestic U.S. Investors.

Second, Apotex claims violations of the minimum standard of treatment in Article 1105. Under this obligation, the treatment accorded to investments of Investors of another Party must be in accordance with the customary international law minimum standard

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of treatment.

And, third, Apotex claims the United States violated the expropriation obligation of Article 1110, which requires payment of compensation for any expropriation of an investment of an Investor of another Party.

As Apotex notes in its Statement of Claim, both Apotex's Sertraline and Pravastatin Claims relate to the treatment accorded to Apotex by the Government of the United States under Chapter Eleven of the NAFTA and, in particular, Articles 1102, 1105, and 1110.

Although investor-State arbitration under Chapter Eleven involves the application of the same limited set of substantive obligations, the range of statutory and regulatory matters potentially at issue vary significantly. Of the claims submitted to arbitration against the United States under NAFTA Chapter Eleven, seven have been resolved through Final Decision. Those claims represented seven distinct industries ranging from funeral homes to gasoline additives to gold mining to generic cigarettes. This Tribunal is being asked to look at the regulation of

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the generic drug industry.

Threshold questions of jurisdiction are exceptionally important in arbitration, including in NAFTA, the cases in particular. I would like to underscore something that Mrs. McLeod said a moment ago: The NAFTA Parties consented to limited jurisdiction for the arbitration of claims brought under Chapter Eleven. The Claimant must meet these jurisdictional requirements as a condition of the NAFTA Parties' consent to international arbitration tribunal's jurisdiction over the claims. In other words, the NAFTA Parties agreed to open themselves up to potential liability for breaching the terms of the NAFTA and to money damages only for claims brought by foreign investors with qualifying investments who meet the requirements to bring a claim.

The NAFTA Parties carefully balanced the goals of Chapter Eleven, promoting an open investment climate with their domestic responsibilities to act in the public interest through Government regulations and the administration of justice.

As the Tribunal in the Grand River Case

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correctly observed, NAFTA involves a balance of rights and obligations, and it does not point unequivocally in a single direction. While NAFTA's Preamble speaks of promoting investment, it also affirms the need to preserve the NAFTA Parties' flexibility to safeguard the public welfare. If a claimant in a Chapter Eleven arbitration does not qualify as an Investor with an investment in the territory of the host State, then the carefully balanced rights and obligations of the State vis-à-vis Investors are not aligned.

In the recent decision of Gallo v. Canada, the Tribunal looked closely at the jurisdictional requirements of Chapter Eleven. It noted that foreign investors as a matter of legitimate public policy are granted certain protections not afforded to domestic Investors through international arbitration, but it stressed that they must meet the jurisdictional requirements to bring their claims.

The Tribunal said, "For investors to enjoy this additional right, i.e., the right to bring an arbitrable claim, there must be a quid pro quo: Given that the stated objective of investment treaties is to

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09:53:44 stimulate flows of private capital into the economies of Contracting States, the Claimant in any investment arbitration must prove that he or she is a protected foreign investor, who at the relevant time owns or controls an investment in the host country. The Tribunal noted that the Claimant has failed to establish he owned the enterprise in question, and that therefore they had to forego international arbitration in favor of "general remedies available to the Investors under Canadian law."

The Gallo Tribunal thus dismissed the Claimant's claim and awarded Canada the full cost of the arbitration. We will ask the Tribunal to do the same here.

Members of the Tribunal, as Ms. McLeod noted, the Parties have narrowed the issues to three questions. The first question is: Has Apotex demonstrated that the mere filing of an application to export goods to the United States for sale by others constitutes an "investment" in the territory of the United States for purposes of the NAFTA? If Apotex fails to carry its burden of demonstrating that its

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09:54:51 applications to approve the sale of its new drugs in the United States constitute investments in the United States, then the Tribunal lacks jurisdiction, and all of Apotex's claims fail.

That is, if Apotex is not, as it claims, an Investor that made an investment in the United States as those terms are defined in the NAFTA, then the Tribunal lacks jurisdiction to hear either Apotex's Pravastatin claim or its Sertraline Claim.

On the other hand, if Apotex establishes that its applications constituted investments in the United States, the Tribunal will need to decide two additional questions: Time-bar and finality, which relate only to Apotex's Pravastatin Claim. These questions are, first, can Apotex toll the three-year time bar limitation for challenging the final regulatory measure by seeking review of that measure in court; and, second, has Apotex met the international law requirement of finality when it asserts that decisions of U.S. courts breached U.S. obligations under the NAFTA without having petitioned the U. S. Supreme Court for review?

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09:55:57 If the answer to these two questions are in the negative, as we shall demonstrate, then Apotex's Pravastatin Claims must be dismissed.

So, let's look at the NAFTA provisions that bear directly on the three jurisdictional questions presented to the Tribunal. The starting point for interpreting the provisions of the NAFTA, like the terms of any Treaty, is the ordinary meaning to be given to the terms in their context and in light of the Treaty's object and purpose. That is the rule set out in the Vienna Convention on the Law of Treaties and customary international law.

So, the first question is about investment. Apotex has brought its Sertraline and Pravastatin Claims under NAFTA Article 1116. This is stated at Paragraph 4 of its Statement of Claim. And at Paragraph 6 in both the Sertraline and Pravastatin Notices of Arbitration.

Article 1116 is titled "Claim by an Investor of a Party on its own behalf." That provision states, in relevant part, "An Investor of a Party may submit to arbitration under this section a claim that another

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09:57:02 Party has breached an obligation under Section A," which, as you will recall was entitled "Investment," and that the investor has incurred loss or damage by reason of, or arising out of, that breach.

Apotex has not brought its claims under NAFTA Article 1117, which is titled "Claim by an Investor of a Party on behalf of an enterprise." Thus, Apotex has brought its claims on its own behalf and not on behalf of any enterprise it claims to have established in the U.S. That reason, of course, is because Apotex does not claim to have established an enterprise in the United States.

We then turn to Article 1139 for a definition of investor of a Party. That provision defines "investor of a Party" as a Party or State enterprise thereof or a national or enterprise of such Party, that seeks to make, is making, or has made an investment.

Thus, under Articles 1116 and 1139, an Investor that seeks to make, is making, or has made an investment may submit to arbitration a claim for a breach of Chapter Eleven's investment protections if

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it incurred loss or damage by reason of or arising out of that breach.

Let me reiterate the point made by Mary McLeod. Apotex does not allege that it was seeking to make or making an investment. Rather, Apotex claims that it made investments, and these investments are its two abbreviated New Drug Applications for sertraline and pravastatin. According to Apotex, its investments were made as soon as it submitted those ANDAs to the FDA. Apotex's Rejoinder thus states, "Apotex's investment in its ANDAs, and its property rights therein, are actualized the moment such ANDAs are filed with the FDA."

It's important to it keep this point in mind because Apotex's Rejoinder also states, "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."

Apotex is not arguing that at the time of the alleged breach it was seeking to make an investment in the United States but was prevented from doing so by

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unlawful government actions. Rather, Apotex consistently has argued and reaffirmed in its most recent filing to the Tribunal that it made an investment in the territory of the U.S. through its ANDAs at the moment it submitted them to the U.S. Government for approval.

Finally, it's important to highlight Article 1101 which Chapter Eleven tribunals often describe as the "gateway" to NAFTA arbitration. That provision, however, also contains important language limiting the scope of NAFTA Chapter Eleven, and it states in relevant part: "This chapter applies to measures adopted or maintained by a Party relating to, A, investors of another Party; B, investments of Investors of another Party in the territory of that Party."

NAFTA Article 1101 thus makes clear that any investment covered by Chapter Eleven must be located in the territory of another NAFTA Party. That is, unsurprisingly, NAFTA Chapter Eleven only protects foreign investments and not domestic investments. As the Tribunal in the Bayview case noted, the Tribunal

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considers that in order to be a "investor" within the meaning of NAFTA Article 1101-A, an enterprise must make an investment in another NAFTA State and not its own."

The Bayview Tribunal added then, "While NAFTA Article 1139 defines the term "investment," it does not define "foreign investment." Similarly, NAFTA Chapter Eleven is named "Investment," not foreign investment. However, this Tribunal considers that NAFTA Chapter Eleven, in fact, refers to foreign investment and that it regulates foreign investors and investments of foreign investors of another Party."

As Mary McLeod has just noted, the United States and its NAFTA partners intended that Chapter Eleven promote investment in their respective territories by providing foreign investors with certain international law guarantees and a mechanism for the settlement of investment disputes. But the United States did not consent to allow domestic Investors in Canada or Mexico to bring their trade-related disputes to arbitration for money damages.

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Mr. Sharpe will address in detail why we believe that Apotex has failed to establish under NAFTA Articles 1101, 1116, and 1139 that the Tribunal has jurisdiction to hear its claims that it had an investment in the United States at the time of the alleged breach and that both claims should therefore be dismissed for lack of jurisdiction.

Let's look next at the provisions relevant to the questions of time bar and finality. Article 1116 Paragraph 2 states a clear time-bar rule: "An 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." Mr. Bergman will demonstrate to you why Apotex had knowledge of both the alleged breaches charging in this arbitration and the alleged economic loss it is claiming on the April 11, 2006, date that FDA issued its decision letter.

The time limit for filing a NAFTA claim based on this decision which Apotex asserts was unlawful is

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three years later, or April 11, 2009. However, Apotex's Pravastatin Notice of Arbitration was received by the United States on June 5, and is, therefore, time-barred. There is nothing in the text of the NAFTA that suggests it can be tolled by subsequent court challenges.

Now, the finality rule has its source in NAFTA Article 1101, again what we call the gateway to that Chapter Eleven. We'll put it on the screen again. This chapter applies to measures adopted or maintained by a Party relating to Investors of another Party, and Investors of Investors of another Party in the territory of that Party. For a Government "measure" to be "adopted or maintained" for purposes of Chapter Eleven, it must be final. It is not disputed that FDA's decision was final and, therefore, could--it is not disputed that FDA's decision was final and, therefore, could be challenged in a NAFTA Chapter Eleven arbitration if it was not time-barred. However, Apotex also challenges the subsequent federal court proceedings which remain subject to final appeal to the U.S. Supreme Court and therefore were not ripe

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for challenge in a NAFTA Chapter Eleven proceeding. This finality rule is also reflected in customary international law which is applicable to these proceedings under Article 1131 of the NAFTA.

Article 1131 states, in part: "A tribunal established under this section shall decide the issues in dispute in accordance with this agreement and applicable rules of international law."

Mr. Pearsall will demonstrate the finality rule which applies to these proceedings through Articles 1101 and 1131 bars Apotex's challenge to the federal court decisions. Because Apotex failed to make a final appeal to the Supreme Court, it cannot challenge the court decisions as final measures.

Finally, a word on burden of proof. Apotex has the burden to prevail on each of the three questions and to establish that this Tribunal has jurisdiction. This burden is stated in Article 24 of the UNCITRAL Rules, which are the arbitration rules designated for this case.

Article 24 states in part, "Each Party shall have the burden of proving the facts relied on to

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support his claim or defense."

Now, Apotex claims that it is an Investor that made an investment in the United States, and thus under the UNCITRAL Rules it carries the burden of proving the factual basis for this claim. NAFTA Chapter Eleven tribunals like other international arbitral tribunals have confirmed that it is the Claimant's burden to establish that it meets this essential requirement for the Tribunal's jurisdiction. As the Gallo Tribunal recently observed, both Parties submit and the Tribunal concurs that the maxim "who asserts must prove," or actori incumbit probatio applies also in the jurisdictional phase of this investment arbitration. A claimant bears the burden of proving that he has standing and the Tribunal has jurisdiction to hear the claim submitted. If jurisdiction rests on the existence of certain facts, these must be proven at the jurisdictional stage.

In support, the Gallo Tribunal cited Phoenix Action versus the Czech Republic, which the United States also cited in its Memorial. That Tribunal similarly concluded, "If jurisdiction rests on the

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existence of certain facts, they have to be proven at the jurisdictional stage. For example, in the present case, all findings of the Tribunal to the effect that there exists a protected investment must be proven, unless the question could not be ascertained at that stage, in which case it should be joined for the merits."

A principal reason that the Claimant bears this burden even at the jurisdictional stage is a practical one. The Respondent State usually does not have and cannot be expected to have complete or reliable information on the Claimant's nationality, on the nature of the Claimant's investments, on the ownership structure of the claimed enterprise, and so forth. Only the Claimant has that information.

Here, jurisdiction rests on proof that Apotex is an Investor that made an investment in the territory of the United States as those terms are defined in NAFTA Article 1139, that its claims were timely filed under Article 1116(2), and that the judicial measures challenge were adopted or maintained by the United States under Article 1101. Apotex thus

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10:08:13 1 bears the proving of each of those claims.
2 I stress the burden of proof because it is
3 crucial in a case such as this one, where the Claimant
4 has failed to produce evidence supporting critical
5 elements necessary to establish the Tribunal's
6 jurisdiction. In particular, as Mr. Sharpe will
7 discuss later this morning, Apotex has failed to
8 establish that the applications it made to FDA to
9 enable it to export its products to the United States
10 constitute investments under Article 1139.
11 As our pleadings demonstrated and as we will
12 explain today, Apotex has failed to meet that burden.
13 Mr. President and Members of the Tribunal,
14 we're prepared to move to the first question related
15 to whether Apotex has an investment in the United
16 States. I would ask the Tribunal to call on
17 Mr. Bigge. He will explain what an abbreviated New
18 Drug Application is, and then he will be followed by
19 Mr. Sharpe, who will explain why Apotex has failed to
20 establish that its ANDAs fall within the definition of
21 "investment."
22 Thank you.

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10:09:20 1 PRESIDENT LANDAU: Thank you very much.
2 Mr. Bigge, you have the floor.
3 MR. BIGGE: Thank you. Mr. President, Judge
4 Smith, Mr. Davidson, Apotex's sole claimed investments
5 in this case are its abbreviated New Drug Applications
6 or ANDAs that it submitted to the U.S. Food and Drug
7 Administration. I will address two issues related to
8 the ANDAs to get us all on the same page in terms of
9 the relevant statutes and terminology.
10 First, I will discuss the statutory
11 background of the ANDA process. That process involves
12 FDA review of the ANDA, which is an application for
13 revocable Government permission to sell generic
14 pharmaceuticals in the U.S. market. This Tribunal
15 will be tasked with deciding, among other things,
16 whether such applications for revocable permission
17 constitute investments under Article 1139 of the
18 NAFTA.
19 Second, I will address the 180-day
20 exclusivity period and the court decision trigger
21 under the governing statute. As I will describe in
22 greater detail in a moment, the Applicant who submits

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10:11:06 1 the first substantially complete ANDA with the
2 so-called paragraph IV certification may be entitled
3 to 180 days of market exclusivity. Under the statute
4 applicable at the time, the court decision trigger was
5 one of the means for starting that 180-day exclusivity
6 period. The court decision trigger is at the heart of
7 Apotex's claims.
8 As Ms. McLeod noted earlier, Apotex is not
9 claiming that its ANDAs were wrongfully denied by the
10 FDA. Both ANDAs were in fact approved after the
11 events at issue. Nor is Apotex arguing that it was
12 entitled to 180 days of market exclusivity for its
13 products. It was not. Rather, Apotex is claiming
14 that its failure to prematurely trigger the start of
15 the running of other companies' 180-day exclusivity
16 through the so-called "court decision mechanism" was
17 the result of violations of NAFTA Chapter Eleven.
18 Understanding these statutory issues is crucial to
19 both our jurisdictional objections and our merits
20 defenses.
21 To set the stage, the U.S. pharmaceutical
22 market includes both pioneer drugs, sometimes called

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10:12:23 1 branded drugs, and generic drugs. Both pioneer drugs
2 and generic drugs are regulated by the U.S. Food and
3 Drug Administration, or FDA, an agency of the
4 Department of Health and Human Services. FDA is
5 responsible for, among other things, protecting the
6 public health by assuring that human and veterinary
7 drugs, vaccines, and other biological products and
8 medical devices are safe and effective.
9 Pioneer drugs are developed by companies like
10 Pfizer or Bristol-Myers Squibb, the companies that
11 developed the two pioneers drugs at issue in this
12 case, Zoloft and Pravachol. The pioneer drug
13 manufacturers apply for FDA approval to market those
14 drugs in the United States through a New Drug
15 Application or NDA. The NDA includes reports of
16 extensive clinical testing to show how the proposed
17 new drug is both safe and effective.
18 Pioneer drug developers spend a great deal of
19 time and money researching and developing the drugs
20 and putting them through clinical tests to meet the
21 FDA requirements for approval. These pioneer drugs
22 are usually patented, so until the patents expire, the

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10:13:31 pioneer drug manufacturers generally have the exclusive right to sell that medication in the U.S. market. When a pioneer drug is approved by the FDA, the brand-name manufacturer is required to submit to the FDA all patents for the approved drug substance, the approved drug product, or an approved method of use for the drug. These patents are listed in an FDA publication called "approved drug products with therapeutic equivalent evaluations known colloquially as the Orange Book, and I will come back to the Orange Book momentarily.

Typically pioneer drug developers obtain multiple patents for any given drug. There will often be separate patents governing, for example, both the active ingredient and the precise formulation of active and inactive ingredients in the same drug. A company might also maintain separate patents to cover different uses of the same drug.

Generic pharmaceuticals, on the other hand, are generally nonpatented, usually less costly versions of the pioneer drugs. Prior to 1984, a generic drug manufacturer seeking access to the U.S.

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10:14:40 market would have to submit the same New Drug Application as the pioneer drug manufacturers. This would have resulted in redundancy in terms of both time and expense for generic drug manufacturers who had to--who would have had to run the same clinical safety and effectiveness tests that pioneer drug manufacturers already ran.

To address this redundancy among other issues, the U.S. Congress amended the Food, Drug, and Cosmetic Act, 21 USC Section 355 in 1994. The amendments passed in a bill called the Drug Price Competition and Patent Term Restoration Act are often referred to as the Hatch-Waxman Amendment, named after their congressional sponsors, and from here on out I will just refer to them as the Hatch-Waxman Amendments.

The purpose of the Hatch-Waxman Amendments was to streamline the approval of generic drugs for the U.S. marketplace as a means for bringing cheaper alternatives to pioneer drugs to U.S. consumers more quickly, while also carefully balancing incentives for brand manufacturers to continue researching and

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10:15:47 developing pioneer drugs. The principal means of achieving this streamlining was through the addition of USC Section 355(j) which described an abbreviated pathway for generic drug approval known as an abbreviated New Drug Application referred to in shorthand as the A-N-D-A, or ANDA.

The ANDA process allows generic drug manufacturers to forego the time-consuming and expensive clinical studies required for new drug Applicants. Instead, the Hatch-Waxman Amendments require ANDA applicants to show that their products are bioequivalent to the brand drug. According to the governing statute and regulations, the generic drug manufacturer must also show, among other things, that the proposed generic is the same as the pioneer drug in terms of active ingredient, dosage form, strength, route of administration, and with certain exceptions labeling.

In addition, the ANDA Applicant must show that its manufacturing facilities meet current good manufacturing practices guidelines. Foreign ANDA Applicants must also include information on their U.S.

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10:16:58 agents and distributors.

To be abundantly clear, an ANDA is an application, no more and no less, for regulatory permission from the FDA to market a generic drug in the United States. There is no filing fee to submit an ANDA to the FDA. Once submitted, the application is reviewed by the FDA's Office of Generic Drugs. The FDA may disapprove an ANDA for any one of a number of health and safety reasons listed in the governing statutes and regulations. We do not need to march through them now, but we've included them--we've included the relevant statute, 21 USC Section 355(j)(4) in Exhibit R-3, and we've also included that part of the statute in the slide for your convenience.

Often, instead of rejecting an application, the FDA will request new or different information from the ANDA Applicant. In Footnote 17 of our reply, and again on the slide in front of you, we've included a list of the numerous times FDA requested additional information from Apotex during its review of Apotex's Sertraline and Pravastatin Applications.

If, after this rigorous review process the

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10:18:17 FDA determines that the application meets the conditions for approval, it will either be finally approved or granted tentative approval. Tentative approval is provided when there is something that prevents final approval, including, among other things, existing and unchallenged patents for the pioneer drug that prevent final approval of the ANDA until those patents expire. The tentative approval letters themselves make abundantly clear that they do not constitute final approval to market the proposed generic drug in the United States.

An example of a tentative approval letter is included as Exhibit R-99, which was referenced in Apotex's Rejoinder and is on the slide before you. Apotex's application for pravastatin was first tentatively approved in 2003. The tentative approval letter in Exhibit R-99 was sent in April 2006, and affirms that the application for pravastatin, "remains tentatively approved."

In our exhibits we've also included the sertraline tentative approval letter at Exhibit R-96, and the pravastatin tentative approval letter at

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10:19:25 Exhibit R-98, but all the tentative approval letters have similar language, so we will focus on the one quoted by Apotex in its papers at Exhibit R-99.

I should mention this document is not confidential, so there is no need to close the feed.

In its Rejoinder at Pages 5 and 6 Apotex relies on the finding in the third paragraph of Exhibit R-99 that, "Based upon the information Apotex had presented to date, the FDA had determined the drug was safe and effective." As Apotex points out. FDA explained in this letter that the ANDA could not be finally approved due to exclusivity issues.

Apotex's reading of the letter, however, ignores several important passages that make clear that Apotex's applications were not approved and that Apotex had not obtained any rights.

In the middle of the third paragraph, for example, just after the passage Apotex cites, FDA writes, "This determination is based upon information available to this Agency at this time; i.e., information in your application (and the status of current good manufacturing practices of the facilities

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10:20:39 used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention."

The tentative approval letter also makes clear at the bottom of Page 3 that the FDA, "may request at any time prior to the final date of approval that you submit an additional amendment," filed with information related to labeling, chemistry, manufacturing, or controls data. Failure to submit such information may result in, "rescission of this tentative approval determination or delay in the issuance of the final approval letter."

In closing, the tentative approval letter warns that the drug may not be marketed without final Agency approval. In fact, FDA did request additional information from Apotex after the ANDA for pravastatin was first tentatively approved in 2003, as indicated in Footnote 17 of our Reply and Exhibit R-109, which is now before you on the screen. Again, this document is also not confidential. The confidential information has been redacted from the exhibit.

Exhibit R-109 is a 2004 FDA request for

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10:21:51 additional information for Apotex's Pravastatin Application. It states that, despite the ANDA having been tentatively approved, the Pravastatin Application was, "deficient and therefore not approvable."

This letter further indicates on Page 3 that despite the tentative approval, FDA was still reviewing Apotex's bioequivalence and labeling information.

Of course, the FDA's health and safety responsibility does not cease even when an ANDA is finally approved. Finally approved ANDAs, which authorize the generic drug manufacturer to begin selling the drug in U.S. market may themselves be revoked by the FDA for a variety of reasons. In fact, as we noted in our pleadings, Apotex itself had its finally approved ANDA revoked for another drug, a drug called Omeprazole.

In short, the ANDAs, the sole investments alleged by Apotex, were nothing more than applications for revocable permission from the FDA to export sertraline and pravastatin from Canada for sale in the United States.

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10:23:01 Turning now to my second set of topics, 180-day exclusivity and the court decision trigger, the ANDA must also detail how the proposed generic drug relates to patents governing the pioneer drugs. A few minutes ago I told you that pioneer drug manufacturers must submit all patents that cover their drugs for listing in the Orange Book. Generic manufacturers applying to sell their drugs in the United States are required to consult the Orange Book and with respect to each patent listed for the pioneer drug, the ANDA Applicant must make one of four certifications:

One, no patent has been filed;

Two, the patent has expired;

Three, the generic manufacturer is not seeking ANDA approval until after the patent expires;

Or, four, the patent is invalid, not infringed by the generic drug, or otherwise not enforceable against the generic manufacturer.

Neither Category I nor Category II is relevant to this case. However, both category III and Category IV are.

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10:24:09 You will recall that pioneer drug manufacturers often list multiple patents for the same drug to cover different ingredients in the drug, different aspects of the formulation, or different uses of the drug. Sometimes these patents are registered to expire on different dates or the strengths of the patents will differ. Thus, the generic manufacturer can make different patent certifications in the same application covering the same drug.

What many generic manufacturers do is file in the same application both paragraph III certifications usually for the patents covering the active ingredient, and then paragraph IV certifications for weaker patents covering other aspects of the same drug. The generic manufacturer is saying, in essence, we challenge most of the governing patents as invalid, not infringed, or unenforceable, but we agree that this one patent is valid, and we will wait to market our generic drug until that one patent expires.

For both sertraline and pravastatin, Apotex made a paragraph III certification for the patents

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10:25:16 covering the active ingredient and paragraph IV certification for all other patents covering the pioneer drugs. As it happens, the other ANDA applicants for sertraline and pravastatin made certain certifications, including both Photograph II and paragraph IV certifications in their ANDAs.

Why is this important? Congress carefully designed the ANDA process to encourage generic manufacturers to file paragraph IV certifications challenging weak patents. Under the Hatch-Waxman Amendment, the first Applicant to submit a substantially complete application with a paragraph IV certification may be eligible for 180 days of market exclusivity. In other words, that first ANDA Applicant for a generic version of a particular pioneer drug may have the market for that generic and strength all to itself for six months. No other ANDA Applicants referencing that same pioneer drug and strength can be approved until the expiration of that 180-day period. This is obviously a major and highly sought benefit for the first ANDA Applicant with a paragraph IV certification.

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10:26:29 This gets slightly more complicated when, as here, all of the ANDA Applicants file both paragraph III and paragraph IV certifications. Under the Hatch-Waxman Amendments, the first ANDA Applicant with both paragraph III and paragraph IV certifications may still be eligible for 180 days of exclusivity, but that first ANDA Applicant will have to wait until the paragraph III patent expires to begin marketing its drug.

In this case, Apotex was not the first ANDA Applicant to file a paragraph IV certification for either sertraline or pravastatin. Therefore, Apotex was not eligible for 180 days of exclusivity for either drug.

For sertraline, the first ANDA Applicant with a paragraph IV certification was a company called Ivax Pharmaceuticals. For pravastatin, the first ANDA Applicant with a paragraph IV certification was Teva Pharmaceuticals for the 10, 20, and 40-milligram strengths. For the 80-milligram strength of pravastatin, a company called Ranbaxy was the first to substantially complete and a filer.

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Ivax, Teva, and, Ranbaxy were each eligible for 180 days of market exclusivity for their respective drugs and strengths once the unchallenged patents, the paragraph III patents, governing sertraline and pravastatin expired.

In this arbitration, Apotex's sole complaint is that it was unable to eliminate Ivax's, Teva's and Ranbaxy's 180 days of exclusivity. Apotex wanted to be able to go to market the same day as those companies, as soon as the paragraph III patents expired. For both sertraline and pravastatin, Apotex was trying to eliminate the other companies' 180 days of exclusivity through the so-called "court decision trigger."

Under the Hatch-Waxman Amendments, there are two possible ways to trigger the start of the 180-day exclusivity period. The first trigger is the first day of commercial marketing of the generic drug. In the case of sertraline and pravastatin, that could not occur until after the paragraph III patent expired.

For example, Ivax's sertraline application would be approved when the relevant paragraph III

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patent expired, and Ivax would presumably begin marketing the drugs soon thereafter. Its 180-day exclusivity would be measured from that first day of commercial marketing, and no other sertraline ANDAs could be approved until that period expired.

The second way the 180-day exclusivity period is triggered by obtaining, "a decision of a court holding the patent which is the subject of the paragraph IV certification to be invalid or not infringed." This is the court decision trigger.

To understand why it exists, imagine a situation where there is only one patent governing a drug and that patent was subject to a paragraph IV certification. Under the Hatch-Waxman system, any ANDA Applicant can bring a declaratory judgment action against the patent holder, to the extent otherwise permitted by law. To get a court decision having that patent declared invalid, not infringed, or unenforceable this court decision provides assurance to the ANDA Applicant that it will not be violating the patent by marketing the generic drug. Once a court decision holding that the patent is invalid,

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unenforceable, or not infringed is obtained by any ANDA Applicant, the 180-day exclusivity period begins immediately. The first ANDA Applicant with a paragraph IV certification, the one eligible for 180-day exclusivity, must go to market shortly thereafter, or it will not be able to enjoy the commercial advantages of its 180-day exclusivity right. If that first Applicant is not ready for ANDA approval when its 180-day exclusivity is triggered, it will lose the benefits of its exclusivity period.

This latter case was the situation Apotex was attempting to exploit. For both sertraline and pravastatin, all ANDA Applicants--Ivax, Teva, Ranbaxy and later applicants like Apotex, have filed both paragraph III and paragraph IV certifications. This meant that all generic manufacturers that submitted applications for sertraline and pravastatin, including the first Applicants, were forced to wait at least until the patents subject to the paragraph III certification expired to have their ANDAs approved.

In both cases, what Apotex was seeking was a court decision that would trigger the 180-day

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exclusivity period prior to the expiration of the paragraph III patents. Had Apotex successfully obtained a court decision trigger, the 180-day exclusivity period would have started to run immediately while Ivax, Teva, and Ranbaxy were prevented from having their ANDAs finally approved due to the paragraph III certifications. This would have effectively eliminated the 180-day exclusivity period for Ivax, Teva, and Ranbaxy.

Apotex, however, failed in its attempts to eliminate the other companies' 180-day exclusivity because it failed to get a triggering court decision. That is a decision of a court holding the patent which is the subject of the paragraph IV certification to be invalid or not infringed.

Mr. President, Judge Smith, Mr. Davidson, with that background, I would ask you to call on my colleague, Jeremy Sharpe, who will discuss Apotex's failure to establish that it is an Investor with an investment in the territory of the United States.

ARBITRATOR SMITH: Point of clarification.

It is correct, is it not, that under no

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circumstances would the exclusivity period have ever transferred to Apotex? The most they could have done was to eliminate it as to these other companies; is that correct?

MR. BIGGE: That is correct.

ARBITRATOR SMITH: Okay. Thank you.

PRESIDENT LANDAU: Thank you very much.

Mr. Sharpe.

MR. SHARPE: Thank you, Mr. President and Members of the Tribunal. As my colleague Mr. Bigge noted, I will now address Apotex's failure to demonstrate that it is an Investor that made an investment in the United States as those terms are defined in NAFTA Chapter Eleven.

Apotex certainly is not a foreign investor in the usual sense of that term. Apotex is a Canadian company that exports its products from Canada to more than 115 countries around the world, including the United States, where its products are sold by others. Apotex's manufacturing facilities are in Canada. Its employees are in Canada. Thus, it's not surprising that outside of this arbitration, Apotex holds itself

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out as a Canadian exporter and not as a Canadian investor in the United States.

Nor has Apotex made foreign investments in the usual sense of that term. Apotex does not claim to have established a company in the United States. It does not claim to have an equity or a debt interest in any U.S. company. It does not claim to have purchased property or to have built facilities or to have hired a workforce in the United States. It does not claim to have developed, tested, or manufactured its drugs in the United States.

Apotex even submitted its ANDAs to FDA through its U.S. Agent.

Apotex admits in its Counter-Memorial that it, "does not reside or have a place of business in the United States." Apotex, Inc., the Claimant in this arbitration, does not claim any presence whatsoever in the United States.

So, what exactly is Apotex's alleged investment in the United States? The answer has been a moving target throughout these proceedings. In its submission to this Tribunal in support of a stay,

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Apotex claimed that it was investment was its ANDA products; that is, its sertraline and pravastatin drugs. In its Statement of Claims, by contrast, Apotex suggested this investment was the money it spent preparing ANDAs and producing those drugs. It claims to have "made substantial investments including, but not limited to, the expenditure of millions of dollars each year in preparing ANDAs for filing in the United States, and formulating, developing, and manufacturing those approved generic pharmaceutical products for sale in the United States and throughout the world."

United States observed in its Memorial that Apotex prepared its ANDAs and formulated, developed, and manufactured its drugs in Canada. No doubt these activities cost money, but it was money spent entirely in Canada. What's more, development of drugs in Canada for export throughout the world hardly suggests a U.S. investment.

Apotex then changed tack again. In its Counter-Memorial, Apotex argued two sources of investment. Apotex claims, without providing any

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evidence, that it made a commitment of capital in the United States for purposes of Article 1139(h) by purchasing inactive ingredients from U.S. suppliers, by hiring U.S. litigation counsel, and by designating a U.S. Agent and distributor.

In its Reply, the United States observed that Apotex failed to establish how its alleged commitment of capital fell within the definition of Article 1139(h), which includes 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, one, contracts involving the presence of an Investor's property in the territory of the Party, including turnkey or Construction Contracts or concessions; or, two, contracts where remuneration depends substantially on the production, revenues, or profits of an enterprise."

Article 1139(h) thus covers interest arising from the commitment of capital in the United States that gave rise to the investor's claims to money in this country and not simply cross-border trade interests.

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10:37:46 As the Canadian Cattlemen Tribunal put it, mere cross-border trade interests are not sufficient to trigger Chapter Eleven--something more permanent--such as a commitment of capital or other resources in the territory of a Party to economic activity in such territory--is necessary for a contractual claim for money based on cross-border trade to rise to the level of an investment."

An example of an Article 1139(h) investment is found in Mondev versus United States. There, the Canadian Claimant alleged that through its wholly owned U.S. limited partnership, it obtained interests arising from contractual rights to develop large parcels of property in downtown Boston. The Tribunal thus concluded that, through the rights acquired in these construction contracts, "Mondev's claims involved interests arising from the commitment of capital or other resources in the territory of the United States," which fit squarely within the definition of "investment" under Article 1139(h).

That Article clearly does not cover, as Apotex alleges, the purchase of U.S. inactive

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10:38:59 ingredients for export, the hiring of U.S. litigation counsel, or the designation of a U.S. agent and distributor, as those expenditures do not create in the United States interests that rise to the level of an investment. Even if Apotex were entirely dependent, for example, on purchasing inactive ingredients from U.S. suppliers, that would still not make Apotex an Investor in the United States. As the Tribunal observed in Bayview versus Mexico, the economic dependence of an enterprise upon supply of goods--in this case, water--from another State is not sufficient to make that dependent enterprise an Investor in that other State."

We think this proposition is obvious under the NAFTA, both its plain language and when read in context and in light of the Treaty's object and purpose. We believe that Apotex's interpretation would lead to absurd results. As we note in our Reply, if a Canadian exporter could transform itself into an Investor in the United States by designating a U.S. Agent and distributor. By purchasing U.S. goods for its use in Canadian operations and by filing a

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10:40:14 lawsuit to further its cross-border trade, and presumably every such exporter could bring its trade disputes to investment arbitration under the NAFTA. As Ms. McLeod discussed this morning, the NAFTA Parties did not consent and could not accept this.

Apotex's second argument for its Counter-Memorial is that its ANDAs themselves are investments because they are property under NAFTA Article 1139(g). Thus, according to Apotex, both of Apotex's sertraline and pravastatin ANDAs are investments in the United States. More specifically Apotex's ANDAs are property acquired in the expectation or used for the purpose of economic benefit or other business purposes in the United States.

Still, it remained unclear exactly what Apotex considered as its property interest. Was Apotex claiming that finally approved ANDAs are property or tentatively-approved ANDAs, or even ANDAs at the moment they're filed with the FDA.

Apotex's most recent pleading has clarified this point, underscoring that its alleged investments

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10:41:19 are its unapproved applications as filed with the FDA. Apotex's Rejoinder states that, "Apotex's investment in its ANDAs, and its property rights therein, are actualized the moment such ANDAs are filed with the FDA."

Apotex's Rejoinder reiterates the point, "ANDA meets the Article 1139(g) definition of 'investment' at the very moment it is submitted to FDA."

The Rejoinder further explains that, "Apotex has property rights in its ANDAs, regardless of whether the FDA's approval of such ANDAs or the products that are the subject 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. "Apotex nonetheless admits that it could not do anything with its ANDAs in the United States without FDA's approval," stating, "If an ANDA is never approved and the product can never be sold, such ANDA is essentially worthless." And there is no dispute that under U.S. law, even an approved ANDA is

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revocable by FDA for reasons related to safety and effectiveness of the drug product.

So, after offering various theories about the nature of its investment, Apotex seems to have settled on a single argument; thus, it's crystallized the key jurisdictional question for this Tribunal.

Has Apotex established that the mere filing of the application with the U.S. Government for revocable permission to allow it to export generic drugs to the United States for sale by others constitutes an investment in the United States under NAFTA Article 1139? The answer, we submit, is no. As Ms. McLeod observed this morning, Apotex has cited nothing in the text of the NAFTA, in the statement of administrative action submitted to Congress, and the statements or notes of interpretation of the NAFTA Free Trade Commission, or in the pleadings or other statements of the NAFTA Parties to sustain its theory.

Members of the Tribunal, there's simply no evidence before this Tribunal supporting Apotex's far-reaching interpretation of NAFTA Article 1139.

Helpful guidance on this issue can be found

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in the awards of NAFTA Chapter Eleven tribunals. The Award in Grand River versus the United States is particularly helpful because the Claimant in that case devised theories very similar to Apotex's theories in this case. The Grand River Case principally involved claims of Canadian generic cigarette manufacturer concerning the regulatory costs imposed on manufacturers wishing to participate in the U.S. cigarette market. United States objected to the Tribunal's jurisdiction in that case on various grounds, including the fact that Grand River was not an Investor with an investment in the United States as those terms are defined in Article 1139.

The Grand River Tribunal first observed that, NAFTA's Article 1139 is neither broad nor open-textured. It prescribes an exclusive list of elements or activities that constitute an investment for purposes of NAFTA. This definition is exclusive and not illustrative.

The Tribunal then observed that Grand River's alleged investment was unusual. It stated, "Whether a given activity constitutes an investment for purposes

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of Article 1139 has not figured prominently in past NAFTA cases."

In cases involving each of the three NAFTA Parties, the economic relationships or transactions at issue typically have involved some presence by the foreign investor in the territory of the Respondent country in the form of a local company, a locally incorporated subsidiary or affiliate, or other form that fits without great difficulty within some portion of Article 1139's definition. Hence the question of whether there was an investment typically has not arisen or has been readily dealt with.

The Grand River Tribunal cited various Chapter Eleven cases in which the Claimant had demonstrated that it made investments in the territory of the host State for purposes of Article 1139. In Thunderbird versus Mexico, the American Claimant operated gaming facilities in Mexico. In Glamis Gold versus the United States, the Canadian Claimant had obtained property interests in mining claims on Federal land in California.

In Mondev versus the United States, as I

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noted, the Canadian Claimant had obtained contractual interests in a large construction project in downtown Boston. And in Metalclad versus Mexico, the American Claimant had established an enterprise in Mexico that owned a hazardous waste transfer station and landfill.

The Grand River Tribunal then discussed two cases in which Chapter Eleven tribunals had found that Claimants were not Investors with investments in the territory of the Respondent State: Canadian Cattlemen versus the United States and Bayview versus Mexico. The Canadian Cattlemen Case concerning the United States closure of the border to Canadian cattle because of health concerns arising from the occurrence of Mad-Cow Disease in Canada. The Tribunal had objected to jurisdiction in that case on the grounds that the Claimants were not investors that had made, were making, or had sought to make an investment in the United States.

The Claimants argued that NAFTA did not require investors to make investments in the United States, so long as they had made investments in the North American free trade area in an independent and

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integrated market such as the North American cattle industry. That argument failed. The Claimants could not establish that the NAFTA Parties intended to create a radical new scheme in which investment tribunals would protect investments made outside of the Respondent State.

And although the Claimants in that case made far-reaching arguments, notably, they did not assert that their applications for permission to export their cattle to the United States, or the accompanying health certifications, or the various U.S. Government testing requirements constituted investments in the United States.

In Bayview versus Mexico, the Claimants claimed rights in river water in Mexico as a result of a U.S.-Mexico water treaty. They claimed that Mexico's diversion of that water harmed the irrigation districts in Texas. Mexico objected to jurisdiction in that case on grounds that the Claimants were not Investors that had made, were making, or had sought to make an investment in Mexico.

The Bayview Tribunal observed, "It is

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possible that the States Parties to the NAFTA might have given Investors who are nationals of one NAFTA state and who had made investment, an investment in the same State of which they are nationals, the right to bring a claim against another NAFTA Party in respect of a measure of that other Party which had adversely affected their investments in their National State." But the Bayview Tribunal concluded that the NAFTA Parties had intended no such thing. The Claimants in that case failed to prove that the NAFTA Parties had created such a revolutionary scheme. The Tribunal stated: "If, however, the NAFTA were intended to have such a significant effect, one would expect to find very clear indications of it in the travaux préparatoires. There are no such clear indications in the travaux préparatoires or elsewhere, and the Tribunal does not interpret Chapter Eleven of the NAFTA, and in particular Articles 1101 and 1139 in that way." The Bayview Tribunal thus dismissed the claims for lack of jurisdiction.

The Grand River Tribunal took these various cases into account when evaluating whether the

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Claimants in that case were Investors with investments in the United States. There are significant parallels between this case and Grand River, and I would like to highlight seven of them.

First, Grand River did not maintain a place of business in the United States. It had no personnel, no office, no real estate, and so forth. Similarly, Apotex alleges that it does not reside or have a place of business in the United States. It has no personnel, no office, no real estate.

Second, Grand River had extensive facilities for manufacturing its generic products in Canada. Similarly, Apotex has extensive facilities for manufacturing its generic products in Canada.

Third, Grand River exported its generic products from Canada to its U.S. distributors, where they were sold by entities not owned or controlled by Grand River. Apotex similarly exports its generic products from Canada to U.S. distributors where they're sold by entities not owned or controlled by Apotex, Inc., such as Apotex Corp.

Fourth, Grand River allegedly invested

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millions of dollars in state-of-the-art equipment for the sole purpose of marketing its generic products in the United States. Apotex similarly alleges it spent more than $1 million developing its generic drugs for the sole purpose of marketing its drugs in the United States.

Fifth, Grand River allegedly spent significant sums on various other activities in the United States: Hiring U.S. counsel for litigation, developing tobacco blends for the U.S. market, promoting its cigarettes in the United States, lending money and a truck and trailer to a U.S. affiliate and distributor, purchasing vehicle licenses in several U.S. states, paying a lease/warranty/insurance on the truck and trailer. Apotex similarly alleges that it spent significant sums on various other activities in the United States. For example, Apotex claims to have spent significant sums on U.S. litigation, and in buying inactive ingredients for use in the Canadian manufacturing operations.

Sixth, Grand River claimed that its close cooperative relationship with the U.S. affiliate and

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distributor constituted an enterprise for purposes of Article 1139. Apotex similarly claims that its, "relationship with its U.S. affiliate, Agent, and distributor (Apotex Corp.) also independently qualifies as an interest in an enterprise that entitles the owner to share in income and profits of the enterprise for purposes of Article 1139."

Last, seventh, Grand River spent millions of dollars complying with U.S. statutory and regulatory requirements to enter the U.S. market. Its expenses included escrow payments in United States to cover possible future settlements or judgments and lawsuits arising from the sale of its generic cigarettes in the United States. These costs were a condition to marketing its cigarettes in the United States. Apotex similarly claims to have spent more than a million dollars complying with U.S. statutory and regulatory requirements to enter the U.S. market. Its expenses included the costs of preparing ANDAs, which are required of all companies, foreign and domestic, that wished to market generic drugs in the United States.

The Grand River Tribunal evaluated the

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various activities and concluded that individually or cumulatively they did not constitute an investment under Article 1139. The Tribunal stated: "Given the relatively restricted definition of 'investment' under Article 1139, the Claimants must nonetheless establish an investment that falls within one or more of the categories established by that Article."

The Tribunal then concluded: "The evidence did not establish that these Claimants had constituted an enterprise in the United States or engaged in other significant activities there satisfying the definition of 'investment' in Article 1139 of NAFTA. Instead, the record shows that as relevant here, their activities centered on the manufacture of cigarettes at Grand River's manufacturing plant in Canada for export to the United States. The Tribunal concludes that such activities and investments by Investors in the territory of one NAFTA Party do not satisfy the jurisdictional requirements for a claim against another NAFTA Party."

I want to draw your attention in particular to the Grand River Tribunal's discussion of the

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Claimant's argument that its expenses incurred complying with U.S. regulatory requirements constituted an investment. Grand River claimed to have spent roughly 29 million dollars complying with U.S. statutory and regulatory requirements for the sale of its--for the purposes of allowing Grand River to market its generic cigarettes in the United States.

The United States has opposed Grand River's arguments, observing that, under Article 1139, investment does not mean claims to money that arise solely from, one, commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party. The United States thus argued to the Grand River Tribunal that, "Article 1139's definition of 'investment' did not embrace costs of complying with the State regulatory requirements incident to product sales and thus are excluded from the scope of Article 1139."

The Grand River Tribunal found the United States argument compelling. It stated, "The obligations to comply with escrow and other regulatory

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requirements existed solely because of sales of cigarettes. They thus were incident to commercial contracts for the sale of goods or services which generally fall outside of Article 1139's definition of "investment."

Let me reiterate, Apotex claims to have spent substantial sums in Canada complying with U.S. statutory and regulatory requirements for the preparation of its ANDAs in order to export its drugs to the United States for sale by others. Apotex's Counter-Memorial states, "Apotex's purchase of the necessary ANDA product ingredients from the United States, along with Apotex's investment in capital and resources in preparing and filing its pravastatin and sertraline ANDAs in accordance with U.S. statutory and regulatory requirements for FDA approval, were done for the sole purpose of securing an economic benefit from the sale of its sertraline and pravastatin ANDA products in the United States.

It then adds, "Apotex would never have incurred these expenses if it had not been required to do so under U.S. statutory and Federal regulatory

10:56:00 requirements. Likewise, the only reason Apotex undertook the enormous expense and effort to comply with these U.S.-specific requirements was to obtain approval for, and to market and sell, its sertraline and pravastatin ANDA products in the United States."

But all of Apotex's expenditures like all of Grand River's expenditures are incident to commercial contracts for the sale of goods; that is, they facilitate Apotex's export of its products to the United States for sale by others. Those expenditures cannot be investments in the United States because they fall outside of the exclusive list of investments in Article 1139.

PRESIDENT LANDAU: We must take a break fairly soon as well, but I just want to ask one question.

There's emphasis throughout the United States submissions on the fact that sales of the actual products in the U.S. were via other entities and not conducted by Apotex itself. How significant is that point? Does it change the United States analysis? Would it change the United States analysis if Apotex

10:57:08 itself were then selling, distributing and selling the products within the U.S.?

MR. SHARPE: My very next point was to point out that in the Grand River Case, there was another Claimant, Mr. Arthur Montour, whose claim was accepted, for two reasons, one, and I will just bring the next slide. It says, "Both Parties agree that Claimant Arthur Montour has an investment in the United States. The record demonstrates that he owns a substantial tobacco distribution business in the United States as well as the Seneca trademark.

So in that case, one of the Claimants had established a distribution facility in the United States for marketing--for selling Grand River's drugs, and so although Mr. Montour's claims failed on other grounds, both Parties including the United States accepted that Mr. Montour did have an investment in the territory of the United States for purposes of Article 1139.

I think this is--let me just wrap up one more point and then perhaps we can--I think actually this is a very good place to break, if it's convenient.

10:58:14 PRESIDENT LANDAU: That's fine, if that's convenient for you.

MR. SHARPE: Sure. I have another 20 minutes or so.

PRESIDENT LANDAU: All right. Let's break now for 15 minutes. Thank you.

(Brief recess.)

PRESIDENT LANDAU: Mr. Sharpe.

MR. SHARPE: Thank you.

Picking up Apotex's argument, it cites two cases, SGS versus Pakistan and SGS versus the Philippines to suggest that money spent outside of the host State can be deemed an investment in the host State. These cases, of course, are not NAFTA Chapter Eleven cases, and the definition of "investment" in those Treaties is different from the definition of "investment" in the NAFTA. And that's the reason that the Grand River Tribunal observed that "on jurisdictional aspects, NAFTA awards are more relevant and appropriate than Decisions in non-NAFTA investment cases."

But even setting that aside, the SGS cases do

11:13:45 not support Apotex's claims. In fact, Apotex's own pleadings highlight crucial differences between its case and those two cases.

Apotex states, "in SGS versus Philippines, Claimant SGS provided customs certification services for the Philippines based on pre-shipment inspections carried out in the exporting country. Though the bulk of the costs of providing the service was incurred outside of the Philippines, SGS's inspection of operations abroad were organized through an office located in the Philippines."

Apotex further states, "similarly the Tribunal in SGS v. Pakistan found that the Claimant SGS was an Investor with an investment in Pakistan." There, SGS provided pre-shipment inspection services for Pakistan. The pre-shipment inspections occurred outside of Pakistan but they were processed at a liaison office located in Pakistan.

Apotex's own statements thus make clear that in both cases the foreign Investor established the liaison offices in the host State.

The SGS v. Philippines Tribunal characterized

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11:14:58 the Claimant's investment in the Philippines as a "substantial office, employing a significant number of people."

Here, Apotex does not allege that it established any office in the United States, let alone a substantial office employing a significant number of people.

In addition, the SGS v. Pakistan Tribunal concluded that the Claimant had obtained a Public Law Concession which the Treaty expressly protected as an investment. These two cases simply do not support Apotex's claim.

Though the only thing left for Apotex to argue is that its application somehow constituted property under the NAFTA. Article 1139 includes as investments, G, real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefits or other business purposes.

As Ms. McLeod observed this morning, Apotex's argument makes no sense even on a plain reading of the text. Apotex's ANDAs are applications. They're not

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11:16:04 claimed, to be, for example, intellectual property like Arthur Montour's trademark rights in the Seneca brand in the Grand River Case, nor are they mining claims like Glamis' interests in California or Concessions or other sorts of intangible property rights that often are protected by Domestic Law and International Investment Agreements. Rather, as FDA explains, "an abbreviated new drug application, ANDA, contains data which, when submitted to FDA's Center for Drug Evaluation and Research Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

Apotex did not have, and does not claim to have had, an approved ANDA at the time of the alleged breaches. Article 1139, however, requires that the property be acquired in the expectation or used for the purpose of economic benefit. Apotex does not claim to have acquired or used anything. At the time of the alleged breaches, Apotex ANDAs were still

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11:17:23 pending with the FDA.

As Apotex has repeatedly emphasized throughout these proceedings, the economic benefit it sought to exploit through the ANDAs was the ability to market its drugs in the United States. But the ability was not acquired and certainly could not be used while its ANDAs were still pending with the FDA. Apotex, in fact, expressly acknowledges that it, "may not lawfully sell its generic pharmaceutical products in the United States unless such products are the subject of an FDA-approved ANDA."

And under U.S. law, FDA may decline to approve ANDAs or may revoke tentatively approved or even finally approved ANDAs for a variety of reasons related to the new products' safety and effectiveness. Reasons include, a finding that there is an imminent hazard to the public health, clinical or other experience tests, raw scientific data shows the drug is unsafe for use. New evidence of clinical experience or tests by new methods reveal that the drug is not shown to be safe for use. New information reveals a lack of substantial evidence from adequate

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11:18:41 and well controlled investigations that the drug will have the effect it is reported or represented to have. And the application or abbreviated application contains any untrue statement of a material fact. The regulation thus expressly affords FDA discretion to decline to approval or revoke approval of ANDAs for any number of stated reasons related to the drug product itself. Apotex thus has had no legitimate claim to entitlement in its pending applications.

Apotex does not dispute this regulatory scheme. Instead, it alleges that its ANDAs, which were tentatively approved at the time of the alleged breaches, would have been finally approved but for the allegedly unlawful acts of the United States that complains about in this arbitration.

PRESIDENT LANDAU: I'm sorry to interrupt. I have just one or two questions on the issue about the characterization of an ANDA as property. I wonder if I could put those questions and you can either answer them or address them later. I don't want to blow you off course, but it seems to me you're moving on to a specific point now about whether or not the tentative

approval would have been finalized and the reasons why that may or may not have been.

There is a certain amount of focus in the United States submissions on the ANDAs being tentative and not finalized or approved. What I wonder is, what would be the United State's position if the ANDA was approved, a final ANDA? Would that be property, or not?

MR. SHARPE: Right. We think it's clear that even a finally approved ANDA would not be property, and the reason is that the FDA retains discretion by law to revoke approval of even a finally approved ANDA for any of the number of the stated reasons that are up on the Slide without any payment of compensation. There's been no evidence adduced, as I'll discuss momentarily, that United States law recognizes even an approved ANDA as a property right that would give rise to--that would give a property right to--rise to a claim that the Applicant has a property right under U.S. law.

PRESIDENT LANDAU: But is it your position that it's not a property right because the ANDA might

be revoked?

MR. SHARPE: I think there are--the principal reason--I don't think Apotex has established how a finally approved ANDA could be a property right under U.S. law. But even Apotex recognizes that one of the principal tenets of property would be exclusivity, and yet FDA has the discretion by law to decline to approve or even revoke an ANDA, even a finally approved ANDA.

So, we have not seen any evidence of how a person could claim a property right in something when the Government entity has discretion by law to revoke that without giving any property-like remedies to the Applicant.

PRESIDENT LANDAU: You might forgive me for continuing, but it might not be a question of evidence, rather than simply a question of legal analysis and submission. Isn't the question simply a question of law as to whether or not an ANDA can qualify as a matter of law as a property interest?

MR. SHARPE: Certainly Article 1139 recognizes real property and intangible property. But

as Mr. Kovar discussed, it's incumbent upon the Claimant to adduce evidence that there is a property right. That's Point Number 1.

Once you have the existence of the right, what is the scope of the right, and in whom does the right vest, then the next question would be, is that property an investment that is acquired or used for purposes of the NAFTA?

So, we think there is an underlying question of U.S. law, and there's the secondary question is what does that mean for the definition of "investment" in an investment chapter of a Free Trade Agreement like the NAFTA?

So--we had not seen any evidence that Apotex has satisfied its burden at either level, first to establish that the U.S. law recognizes an ANDA tentatively-approved, finally approved, or as they claim at the moment of submission to the FDA, as a property right or that even if it were property under U.S. law there would be property acquired or used for purposes of economic benefit; that is, that it's an investment in the United States.

PRESIDENT LANDAU: Just on the first of those issues, leaving for the moment the second element, which is acquired or used for certain purposes as set out in 1139, just on the first question of it actually amounting to property, tangible or intangible itself, does the U.S. have a position as to whether or not you can buy or sell an ANDA?

MR. SHARPE: Apotex has introduced evidence that ANDAs may be sold, especially it would appear when they are associated with the manufacturing facilities that are associated with that ANDAs. But that certainly doesn't answer the question of whether it is a property right under U.S. law simply because it has been--can be sold. That is there's the other attributes, the other sticks in the bundle of property, notably exclusivity. In fact, we have seen no evidence of U.S. law whatsoever that either the Congress intended an ANDA, even finally approved, to be property, or that the FDA intended that it would be property or that the Courts have recognized that it is property under U.S. law.

So, the mere ability to sell the thing does

not mean that there is a legally cognizable property right as a matter of U.S. law.

PRESIDENT LANDAU: Again, forgive me for continuing, but the other query I have is about 21 CFR Section 314.72, which is at Exhibit C-71, which is cited by Apotex, which talks about changes in ownership of an application, which might be curious language to be using the terminology of ownership if the thing in question doesn't constitute property.

MR. SHARPE: Well, I think that Apotex is the owner of its application, and that's precisely what is being sold.

But again, I think there's the underlying question is: What is the thing, what is the scope of the rights protected by--under law for that thing, and then in whom does those rights vest? And the question is does U.S. law protect this thing as a property right? And there is no evidence whatsoever and I think it's inappropriate for an International Tribunal such as this one to have to ascertain without evidence that this thing is a property right under U.S. law. There should be evidence of this, we think, in the

domestic law, to satisfy the first question, which is: Is this thing property? Before you even get to the second question, is it property acquired to use for the purpose of business activity under the definition of "investment" in this Investment Chapter.

But we have no evidence on either of those points.

PRESIDENT LANDAU: But again, this may not be a question of evidence. This may be a question of straightforward submission.

MR. SHARPE: Well, then I guess the question would be is this Tribunal prepared to recognize for the first time when no other authority has recognized that an ANDA is property and including property for the purposes of domestic law and international law under this Treaty. We think that's just not appropriate. There should be evidence submitted by the Claimant that it meets these two--the two parts of this test, that it's property recognized under domestic law and that it's property acquired to use for purposes of business activity for purposes of the NAFTA Article 1139.

And we don't think it's appropriate for the Tribunal just to determine that well, it has certain attributes of property, but there is no evidence that the domestic law recognizes that thing as property and simply to make a finding on that basis.

PRESIDENT LANDAU: Are your answers premised on the idea that we will only make findings about U.S. law on the basis of evidence rather than submission?

MR. SHARPE: There are certain--certainly the NAFTA itself provides criteria. This is an exclusive list of things that are recognized as investment, real property. And as the Grand River Tribunal recognized, most of the time the Tribunal doesn't have to go to the second level of analysis. What is the underlying right of this thing that is being claimed because it's fairly obvious. In cases like Glamis Gold, it was a little bit more complicated because even though Federal law recognizes mining rights as property rights, there are some background principles of U.S. law that circumscribe the nature of the right, the thing that you have acquired, and so you have to look to domestic law, evidence of what domestic law is on

this question to determine what the Claimant actually has as a matter of law before you even get to the international law question under the NAFTA.

So, we don't think it's--in a case where it's not clear what the thing is that the Claimant has or purports to have, you do have to look at evidence of the underlying law. Here, there is no evidence. And as we--as suggested, we think it would be inappropriate for the Tribunal on the basis of the evidence that has been put forward or the lack of evidence put forward by the Claimant simply to determine for the first time that an ANDA is property or let alone an ANDA at the moment of submission to the FDA is property under U.S. law. We just don't think that there is support for this proposition before this Tribunal.

PRESIDENT LANDAU: Thank you.

ARBITRATOR DAVIDSON: I have a question while we're at it. Is the U.S. taking a position that there's a distinction between the property rights of a first-filed ANDA as compared to a subsequent ANDA? The first-filed ANDA has the possibility of 180-day

11:28:58 exclusivity?
MR. SHARPE: I think probably not, although that question I don't think is relevant for us here.
But the Courts have recognized, as far as I understand, that you do not have a right even to the market exclusivity. But, of course, even if you have the right to market exclusivity, I'm not sure how that's relevant here, where the Claimant was not claiming any kind of rights, entitlement and so forth to market exclusivity. Rather, it was seeking through the ordinary course to get its ANDA approved to enter the market with the other non-first-filers.
So, I can consult with, of course, with our FDA colleagues and get a better informed answer for you, Mr. Davidson, but I'm just not sure I see the relevance.
ARBITRATOR DAVIDSON: I'm trying to understand when ANDA might be a property right and when it might not be a property right.
MR. SHARPE: Right.
ARBITRATOR DAVIDSON: Thank you.
MR. SHARPE: Certainly, we have seen no

11:29:51 evidence.
Of course, as we noted, the only question we think for the Tribunal is as proposed by the Claimants, which is: Did the Claimants obtain a legally cognizable property right the moment it filed its application with the FDA? We think the answer is obvious. It did not. There is no evidence whatsoever. Even though, of course, the Claimant can sell that application, but there is no property right that they've established simply by the fact that they can sell this application. That is because, as noted among other reasons, the Government has the ability--the discretion not to approve that thing or to even revoke it by law even--you know, at any stage of the process as an ongoing regulatory obligation to monitor this thing and can revoke it without any compensation.
ARBITRATOR DAVIDSON: I hate to digress to another point, but I had a question on an earlier point you raised about the SGS Cases. You had mentioned that the definition of "investment," those cases differed because they were not NAFTA cases. I

11:30:54 was wondering if you could elaborate on what the difference and the definitions are.
MR. SHARPE: I will have to pull out the Treaties, but I think in both cases it was probably a more common formulation all assets. The NAFTA has an exclusive list rather than an illustrative list. And if I'm not mistaken, and I'll double-check that for you, Mr. Davidson. I believe both of those cases had the illustrative list assets, all assets relating to, and then there's a laundry list of things that--
PRESIDENT LANDAU: Any asset including?
MR. SHARPE: Any asset including, thank you.
ARBITRATOR DAVIDSON: Thank you.
PRESIDENT LANDAU: Forgive me, this is my last interruption. I just wonder whether--I'm inviting the Parties to reflects perhaps a little bit further on the exchange that we've just had, just so that everybody is satisfied they've made all the points they want to make by the end of this hearing, simply because I have a sense that the answers to my questions, which I fully appreciate, I have not given you any warning of, the answers seem to me to be

11:31:58 premised upon a procedural point as to the way in which United States law is to be proven in this case and whether it's by way of evidence or submissions so that in the absence of evidence of U.S. law the Tribunal is to be pointed in a particular direction, and there could be a procedural answer to that, which is that this is not a question of evidence but rather submission as with any other point of law, i.e., national law would be treated in the same way as international law and, therefore, it may be something which the United States might want to say something--may or may not want to say something further beyond just the question of evidence.
MR. SHARPE: Right. Thank you.
PRESIDENT LANDAU: But I leave that with you.
MR. SHARPE: Thank you. I appreciate it.
Let me just pick up with the tentative approval letter that the FDA provided to Apotex, and the notion that Claimant makes--suggests that somehow that tentative approval letter conveys some sort of property right. In our view, those letters do not convey that. They make clear that final approval

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depended not just on resolving the underlying patent and exclusivity issues but also on FDA's continued finding that the products met the FDA requirements.

As I noted, FDA reserved the right to refuse final approval of the tentatively approved ANDA for any number of reasons related to safety and effectiveness of the drug product beyond patents and market exclusivity.

This is the reason that U.S. Courts have found that there's no vested right in tentatively-approved ANDA. The U.S. District Court for the District of Columbia, for instance, stated in the Ranbaxy Case, "approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform, an applicant has no vested right to enter the market until the FDA gives its final formal approval." As it has noted, Apotex has not produced or identified a single case in which a U.S. Court has found that an ANDA Applicant has a property interest in its application.

Instead, as we noted, Apotex simply asks this

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Tribunal to consult a legal dictionary to find that its applications are property under the NAFTA the moment they're filed with FDA, as the exchanges illustrated, claims that its pending applications are valuable and transferable. And as noted, these ANDAs may be valuable, especially when attached to the underlying facilities for manufacturing them. But as noted, it has not produced any evidence these unapproved ANDAs had value at the time of the alleged investments.

Apotex always claims that its ANDAs gave it the exclusive right to possess, use and enjoy the ANDA and the ANDA products approved thereunder. But as we noted, Apotex's ANDAs had not been approved at the time of the alleged breaches. It thus could not lawfully use its ANDAs and its ANDA products in the United States. Apotex had not cited any statutes, any regulations, any decisions of the FDA and so forth, illustrating that it acquired a legally cognizable property right in the United States. As Ms. McLeod noted, nor has Apotex cited anything in the NAFTA, decisions of NAFTA Chapter Eleven Arbitral Tribunals

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indicating that the NAFTA Parties intended to protect as an investment an application that if approved would give a foreign company revocable permission to export its products into that State for sale by others. As the Grand River Tribunal concluded, NAFTA Chapter Eleven requires that the foreign company make, be making or seek to make an actual investment in the territory of the host State, so it was not enough for Grand River to spend tens of millions of dollars in the United States on these required escrow payments for the sale of its cigarettes in the United States or on advertising or even allegedly for the lease of the truck and the trailer for its distributor. Surely the money and the vehicles were property, they're transferable, exclusive and so forth. But the money spent and the property allegedly acquired did not constitute an investment for purposes of NAFTA Article 1139. They did not have the characteristics of a foreign investment in the United States.

The question, we believe, is whether Apotex has demonstrated not through say so but evidence that its pending applications afforded it a legally

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cognizable property right that were acquired or used in the United States or by contrast, did Apotex prepare its ANDAs so that it could export those products to the United States for sale by others. Again, we believe the answer to this question is quite clear. Applications--its applications merely facilitated its cross-border trade. They were not investments. And as Ms. McLeod observed this morning if a Canadian exporter could transform itself into an Investor with an investment in the United States simply by pointing to something in the host State, some connection, some interest, some activity no matter how remote or no matter how contingent, it would radically transform the scope of Chapter Eleven, it would open the doors to investment arbitration by companies that did not have investments in the host State.

The United States, and we believe that NAFTA partners did not consent to this and could not accept such a scheme.

Mr. President, Members of the Tribunal, contrary to Apotex's unsupported allegation, we

11:38:01 believe Apotex is not an Investor that made an investment in the United States as those terms are defined in the NAFTA. Its claim should be dismissed and the United States should be awarded its full costs. And unless there are further question, I would ask that the Tribunal call on Mr. Kovar who is going to discuss the U.S. Court proceedings.

PRESIDENT LANDAU: Thank you very much.

Mr. Kovar.

MR. KOVAR: Thank you very much, Mr. President.

If I can then shift gears. Even if Apotex were able to establish that its tentatively-approved applications for permission to export its generic drugs to the U.S. were investments under the NAFTA, that finding would only allow its Sertraline Claims to advance past this phase of preliminary issues.

The United States has two additional objections, which we believe bar this Tribunal's jurisdiction over the Pravastatin Claims.

First, Apotex's challenge to the FDA Measure is time-barred by NAFTA's three-year limitations

11:39:08 period and cannot be extended by Apotex's court challenges.

And, second, to the extent Apotex argues that the U.S. Federal Court's failure to grant a Temporary Restraining Order or a Preliminary Injunctive Relief concerning that measure is the basis of its claim. Apotex failed to obtain the requisite finality for the judicial acts upon which it bases such claims.

Mr. Bergman will address the first objection, and Mr. Pearsall will address the second.

What I would like to do for you is to begin with a review of the various proceedings in U.S. Courts involving Apotex and FDA.

As part of its Pravastatin Claim, Apotex sought to prevent two other companies, Teva and Ranbaxy, from enjoying the 180-day exclusive marketing period available to them for being the first to challenge certain of the pioneer drug Pravachol's patents. Apotex initially brought a declaratory judgment action against Bristol Myers Squibb, we can say BMS, the patents holder of the name brand drug in the U.S. District Court for the Southern District of

11:40:19 New York, seeking a judgment that's certain of BMS's patents, which Apotex had challenged in its ANDA through paragraph IV certifications, were invalid or not infringed.

The case was then voluntarily dismissed on July 23rd, 2004, by Apotex and BMS when that Court entered its Stipulated Dismissal Order as submitted by the two companies. The Stipulated Dismissal Order noted that, "based on BMS's pre-complaint representations, BMS had no intention to bring suit against Apotex with respect to Apotex's generic pravastatin sodium products that are the subject of its ANDA.

Upon receiving the Dismissal Order, Apotex petitioned FDA for a determination that this voluntary dismissal had successfully triggered any 180-day exclusivity with regard to BMS's patents. Recall that under the Statute, a court decision trigger is, "a decision of a court holding the patent which is subject of the certification to be invalid or not infringed."

On June 28th, 2005, FDA informed Teva by

11:41:29 letter that, according to what FDA understood to be the controlling legal precedent, the voluntary dismissal of Apotex's lawsuit which was entered as an Order of the District Court for the Southern District of New York, constituted a "court-decision trigger." FDA further informed Teva that the 180-day exclusivity period that otherwise would have been available to it upon expiration of BMS's challenged patents had been triggered on the date of that Voluntary Dismissal Order and thus had already run out.

With the premature expiration of Teva's exclusivity period, Apotex was therefore in a position to market its own generic pravastatin drug simultaneously with Teva as soon as, one, Apotex and Teva received final approval of their ANDAs; and, two, another patent which was subject to paragraph III certification and not challenged in the ANDAs, expired on April 20th, 2006.

Shortly after being informed of FDA's Decision with regard to the 180-day exclusivity for pravastatin, Teva sued FDA in the U.S. District Court for the District of Columbia seeking to reverse FDA's

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11:42:44 Decision. Apotex joined the case supporting the legality of FDA's Decision. The District Court held that FDA was wrong to conclude that the voluntary dismissal of Apotex's declaratory judgment patent infringement action against BMS could qualify as a court decision trigger under the statute.

Apotex appealed the District Court's Decision to the U.S. Court of Appeals for the D.C. Circuit. The Court of Appeals determined that FDA was wrong to conclude that it was compelled by previous case law in the D.C. Circuit to treat the Apotex BMS voluntary dismissal as a decision of a court holding the patent invalid or not infringed. The Court of Appeals ruled that its previous decisions did not legally compel that result. At the same time the Court rejected the District Court's holding that FDA could not find that voluntary dismissal constituted a court decision, holding a patent invalid or not infringed. The Court of Appeals explained its holding.

While the Statute may preclude treating Voluntary Dismissals or for that matter Involuntary Dismissals as triggering events, we express no opinion

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11:43:58 on the matter. It is up to the Agency to bring its experience and expertise to bear in light of competing interests at stake and make a reasonable policy choice. The FDA has not yet done so.

Thus, on March 6th, 2006, the Court of Appeals vacated the District Court's ruling, remanded the question to FDA, and directed FDA to re-examine the issue under the Statute. In other words, the ball was back in FDA's court.

In response to this decision, FDA issued a new carefully reasoned letter decision on April 11, 2006. In that decision, FDA interpreted the Statute to require a court decision holding on the merits that the patents being challenged were invalid, not infringed or unenforceable in order to constitute a court decision trigger and to initiate the running of the 180-day exclusivity period.

FDA's later decision stated, FDA has brought its experience to bear and now makes an independent interpretation of the Statute. FDA has determined that it is most appropriate to interpret the Statute consistently with its plain language. Thus, the

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11:45:13 FDA--excuse me--thus, the Agency is interpreting the Court Decision Trigger Provision to require a decision of a Court that on its face evidences a holding on the merits that a patent is invalid, not infringed, or unenforceable. This interpretation follows most readily from the statutory language and FDA's long-standing regulation.

Because the District Court for the Southern District of New York had not made a finding on the merits, FDA determined that the Apotex Voluntary Dismissal Order did not trigger Teva's 180-day exclusivity period. So, with BMS's unchallenged patent and its corresponding exclusivity due to expire in nine days, on April 20th, and Teva poised to take advantage of the exclusive period of 180-days to market the first generic version of pravastatin, for the 10, 20, and 40 milligrams strengths, Apotex filed a action challenging the FDA Decision under the Administrative Procedure Act as arbitrary, capricious, and not in accordance with the law, and included a request for a Temporary Restraining Order or a preliminary injunction.

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11:46:31 The legal standard for such an injunction involves a balancing test, which requires the Court to examine, first, the prospective irreparable harm to the moving Party if the requested relief is denied, and second, the possibility of harm to other Parties if the relief is granted; third, the likelihood that the moving Party will succeed on the merits of its claim; and, fourth, the public interest.

Five days later, after Apotex had refiled its original motion, on April 19th, the U.S. District Court for the District of Columbia denied Apotex's request, reasoning that Apotex was unlikely to prevail on the merits. The Court found: "Not only did the Agency's 15-page, single-spaced remand decision thoughtfully deconstruct the multifaceted implications of the estoppels and holding-on-the-merits approaches, but it also sufficiently addressed each of the three concerns raised in the earlier cases. There is no want of reasoned decision-making here.

The Court then added, "the Agency's remand decision represents a permissible construction of the Statute as a matter of textual interpretation as well

11:47:50 as practice. Apotex is, accordingly, unlikely to prevail on the merits of its claim that FDA acted arbitrarily, capriciously, in excess of statutory authority, or otherwise not in accordance with law when it determined that the Apotex-BMS dismissal is not a qualifying triggering event under the Statute.

So, Apotex immediately appealed that denial of injunctive relief to the U.S. Court of Appeals for the District of Columbia Circuit, which granted a temporary administrative injunction, enjoining FDA from approving any ANDA for pravastatin and preventing Teva from beginning to sell its product on April 20th when the relevant BMS patent expired.

On April 24th, however, the Appeals Court denied Apotex's request for State pending appeal. It also listed the administrative injunction on the approval of any Pravastatin ANDAs finding that Apotex had "not satisfied the stringent standards required for an injunction pending appeal. From that date, FDA approved Teva's ANDA. Teva was free to begin marketing its strengths of generic pravastatin; and, according to Apotex, it did so two days later on

11:49:09 April 26th.

On May 18th, Apotex filed a motion for expedited consideration of its appeal. The Appeals Court rendered its decision on Apotex's Preliminary Injunction Motion 19 days after that, on June 6th. The Court noted that according to FDA's Letter Decision, a court decision trigger required an actual holding on the merits so as to provide certainty to the market and avoid endless litigation over whether, for example, a stipulated dismissal amounted to a court decision trigger. The Court reviewed the reasoning in FDA's Letter Decision and concluded: "In our view, these perfectly reasonable propositions adequately support FDA's position." The Court of Appeals thus affirmed the decision of the District Court denying Apotex's request for preliminary injunctive relief and remanded to the District Court for proceedings on the merits.

Oddly, given its arguments in this arbitration, Apotex then stopped moving so quickly. At this point, Apotex could have immediately sought final review on its request for preliminary injunctive

11:50:24 relief through an application for writ of certiorari to the U.S. Supreme Court on an expedited basis.

Although not necessary, it could have also immediately sought additional intermediate review through a rehearing en banc by the full Court of Appeals prior to seeking certiorari. Instead, Apotex waited 44 of the 45 days available to it before deciding to seek further intermediate review through en banc review in the Court of Appeals. It asked the full court on July 21st, 2006, to review the decision of the three judge panel not to grant preliminary injunctive relief. The Court of Appeals denied en banc review on august 17th. And all of those nearly 67 days remained in Teva's 180-day market exclusive marketing period for the 10, 20 and 40 milligram strengths of pravastatin. Apotex chose not to petition for a writ of certiorari for review by the Supreme Court of the denial of its request for preliminary injunctive relief.

Finally, rather than litigating the merits of its case in the District Court after losing its bid for rehearing en banc in the Court of Appeals of the

11:51:45 denial of preliminary relief, Apotex stipulated on October 3rd, 2006, to the dismissal of its claims with prejudice for the 10, 20, and 40 milligrams strengths of the drug, and without prejudice for the 80-milligram strength. At the time of this dismissal, Ranbaxy had not even begun marketing the 80-milligram strength of pravastatin. It did not launch that product until June 25th, 2007, and its 180-day exclusivity period would not end until December 22nd, 2007, more than a year later.

It's important to note that Apotex did not seek review as quickly as it reasonably could have, and it pointedly failed to seek final review in the U.S. Supreme Court. Nevertheless, Apotex now argues that because the timing of a further Appeal would not provide it with the most commercially advantageous launch of its generic drug, further Appeals were "obviously futile." Mr. Pearsall will address that issue, but first I would ask the Tribunal to call on Mr. Bergman, who will discuss Apotex's failure to establish a challenge of the FDA Measure within NAFTA's three-year time limitations period.

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Thank you.

PRESIDENT LANDAU: Thank you very much. Mr. Bergman.

MR. BERGMAN: Thank you, Mr. President, Members of the Tribunal. My name is Neale Bergman, and it is my privilege to speak to you today about the United States's time-bar objection to Apotex's Pravastatin Claim. I want to address why the FDA's April 11th, 2006, Administrative Decision is time-barred and cannot form the basis for a finding that the United States breached the NAFTA.

Apotex brought its claims under NAFTA Article 1116. That Article contains a very important limitation on the United States's consent to arbitrate NAFTA Chapter Eleven disputes and, therefore, on the Tribunal's jurisdiction. As stated in Article 1122, the United States consented to investor-State arbitration under Chapter Eleven "in accordance with the procedures set out in this Agreement." As you can see on the slide, Article 1116(2) states that an Investor may not make a claim if more than three years have elapsed from the date on which the Investor first

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acquired or should have first acquired knowledge of the alleged breach and knowledge that the Investor has incurred loss or damage.

An Investor makes a NAFTA Chapter Eleven claim when it submits its Notice of Arbitration. For a claim such as this one, brought under the UNCITRAL Arbitration Rules, NAFTA Article 1137(1)(c) defines the time that a claim is made as the date on which the Notice of Arbitration is received by the disputing Party. In the case of Apotex's Pravastatin Claim, that date is June 5th, 2009. Thus under Article 1116(2), the date on which Apotex first acquired knowledge, either actual or constructive, of the alleged breach and of any alleged loss or damage must be no later than June 5th, 2006. However, the FDA Letter Decision was dated and became known to Apotex on April 11th, 2006, which is outside the three year filing period of Article 1116(2). As we will see, this decision provided Apotex on the day it was issued with actual knowledge of the grounds on which Apotex now alleges the United States breached the NAFTA and the basis for its claims for losses from

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that alleged breach.

Let's look at Apotex's knowledge of the alleged breach and loss.

First, the alleged breach.

Apotex knew when it read the FDA Decision that, in its own words, the FDA had determined that only a decision of a Court holding on the merits that a particular patent is invalid, not infringed or unenforceable would suffice to trigger the 180-day exclusivity period, and that the BMS-Apotex dismissal was insufficient to do so. For Apotex, it was clear that the outcome of the FDA Decision was an unlawful, arbitrary, and capricious ruling by FDA.

Second, the alleged loss or damage. Apotex knew, again in its own words in this arbitration, that on April 11th, 2006, FDA issued a second Administrative Decision, refusing to approve Apotex's Pravastatin ANDA in April 2006. Consequently, Teva and Ranbaxy alone were allowed to market their pravastatin products while Apotex was not. As Apotex alleges in this case, this outcome in April, 2006, caused it significant lost sales and lost market

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share. Because Apotex's Pravastatin Claim was filed more than three years after the date on which it first acquired knowledge of the alleged breach and loss or damage from the FDA Letter Decision, that FDA Measure is, therefore, time-barred from these proceedings. Indeed, the three NAFTA Parties did not consent to putting themselves in the hook for money damages for potential NAFTA violations for any period longer than three years. Thus, to review the relevant dates, under Article 1116(2), the date on which Apotex first knew or should have known of both the alleged U.S. breach and its own alleged loss as claimed in this case, must have been no earlier than three years prior to the date on which Apotex made its Pravastatin Claim. The United States received Apotex's Pravastatin Notice of Arbitration on June 5th, 2009. The time-bar deadline three years prior to that date is, therefore, June 5th, 2006.

The FDA Letter Decision, which denied Apotex's attempt to extinguish other companies' 180-days of market exclusivity and preventing Apotex from entering the market simultaneously with them, was

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11:58:57 dated April 11th, 2006, which is nearly two months outside the time-bar limitations period of the NAFTA.

Even if the Tribunal were to look for the date when Apotex had knowledge of actual pecuniary loss rather than knowledge of the legal basis for that loss, it need look no further than April 24th through April 26th, 2006, the respective dates that FDA approved Teva's ANDA and Teva entered the market exclusively for the 10, 20, 40 milligram strengths of generic pravastatin.

As Apotex itself has said in this arbitration, Apotex was unable to promptly bring its generic pravastatin products to market as soon as the 227 Patent and its associated period of pediatric exclusivity expired, causing Apotex to suffer substantial damages.

As you can see on the Slide, those dates listed below the red line are outside of the three-year limitations period. Because the very foundation of its Pravastatin Claim is time-barred, Apotex seeks to avoid the barrier of Article 1116(2) by arguing that the FDA Measure was somehow not final

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12:00:11 because Apotex promptly challenged it in Court. In its Counter-Memorial, just like it argues for the Sertraline Claim, which only involves judicial action, Apotex argues that the FDA Measure and the subsequent judicial proceedings in the Pravastatin Claim are simply part of the same single continuous action that only became ripe for a NAFTA challenge after Apotex's later appeals were exhausted.

Apotex also accuses the United States of completely ignoring the fact that the FDA Decisions gave way to the litigation and Court Decisions at issue in Apotex's Pravastatin Claim and, therefore, cannot be considered as a separate breach.

However, there is no debate between Claimant and Respondent that the FDA Letter Decision was a separate and final Agency action; and, as the NAFTA's text consistently confirmed by decisions of other NAFTA Tribunals makes clear, it is not possible to evade NAFTA's limitations period in this manner.

Under the plain terms of Article 1116(2), as you can see on the Slide again, the relevant date is when the Claimant first acquired knowledge of the

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12:01:23 alleged breach and alleged loss or damage. That date clearly the date of the FDA Decision. It is not the date when all Court challenges to a final, nonjudicial measure are exhausted.

PRESIDENT LANDAU: I have a question on that. I'm just trying to pick my moment not to upset your presentation.

Is it possible to analyze this simply in terms of the nature of the claim in question? Couldn't one say, I say this simply for the purposes of argument, that there may be a claim brought against a host State on the basis of administrative action of the host State's Government, or alternatively there may be a claim brought against the host State on the basis of judicial action, the courts in the host State?

Doesn't the question really depend upon that? If it's, say, a claim based upon administrative action, whether it's breach of FET or discrimination or whatever substantive ground on the NAFTA, then one would look at the administrative act and the date of it.

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12:02:47 But in contrast, if it's a claim based upon judicial activity, then wouldn't one then look at simply the date of the Court Decisions in question? Isn't that a simpler way through?

MR. BERGMAN: Yes, Mr. President. That's how we view this claim. You have at issue the FDA Measure, a final administrative action, which is clearly time-barred, and then you have nonfinal judicial acts at issue in Apotex v. FDA, which my colleague, Mr. Pearsall, will explain, lacked the requisite judicial finality to give rise to a claim.

PRESIDENT LANDAU: So if, in fact, one assumes that this is--or assume this is a claim in respect of judicial conduct, would we then, as a Tribunal, faced with that claim, looking at the Court Decisions that are impugned, would we be entitled to then also look at the Administrative Decisions upon which those judges were ruling?

MR. BERGMAN: Yes, yes, Mr. President, of course, but only as a background fact, not as a fact that could form the basis--the legal basis, for your decision of finding a NAFTA violation.

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12:04:00 PRESIDENT LANDAU: I just want to take that one step further, and again you don't have to answer it now, what I'm interested in understanding is exactly what that means, whether there's some cut-off beyond which a Tribunal couldn't go.

So, taking your last answer, and perhaps on the reasoning, for example, in Glamis Gold and those sorts of cases, and I think in Mondev as well, if you look at the FDA Decision as a background fact, would a Tribunal then not be entitled to question the correctness of the FDA Decision, again in the context of looking at Court activity? Or would there be some other limitation on the way in which a Tribunal could consider the underlying FDA Decision?

MR. BERGMAN: Mr. President, the short answer to your question is no. We will certainly elaborate on that further tomorrow.

The judicial action, you would have to see the violation emanate from the judicial action itself, not from the FDA's Decision, which is time-barred from this arbitration.

Picking up where I left off, other NAFTA

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12:05:34 Tribunals have upheld this plain reading of the text. The Mondev v. United States Case involves certain final actions of the City of Boston and the Boston Redevelopment Authority that allegedly damaged Claimant's real estate investments in violation of the NAFTA, as well as the subsequent judicial challenge of those actions. There, the Tribunal made clear that a NAFTA Claimant would not be able to evade the NAFTA's limitations period by pointing to the date of a subsequent Court challenge to those Measures because the Claimant may know that it had suffered loss or damage even if the extent or quantification of the loss or damage is still unclear.

In Grand River v. United States, the Tribunal also dismissed Claimant's efforts to evade NAFTA's limitations period. In that case, Claimants alleged that certain State law, regulatory and financial requirements breached the NAFTA and caused them damage. The Grand River Tribunal found that, even though there was insufficient evidence of Claimant's actual knowledge of the new State law requirements outside of the limitations period, Grand River

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12:06:38 Enterprises would be held in that time period to know what a reasonably prudent Investor should have known.

Then the Tribunal found that loss or damage was incurred on the date Claimants first became subject to a clear statutory obligation to place funds in escrow under those laws, even if actual payment was not due for several months.

As a result, the Tribunal did not allow the Claimants to evade the limitations period for State laws and related actions that they should have known about and that caused them damage outside the three-year limitations period.

Apotex's efforts to distinguish Mondev and Grand River fail. First, Apotex dismisses the language in Mondev because, in this case, unlike in Mondev, the NAFTA was in effect throughout the course of the underlying factual proceedings but this does not account for the Mondev Tribunal's rationale. That Tribunal specifically stated that, even if Mondev's claims concerning the conduct of the City and the Boston Redevelopment Authority had been continuing NAFTA claims as at 1 January, 1994, when the Treaty

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12:07:48 entered into force, they would now be time-barred.

Second, Apotex argues that the Mondev Tribunal found it significant that Claimant must have known that not all its losses would be met by the judicial proceedings. Apotex asserts, by contrast, that in this case, the federal courts had the authority to reverse the FDA Measure and immediately approve Apotex's Pravastatin ANDA. But unlike a federal court, this Tribunal is not in the best position to evaluate the specific remedies available to Apotex under Federal law in challenging a separate and final Agency action. Nevertheless, when the D.C. Circuit lifted the temporary four-day injunction on April 24th, 2006, FDA approved Teva's ANDA, then Teva began selling its strength of pravastatin on April 26th, 2006, and Apotex's alleged significant lost sales and lost market share began to accrue.

Indeed, according to language relied upon by Apotex from the Mondev Award, it must have been known to Apotex at the latest by April 26th, 2006, that not all of its losses would be met by the proceedings it had commenced in the U.S. Federal Courts.

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12:09:08 Third, Apotex also fails in its attempt to distinguish Grand River. Although Apotex asserts that the Grand River Claimants had not pled that each State's individual enactment of the law was a separate breach, that is exactly what those Claimants did at the hearing. In response, the Tribunal noted that Claimant's arguments that the time limitation applied separately to each contested measure taken by each State, would render the limitations provision ineffective in any situation involving a series of similar or related actions by a Respondent State, since a Claimant would be free to base its claim on the most recent transgression. Even if it had knowledge of earlier breaches and injuries.

And the Grand River Tribunal, like the Feldman Tribunal, recognized that the three-year limitation is a clear and rigid defense that is not subject to any suspension, prolongation, or other qualification. Nevertheless, Apotex is apparently arguing that the relevant date for purposes of time-bar in this case must be fixed as the date it abandoned its subsequent Judicial Appeals because the

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12:10:16 FDA's April 11th, 2006, decision was part of a single continuous action that culminated at the Federal Appellate Court level.

In support of this argument, Apotex invokes the Loewen Tribunal's recitation of the U.S. position in that case, that a judicial action is a single action from beginning to end, so that the State has not spoken, and, therefore, no liability arises until all Appeals have been exhausted or any such Appeals would be obviously futile. But that statement does not support Apotex's case, either. As Apotex admits, the FDA Measure is a final administrative decision issued by an Executive Agency. It is not a judicial action or judicial decision issued by a U.S. Court and, therefore, cannot be part of a single act with the subsequent Court proceedings.

In its Rejoinder, Apotex states that these are distinctions without a difference. Apotex is not correct. Judicial and Nonjudicial Measures are treated differently under the NAFTA and under customary international law. Judicial Acts that remain subject to Appeal do not constitute a measure

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12:11:28 adopted or maintained by the United States that can be challenged as a breach of the United States Chapter Eleven obligations because they are not final, unless further recourse in the Courts is obviously futile.

By contrast, a final Agency action such as FDA's Letter Decision does constitute a measure adopted or maintained by the United States. Even if that measure can be challenged in U.S. Courts, it is final for purposes of challenge under NAFTA Chapter Eleven. This can be plainly seen in a number of NAFTA cases where a challenged measure is an administrative action, such as the California Air Resources Board Measures in Methanex v. United States, and the animal, plant and health inspection service measures in the Canadian Cattlemen v. United States.

Apotex itself has made statements contradicting its argument that the FDA Decision and subsequent court action denying Apotex preliminary injunctive relief are part of a single continuous action in this case: In its Pravastatin NOA, Apotex argued that the FDA's April 11th, 2006, Administrative Ruling and the subsequent judicial decisions, each

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12:12:43 constitutes a violation of the NAFTA. In its submission in support of a stay in this arbitration, Apotex argued that the Pravastatin Claim arises from injuries suffered due to separate U.S. Agency and Federal Court Decisions denying Apotex the protections and benefits of U.S. Statutory law.

Apotex must not be permitted to blow hot and cold, advancing contrary positions when necessary to seek a stay of one claim in favor of another or to attempt to fit its claims within NAFTA's jurisdictional requirements.

Apotex noted in the same submission that its judicial action was an action for declaratory and injunctive relief challenging final Agency action.

And even in its Rejoinder, Apotex noted that its Pravastatin Claim is based on, inter alia, the unlawful, arbitrary, and capricious ruling by the FDA finding that the dismissal of Apotex's Declaratory Judgment Action against the patent owner failed to constitute a court decision triggered under the Statute, and the subsequent actions by the D.C. District Court and the Court of Appeals for the D.C.

12:13:56 Circuit in wrongfully denying Apotex's federal court challenge to that ruling.

Apotex argues there is no way to divorce FDA's Decisions from the ultimate decision of the D.C. Circuit rejecting Apotex's request to overturn FDA's April 11th, 2006, Decision. But Claimants know this is simply not true. As was similarly done by the D.C. District Court on April 19th, 2006, the D.C. Court or the D.C. Circuit in its June 6th, 2006, decision, did not rule on the merits of Apotex's request to overturn the FDA Decision. Rather it denied Apotex's request for preliminary injunctive relief from that decision and remanded the case to the District Court for proceedings on the merits. As the Circuit Court stated, "thus having no need to address the other preliminary injunction factors, we affirm the District Court's Order and remand for further proceedings consistent with this opinion."

Apotex's efforts to avoid the time-bar for the FDA's Administrative Decision by linking it to a subsequent judicial challenge of that measure should be rejected. Although a legally distinct injury can

12:15:10 give rise to a separate limitations period, NAFTA Chapter Eleven does not allow a disputing Party through the mere filing of a court case to toll the limitations period prescribed by the Treaty for a challenge of a separate regulatory measure.

Again, as the Grand River and Feldman Tribunals have warned, if it were otherwise, a Party could easily circumvent NAFTA's clear and rigid limitation defense, which is not subject to any suspension, prolongation, or other qualification.

There is simply no reason why Apotex could not have made its claims regarding the FDA Measure in a timely manner. The FDA Measure was taken in April 2006. All, U.S. litigation over the measure ended in August 2006, and Apotex voluntarily dismissed all claims relating to the measure in October 2006. Apotex then had ample time to bring its NAFTA claim challenging the FDA Measure. In fact, Apotex brought its Sertraline Claim on December 11th, 2008, which, had it included the Pravastatin Claim, would have been within the required time limit. Apotex, however, did not.

12:16:22 Finally, Apotex suggests in its Rejoinder that nothing prevents this Tribunal from considering underlying facts related to a NAFTA claim that occurred prior to this three-year period, including the FDA Decision. Apotex points to prior U.S. statements in this regard in the Loewen and Glamis arbitrations. While it is true that Apotex may refer to facts that pre-date June 5th, 2006, as background for its claims, facts that pre-date that time may not themselves form the basis for a finding that the United States breached a provision of the NAFTA.

Mr. President, Members of the Tribunal, background facts cannot save Apotex's Pravastatin Claim. If any of Apotex's Pravastatin Claims survive Article 1116(2) time-bar, it can only be allegations that the nonfinal judicial decisions of the D.C. Circuit denying preliminary injunction and rehearing en banc violated the NAFTA. But as you're about to hear from my colleague, Mr. Pearsall, any such claims must also be dismissed because they lack the requisite judicial finality.

Mr. President, that concludes my

12:17:33 presentation, and I would ask the Tribunal to call on Mr. Pearsall.

PRESIDENT LANDAU: Thank you very much.

Just before, although you're probably breathing, thinking you have said the last thing, let me challenge that. I just want to go back to our exchange, if I may, just to fine tune the point a little bit further just insofar as the United States wants to think about it a little bit further.

Still thinking about the distinction between challenging an administrative act as opposed to challenging a judicial act, if one just thinks in terms of challenging a judicial act, would it be possible, in your submission, for a Party in Apotex's position to challenge a judicial conduct before a NAFTA Tribunal, and in so doing to say that the FDA underlying decision was manifestly wrong, and because it was so wrong the United States Courts should have reversed it, the fact that they didn't reverse it thereby constitutes some egregious error in their process, qualifying, for example, as a denial of justice.

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12:18:41 Now, not saying anything about the merits of that kind of argument, but is it an argument that's available?

Again, if you want to park that and come back later, that's fine.

MR. BERGMAN: I think we will come back to that later.

PRESIDENT LANDAU: That's fine.

Can I add something else to the list?

MR. BERGMAN: Yes.

PRESIDENT LANDAU: And that is whether or not you would have any reaction to the observation that the consequences of the United States argument on this point might be to deter Parties from going before the United States Courts to question administrative action for fear that in so doing, the three years might expire and, therefore, the consequence might be to create an incentive for Parties to bring all such applications before NAFTA Tribunals instead? And, of course, the danger from a litigation point of view, the danger might be perceived to be that if you were to commence a process in court and also save the time

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12:19:50 under NAFTA by commencing an arbitration, you might undercut the strength of your arguments before a NAFTA Tribunal if you're questioning administrative action whilst at the same time the Court is reviewing whether or not to reverse it.

Again, if you want to park that, that's fine.

MR. BERGMAN: If I could answer that question now, briefly.

PRESIDENT LANDAU: Thank you.

MR. BERGMAN: The three-year time-bar offers sufficient time for Investors to pursue domestic remedies with respect to an underlying measure, such as an administrative measure. And if they find the proceedings are moving too slowly they may waive further domestic court remedies under Article 1121 and bring their arbitration claim within the designated time limit. Now, there they would be challenging the administrative action not the underlying judicial proceeding.

Moreover, as you heard from Mr. Kovar's overview of the proceedings in Apotex Inc. v. FDA, the D.C. District Court and the D.C. Circuit Court acted

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12:21:04 in a very expeditious manner in this case. That case began in April 2006. Litigation ended in August 2006, and Apotex voluntarily abandoned its claims in October 2006, totaling roughly six months. Apotex still had more than two years to file a timely NOA for the Pravastatin Claim. The three NAFTA Parties consented to allowing an Investor to make its NAFTA claims by receipt of a Notice of Arbitration within 36 months from the date that the Investor first acquires knowledge of alleged breach and loss. That provision is not only the law applicable to this NAFTA proceeding, but we would submit that it is also quite reasonable.

Thank you, Mr. President.

PRESIDENT LANDAU: Thank you very much.

MR. PEARSALL: Good afternoon, Mr. President, Members of the Tribunal. It's my privilege to speak to you today on behalf of the United States about the issue of judicial finality. I'll discuss the last issue described in Ms. McLeod's opening, namely whether Apotex, in bringing claims premised on judicial acts, is excused from the international law

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12:22:44 principle of finality. And I will touch on aspects of the Tribunal's questions from this morning, but with permission of the Tribunal, I'll discuss the Tribunal's in greater detail tomorrow.

Apotex claims that decisions of the District Court and the D.C. Circuit violated U.S. obligations under the NAFTA by denying it a preliminary injunction against the April 11th, 2006, FDA Letter Decision. Despite claiming before this Tribunal that these judicial acts violates its rights under the NAFTA, Apotex chose not to seek review by the Supreme Court. Instead, Apotex chose to abandon its actions in U.S. Court rather than seek review of these alleged errors and cannot now bring its claim premised on a nonfinal judicial act before a NAFTA Chapter Eleven Tribunal.

Under the NAFTA and applicable international law, States cannot be responsible for nonfinal acts of their Judiciaries unless seeking final review would have been obviously futile.

As you already have heard from my colleague Mr. Kovar's presentation this morning, NAFTA Articles 1101 and 1116 allow Investors to bring claims against

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12:24:06 the United States for Measures adopted or maintained that are alleged to breach obligations under Chapter Eleven. Unlike the Final Decision of a regulatory organ of the State, a nonfinal judicial act is not a measure adopted or maintained by the State within the meaning of Article 1101. A State is not responsible for acts by its lower courts when a Party could have sought further review on higher appeal but failed to do so. Customary international law according to the NAFTA under Article 1131 confirms that a nonfinal judicial act cannot constitute a breach of the NAFTA that gives rise to State responsibility.

Indeed, Apotex and the United States agree that under international law applicable to the NAFTA in this case, that an act of a domestic court that remains subject to appeal has not ripened into the type of Final Act that is sufficiently definite to implicate State responsibility unless such recourse is obviously futile. This is the principle of finality.

The finality requirement is fundamental to claims that may result in holding a State's Judiciary in violation of international law. National judicial

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12:25:40 systems including those of the three NAFTA Parties, provide for higher courts to correct errors below. Decisions by higher courts harmonize the interpretation and application of the law by lower courts. A finding by an International Tribunal such as this one, that national courts violated international law implicates a systemic failure of the national judiciary.

International law recognizes, therefore, that the national court system must be given a chance to correct errors. This principle makes good sense. If Investors could bring NAFTA claims alleging violations of international law by national courts after any stage of the domestic proceedings without first exhausting their appeals, it would frustrate the proper administration of justice. Chapter Eleven arbitration was not intended by the NAFTA Parties to be a parallel appellate mechanism for Investors to challenge the decision was national courts. Simply put, and as confirmed by several NAFTA Tribunal Awards in evidence, Apotex may not ask this Tribunal to substitute itself for the Supreme Court of the United

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12:26:48 States and, thereby, sit as a super national Appellate Court.

This Slide before you has just a few examples that illustrate this example.

The NAFTA Chapter Eleven Tribunal in the Loewen v. United States explained the purpose of finality requirement in just these terms. The Loewen Tribunal stated that the purpose of the finality requirement was to "ensure that the State where the violation occurred should have an opportunity to redress it by its open means, within the framework of its own judicial system. Thus, the Loewen Tribunal concluded that the principle imposed on the obligation--imposed an obligation on Claimants to exhaust remedies which are effective and adequate and are reasonably available.

Moreover, the Loewen Tribunal noted that no instance has been drawn to our attention in which an International Tribunal has held a State responsible for breach of international law constituted by a lower court decision where there was available an effective and adequate appeal within the State's legal system.

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12:27:53 Apotex has not drawn such a case to this Tribunal's attention, either.

With these principles as background, let's look a little more closely at Apotex's case. Notably, Members of the Tribunal, there are several aspects of this issue where the Parties agree. First, both the Parties cite Loewen favorably. After agreeing with the United States that the principle of finality applies to nonfinal judicial acts and stating that the United States "prevailed on this very position in Loewen," Apotex stated in Paragraph 73 on Page 27 of its Counter-Memorial that, as the Loewen Tribunal aptly noted, the reason finality is required under international law is to afford the State the opportunity of redressing through its legal system the inchoate breach of international law occasioned by a lower court decision. The requirement has application to breaches of the NAFTA Article 1102 and 1110 as well as 1105.

Second, Apotex admits that the decision of the District Court and the D.C. Circuit challenged in its Pravastatin Claim were not final judicial acts.

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12:29:08 And, third, Apotex admits that following the dismissal of its petition for rehearing en banc to the D.C. Circuit, it could have sought certiorari from the Supreme Court or proceeded with its Pravastatin Claim on the merits in the District Court. However, while Apotex agrees with the United States on the availability of further judicial recourse, it seeks to excuse its failure to obtain finality by claiming the particular relief it sought was so unlikely as to be obviously futile.

In Apotex's view, obvious futility can be demonstrated in this case by two factors. The first, the limited number of days there were for the courts to review its appeals during the pendency of Teva's 180-day market exclusivity; and, the second, what it considers the unlikelihood of the Supreme Court granting it the relief it sought in that timeframe.

In other words, Members of the Tribunal, the question is not whether Apotex's NAFTA claims with respect to the pravastatin issue required judicial finality under international law, but rather, whether obtaining finality is excused because appeal to the

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12:30:26 Supreme Court was so unlikely as to be obviously futile.

Apotex misstates the futility exception under international law improperly conflating an analysis of the availability of a remedy with the prediction of the likelihood of obtaining its preferred relief, stating in its Rejoinder that with the time left in Teva's exclusivity period that the Supreme Court could not have effectively redressed its injuries. However, where an International Tribunal has found obvious futility, it has done so because there was no justice to exhaust, not because success was unlikely. As Judge Amerasinghe of the International Court of Justice has written, for a Tribunal to excuse a Claimant's failure to exhaust all available judicial avenues of relief, a Claimant must demonstrate that further judicial recourse was not available.

Judge Amerasinghe wrote, the test is obvious futility or manifest ineffectiveness, not the absence of a reasonable prospect of success or the improbability of success, which are both less strict tests.

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12:31:38 The Slide before you has just a few examples that demonstrate this principle. Indeed, the Loewen Tribunal, which Apotex and the United States both cite favorably demonstrates this principle also. There, the Tribunal looked carefully at the Supreme Court remedy available to the Claimant, assessed its effectiveness by looking at the availability of the relief, not the likelihood of success, and evaluated Claimant's argument that it was forced to settle rather than appeal the underlying litigation so it could avoid severe damage to the value of its business. The Tribunal there concluded that Claimant's failure to seek Supreme Court review would nonetheless bar its claim based on nonfinal judicial acts. In this case, Apotex does not meet the obvious futility standard because, as Ms. McLeod told you this morning, even if the likelihood of the Supreme Court agreeing to hear Apotex's case was remote, the availability of an effective remedy was certain.

Apotex does not question that the Supreme Court had the power to grant full relief, and thus an effective remedy was available. The Supreme Court

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12:32:48 rules give the Court the ability to act as quickly as necessary. Apotex simply failed to pursue the remedies that it concedes were legally available.

As Mr. Kovar told you this morning, Apotex has the burden to disprove the existence of available remedies, but a review of the facts confirms that it has not met that burden. Not only was an adequate and available remedy before the Supreme Court, it was Apotex's own litigation choices that ran down the clock on its time to appeal during the 180-day exclusivity period, so let's take a closer look at that.

Apotex attempts to make much of the fact that the D.C. Circuit, sitting en banc ruled on its request for preliminary injunctive relief on August 17th, 2006, leaving it only 67 days in Teva's 180-day market exclusivity period to seek appeal to the Supreme Court. According to Apotex, this made seeking further appeal obviously futile. In their words, moot, because the remaining time was so short as not to provide effective relief.

Apotex characterizes the likelihood of

success in the Supreme Court in an advantageous timeframe as absurd, unrealistic. However, Apotex chose the litigation strategy that left it with 67 days to finalize its appeals before the expiration of Teva's 180-day exclusivity period. Apotex could have applied for certiorari immediately after the June 6th, 2006, ruling by the D.C. Circuit.

Let's walk through Apotex's litigation choices. First, Apotex claims to have promptly sought preliminary injunctive relief from the District Court on its Pravastatin Claim, and to have immediately applied--appealed the District Courts decision denying it that relief. Indeed, Apotex did file a request for injunctive relief on April 14th, 3 days after the issuance of the FDA's April 11th Letter Decision and 8 days before the expiration of the patent, which was due on April 20th. Apotex fails to mention, however, that on April 24th, once the D.C. Circuit dissolved the earlier stay, which allowed the FDA to approve Teva's Pravastatin ANDA, Apotex waited 24 days before filing a 14-page petition on May 18th that sought expedited consideration of its request for a

preliminary injunction.

Although the D.C. Circuit rendered its decision in less than 20 days, on June 6th, a quick turnaround for any court, we submit--and well ahead of the schedule proposed by Apotex--Apotex then took 44 of 45 allotted days to file a 15-page petition for rehearing en banc, a motion in any event was not required to seek review by the Supreme Court.

Application to seek review by the Supreme Court was immediately available after the June 6th denial of Apotex's request for preliminary injunctive relief by the D.C. Circuit. Thus, as early as June 7th, Apotex could have sought certiorari to the Supreme Court, a full 138 days before the end of Teva's exclusivity period.

So, let's look at a timeline of Apotex's Pravastatin Claim, and I encourage the Tribunal to look at the screen here. The first click will show all of the action that took place prior to the approval of Teva's ANDA by the FDA. So, we have the April 5th preliminary injunctive, the Temporary Restraining Order. Then we have the April 11th Letter

Decision, and then just three days later, three days after that decision, Apotex files its motion seeking preliminary injunction, five days later, but in reality two business days later, the Court acts, denies its request.

The same day, the same exact day, Apotex files an emergency request for reconsideration. The next day the Court acts, denies the emergency request for reconsideration. The same day, Apotex appeals the denial of its injunctive relief, the same day the D.C. Circuit grants a temporary administrative injunction enjoining FDA from approving the ANDA. And then four days later, which again was two business days, the D.C. circuit dissolves the administrative injunction. FDA approves Teva's ANDA, and Teva markets two days later.

So, that's all the activity that occurred before the approval of Teva's ANDA.

Now, what happens? Click. Apotex waits 24 days before filing a simple 14-page motion for expedited consideration on appeal on May 18th.

Next click, the Court turns that around, less

than 20 days. D.C. Court affirms the District Court's denial of Apotex's preliminary injunction.

Next Slide, what does Apotex do? It waits 44 days until July 21st where Apotex seeks rehearing en banc for denial of its preliminary injunction.

Now, just to remind the Tribunal, on that June 6th date, the day after that, not one day after that, they could have applied for certiorari from the Supreme Court. Instead, they waited 44 days before their next pleading.

Next Slide.

So, the Court turns that around, on August 17th. The D.C. Circuit denied its request for hearing en banc, and then what did Apotex do? It waits 67 more days before--on October 3rd dismissing its claims with prejudice for the 10, 20, and 40-milligram strengths and without prejudice for the 80-milligram strength.

On October 23rd Apotex's ANDA is approved. And then the next click.

With regard to the 80-milligram strength, Members of the Tribunal, the ANDA underlying that

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12:39:08 strength was not approved until one year later, more than one year later from the June 6th date, on June 25th, 2007.

So, just to put this in perspective, all of the red bars is what Apotex did during pendency of Teva's 180-day market exclusivity. All the space between the red bars is occupied by how long it took the Courts to turn around a decision.

So, to summarize, Apotex waited 24 days, then 44 days, then dispensed with the additional 67 days, all without applying for certiorari to the Supreme Court. Apotex spent 135 days of the 180 days delaying the advancement of its own claim in U.S. Courts. Apotex cannot base a claim that implicates a systemic challenge to the United States justice system without first seeking review from that justice system's highest authority simply by asserting that because the timing associated with its litigation strategy, such an appeal was moot.

When the asserted futility of a remedy otherwise available results from the Claimant's own actions, it should be to the Claimant's own detriment.

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12:40:35 While Apotex was free to conduct its litigation on these matters in accordance with its own strategy, it cannot now after the fact bring a NAFTA claim based on nonfinal judicial acts. Apotex attempts to justify its inaction by asserting that the Supreme Court typically does not rule on certiorari requests immediately. Sometimes not for many months. Apotex also suggests that since the D.C. Circuit's Decision related solely to Apotex's request for preliminary injunctive relief and was not a decision on the merits, that the likelihood of the Supreme Court accepting review was even lower. These arguments are also unavailing. Effective relief was available. The Supreme Court has the authority to hear cases that relate only to preliminary procedural matters, and the Supreme Court has the authority to issue stays. The Supreme Court can hear cases that relate to preliminary relief quickly if the case merits immediate attention. Indeed, Apotex itself has sought certiorari in other matters solely relating to the request for preliminary injunction. Apotex has sought certiorari and has been Party to a case where a

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12:41:41 judgment was vacated by the Supreme Court on matters not involving a lower court's decision on the merits.

Moreover, having already done so, Apotex had no reason to think that petitioning the Supreme Court for review was onerous. Apart from the work of the lawyers to prepare the certiorari petition, the only monetary requirement was a $300 filing fee.

Indeed, Apotex has sought certiorari before with regard to judicial acts at issue in this very arbitration. Apotex sought certiorari regarding the judicial acts that underline its Sertraline Claim, and the United States does not raise a similar finality objection there. Apotex simply failed to seek final appellate review for its Pravastatin Claim. Again, as you can see from the timeline, Apotex had 138 days remaining in the exclusivity period.

Moreover, its timing argument is irrelevant with respect to its interests in the 80-milligram dose of pravastatin. For this dosage, Ranbaxy was the first to submit a substantially complete ANDA with a paragraph IV certification; and, as a result of the FDA Letter Decision could anticipate enjoying 180 days

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12:42:54 of market exclusivity. As of June 6th, 2006, the date of the D.C. Circuit's Decision denying Apotex--Apotex had more than one year--one year--until Ranbaxy would even launch its 80-milligram pravastatin generic on June 25th 2007, a dosage potentially worth hundreds of millions of dollars in its own right.

There was more than sufficient time for Apotex to pursue its appeal to the Supreme Court if it believed it had a valid claim that the FDA Letter Decision was not in accordance with U.S. law.

Moreover, even if Apotex calculated that Supreme Court review was unlikely to provide it with the relief it sought in the timeframe that it hoped, it could still have had the case heard on the merits at the District Court. Here, too, Apotex argues that pursuing substantive relief at the District Court would have been absurd because it would have forced Apotex to proceed at a litigation pace--proceed at a standard litigation pace as expedited relief was no longer an option. However, just as Apotex had sought expedited consideration of its appeal before the D.C. Circuit which provided a decision, I remind the

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12:44:11 Tribunal, in less than 120 days, Apotex could have sought expedited consideration of its claims on the merits before the District Court. Again, Apotex simply failed to do so. Instead, after the D.C. Circuit rejected Apotex's petition for rehearing en banc on August 17th, it waited 47 days and then voluntarily dismissed all of its claims against the FDA. It dismissed these claims with prejudice with regard to the 10, 20, and 40-milligram strengths and without prejudice with regard to the 80-milligram strength. Although Apotex preserved its ability to return to the District Court to continue litigating with respect to the 80-milligram strength generic, it never did. Apotex had ample time to seek relief in the District Court for that dosage, but again chose not to do so.

In short, Apotex wants to construe the futility exception as an invitation for this Tribunal to determine whether U.S. Courts could have provided Apotex the relief it sought in a time frame consistent with its own litigation strategy. The Tribunal should decline this invitation. Not only would it be

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12:45:17 inconsistent with international law for the Tribunal to investigate Apotex's likelihood of success before the Supreme Court, it is also not a role NAFTA Chapter Eleven Tribunals are equipped to carry out. Apotex failed to give the United States judicial system the opportunity to correct what it considers to be the lower court's errors in not enjoining the FDA Letter Decision, and thus this Tribunal cannot hear Apotex's claims that the same courts violated the NAFTA.

The Tribunal in Loewen also did not accept Claimant's tactical choices as justifications for failing to seek Supreme Court review. In that case, the Tribunal found that even when the challenged conduct of the trial court was a disgrace, the Claimant could not have maintained his NAFTA claim because after an unfavorable decision by the State Supreme Court, he chose to settle rather than seek review by the United States Supreme Court.

The Tribunal stated there, although entry into the Settlement Agreement may well have been a reasonable course for Loewen to take, we are simply left to speculate on the reasons which led it to the

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12:46:29 decision to adopt that course rather than to pursue other options. It is not a case in which it can be said that it was the only course which Loewen could reasonably have been expected to take.

Accordingly--this is the Tribunal in Loewen--accordingly, our conclusion is that Loewen failed to pursue its domestic remedies, notably the Supreme Court option that, in consequence, Loewen has not shown a violation of customary international law and a violation of the NAFTA for which Respondent is responsible.

To sum up, it was not obviously futile for Apotex to seek certiorari in the Supreme Court before bringing its Pravastatin Claim to this Tribunal. The Tribunal should not excuse Apotex's failure to obtain the requisite judicial finality simply because Apotex did not think it could get its preferred relief in a timeframe consistent with its own litigation strategy.

The question of whether Apotex had a real chance of success in prosecuting its claim before the Supreme Court is one--under U.S. law is not one for this Tribunal. It should have been put to test in

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12:47:41 U.S. Courts. The Tribunal, therefore, should dismiss in their entirety Apotex's claims that the nonfinal judicial acts of the U.S. District Court and the D.C. Circuit breached Articles 1102, 1105, and 1110 of the NAFTA.

Mr. President, Members of the Tribunal, respectfully this ends the United States case-in-chief. Thank you.

PRESIDENT LANDAU: Thank you very much. I have just one short question. Forgive me. I just wonder whether you can just help me.

Going back to the point that you've made that as at the 6th of June 2006, it was open at that point or directly after that, for an application to be made to the Supreme Court. It's a simple question, but can you just talk me through, what would have been the actual relief sought from the Supreme Court? What kind of order would it have made at that point? And then what would be the steps, assuming that would have been done, what would be the steps thereafter that Apotex would have taken in order to try and reverse the FDA's Decision?

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12:48:56 MR. PEARSALL: I can give a more detailed answer on this question in the future if what I'm about to say is not sufficient, but it's my understanding that Apotex could have sought exactly what it sought in the District Court, which was a preliminary injunction against the FDA which would have stopped the exclusivity, stopped--it would have enjoined Teva from continuing to market exclusively its pravastatin generic, at which point the District Court could then take up the claim as to whether the FDA Letter Decision was an abuse of the FDA's discretion on the merits.

PRESIDENT LANDAU: So, the Supreme Court could have made an order that essentially would have held the field pending the District Court's resolution of the issue?

MR. PEARSALL: It's my understanding that the Supreme Court could have granted the relief that Apotex originally sought in the District Court, pending further review on the merits of the District Court.

PRESIDENT LANDAU: Right, thank you.

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12:50:14 Thank you very much. There are no further questions from us at least for the time being. So, as I understand it, that concludes the United States presentation, and brings us to the important issue of lunch, and I think we've agreed to break for one hour, so it's now 10 to 1:00. We'll resume at 10 to 2:00. Thank you very much.

(Whereupon, at 12:50 p.m., the hearing was adjourned until 1:50 p.m., the same day.)

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AFTERNOON SESSION

PRESIDENT LANDAU: Good afternoon. We start now with the presentation on behalf of Apotex.

OPENING STATEMENT BY COUNSEL FOR CLAIMANT

MR. RAKOCZY: Members of the Tribunal, good afternoon. William Rakoczy on behalf of Apotex Inc. We appreciate your time this afternoon. I will try to be as brief as I can. I may be able to skip through some of the statutory background a little quicker.

As a threshold issue, however, I would like to say that addressing your concerns, Mr. President, or your questions at the beginning of the session today, Apotex does not consent to any nonjurisdictional issues being heard or decided in this bifurcated jurisdictional proceeding. So, to the extent that the time-barred issue and finality are nonjurisdictional, we obviously would not consent to those being decided in the jurisdictional phase.

Now, our understanding of jurisdiction--I'm going to use the U.S. term--our understanding is jurisdiction here would be subject-matter jurisdiction or the power of this panel in its mandate to hear a

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01:55:13 case in a subject matter under NAFTA. And if that's the rubric of jurisdiction that we're proceeding under here, again, what, in the United States, we would call the "initial subject-matter jurisdiction," then we would submit that the finality doctrine and the limitations doctrines do not go to subject-matter jurisdiction in the first instance under NAFTA.

We would--or we would agree that whether someone is an investor and there is an investment, that would go to the so-called "gateway" under Article 1101 or Chapter Eleven, but the limitations issue at most would go to--I believe Mr. President used the term "admissibility" or "cutting off claims" or "procedural defect to a claim," and we would submit the finality doctrine would go to the same issue. So it would not go to the subject-matter jurisdiction per se.

So, that's what this bifurcated proceeding is about, original subject-matter jurisdiction under the strictures of NAFTA, or the NAFTA, then we would submit those two issues are not to be decided in this bifurcated part of the proceeding.

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01:56:22 I would be happy to address that more tomorrow. Obviously I'm speaking a bit in a vacuum because I haven't heard the Government's position on that, but I just wanted to give you Apotex's gut or initial reaction to your comments this morning.

PRESIDENT LANDAU: At the moment, as matters stand, these issues have been framed on behalf of Apotex as jurisdiction issues, so there is no--no point has been taken so far that these are issues which this Tribunal should not be deciding at this stage.

MR. RAKOCZY: Absolutely. Thus far we have, and that's why I felt it necessary just to put that on the record right now. I'm not disagreeing that Apotex has briefed in response to the Government's so-called "jurisdictional objections" all three issues today: The investment issue, the limitations issue, and the finality issue, and I'm going to address all three today. I am not going to reserve comments. I will address all three.

PRESIDENT LANDAU: Fine.

MR. RAKOCZY: So, obviously the Government--I

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01:57:32 don't need to go into great detail but they've raised three major issues. We believe that none have merit. We believe that Apotex is an Investor that has made an investment. We believe that its ANDAs are uniquely United States investments. They are not export or import permits. These are the foundation. This is the only way that you can compete in the United States pharmaceutical market is with an ANDA or an NDA. These are by any measure property, by any measure investments, and by any measure they were acquired or used with the expectation of obtaining economic benefit in the United States. And as we will demonstrate, they are investments in the United States.

On the second issue--yes, Judge.

ARBITRATOR SMITH: Just to get the nomenclature clear, would you agree that all property is not an investment? I mean that something can be a property but not an investment, and something can be an investment, I guess, and maybe not property, although I haven't taken it that far.

MR. RAKOCZY: Yes, Your Honor, it is possible

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01:58:34 that something could be property and not an investment because under the definition, it's real property or other property--

ARBITRATOR SMITH: Right.

MR. RAKOCZY: --any intangible or tangible.

ARBITRATOR SMITH: Right.

MR. RAKOCZY: And that has to be with the expectation of pursuing economic benefit or acquiring or going towards economic benefit. So there is that two-part test. And then obviously we don't dispute it has to be an investment in the United States or in the territory of the other Party. So, yes, there could be property that is not an investment.

We take issue with the Government's arguments, and I will get to that more in a moment, with the fact that they seem to focus more on the real property aspects of that NAFTA definition, and they seem to want to stay away from that other property part, because we believe, again under any measure, this is property.

And, by the way, we also find it interesting, the Government accused Apotex of being a moving

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01:59:30 target. Nowhere in the papers submitted to date has anyone in the Government ever taken issue with the second part of that definition, that an ANDA is not for the purpose of obtaining economic benefit in the United States, and we would find it not to even pass the straight face test to say that it's not. The only purpose that pharmaceutical companies file ANDAs and NDAs is to obtain an income benefit in the United States. That is the purpose of the ANDA under the statute.

Very quickly, back to their other two arguments, I will address the time limitations issue and I will address the finality. We again believe both of those should be rejected as well.

Now I would like to just briefly take you back in time. I won't dwell for a long time on the statutory background, but I do want to just add a little bit to what the Government has said here.

I think it's important to remember that we go back in time to prior to 1984. The generic--the vibrant and competitive generic drug industry that we know today in the United States did not exist. There

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were many problems, the first of which was the fact that you couldn't do a generic drug without doing a full drug application. The second problem was the patent estates. Some courts in the United States have likened the patent estates for brand drugs in the United States to something like the Habsburg legacy. Some of these drugs are protected by hundreds of patents. And the unintended consequences of that is generic manufacturers couldn't do the work, they didn't have the funds to do these full studies of safety and efficacy.

And number two, they couldn't play with the drug. They couldn't research and development--or do their research and development without infringing patents.

So, along in 1984, Congress and the United States recognized the huge skyrocketing healthcare cost, and they passed the Hatch-Waxman Act.

A couple of things they did, and just to simplify things for our world here, we can divide our universe into New Drug Applications or NDAs--and I apologize. I lapse into just calling them brand names

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or new drugs--and generic drugs or ANDAs. Brand drugs obviously, as you've heard, contain full studies of safety and efficacy. And to address that second problem or unintended consequence, they also have to identify all the patents that claim or protect the brand drug, and those go in the Orange Book at the FDA.

Now, ANDAs, that's where Congress addressed this new abbreviated mechanism, and where Congress through the Hatch-Waxman Act, and later amended by the Medicare amendments, made the abbreviated New Drug Application or ANDA procedure. Now, it's called "abbreviated," but it's only abbreviated because it doesn't contain the full clinical safety and efficacy studies. Otherwise, it is not abbreviated at all, and I think that's something that has been brushed over a bit today.

Most importantly because, other than the full safety and efficacy studies, ANDAs contain everything else that a brand or new drug submission contains. It contains proprietary, sensitive and trade secret information on the components and compositions of the

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drug; the pharmaceutical development history of the drug, how it was developed and why it was developed. It contained proprietary information on how to make the drug, how to scale it up for commercial manufacture, how to test it, both bioequivalence testing and quality assurance and analytical testing, and then everything from labeling to packaging.

They are chock full of not just confidential and sensitive business information, they are the embodiment of the research and development in the drug themselves. It is intellectual property. It contains protectable information.

So, these things are not just a few pieces of paper sitting at the FDA. This is an embodiment of the whole drug and how to make it. And if you have an ANDA or an NDA, you have the drug. You own the drug itself.

Now, so, yes, abbreviated in that it shows bioequivalence rather than full safety and efficacy, but otherwise it is, again, chock full of confidential information, trade secret information, know-how and technology.

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Now, in addition to that, and we mentioned this in our papers, when you're a foreign Applicant, you also have to designate a U.S. Agent in the United States for purposes of being in contact with the FDA. Having said that, what we've heard thrown around a lot today, export, and I have to say I'm a bit at a loss where that even comes from. Export permits, import permits and certificates: The Government keeps saying that this somehow is some kind of revocable application to export a drug. ANDAs and NDAs are not export permits. They are not import permits. They are not certificates to cross the border in any way whatsoever. Anyone in the world that wants to engage and compete in the United States pharmaceutical market, whether they are domestic or foreign, must put an ANDA or an NDA on file. It is not the ticket to cross the border. It is the keys to the kingdom when it comes to competing in the pharmaceutical market. It is the foundation of a pharmaceutical investment in the United States.

If you want permission to export or import a drug, that is a completely different procedure and

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process. The ANDA is not an export certificate, not in any way, shape, or form.

Now, moving on, you heard a bit about the patent issues and the fact that the ANDAs have to address all the patents with paragraph IV or paragraph III certifications. One thing I wanted to mention and add to what the Government said, that whole patent process, which again was designed to address one of those other concerns that the United States Congress had, which was all these patent estates and how we get generic drugs on the market when there are all these patents protecting them.

So the United States Congress did a couple of things.

First they gave the generic industry a safe harbor provision. So, generics are now allowed to research and develop their drugs without infringing patents. They call it the Bolar provision, or the safe harbor. So, the safe harbor or the Bolar that allow the generics to do R&D without infringing patents.

It was also a compromise, as you heard the

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Government said, for the brand companies. They gave them some things as well in this legislation. They got patent term extensions for time lost off their patents. But the generic companies also got a way for early resolution of patent disputes. So, ANDA Applicants, when they address these patents in their application, when they do what's called the paragraph IV certification, where they say to the brand company "your patent is not infringed or it's invalid," they have actually have to notify their competitor of this. They actually send a submission to the brand company, and this is unique in all the world, or it was in 1984 at least, where you have to tell your competitor "I'm going to compete before I go on the market. This is what I'm going to do. This is going to be my drug, and this is why I don't think I'll infringe your patent or that it's invalid."

And in that letter--we call that "a notice letter"--that's sent to the brand company, you have to designate an Agent for service of process if you are a foreign company. You have to actually expose yourself to litigation in the United States; so, again, another

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price that comes with the ANDA investment for foreign companies. You have to say to the brand company, "here is my Agent, you can sue me here, and we could basically can fight out this patent dispute," and that's exactly, obviously what happened to Apotex here. They designated an Agent, and they ended up going through patent litigation, but of a little bit of a different sort.

Now, two of the consequences, and you heard about these in general, of filing an ANDA with a paragraph IV certification. The first one is the so-called "180-day exclusivity," and this is what Congress did to incentify or incentivize companies to challenge all these brand patents because the U.S. Congress recognized that it was very expensive, time consuming, and risky to challenge a patent. So they wanted to get folks to actually take that risk, consent to jurisdiction in the United States to fight out these patents. So they gave the first filer this 180 days of exclusivity.

But I believe the Government has acknowledged and conceded, it's not an entitlement, not by any

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means. It's eligibility. You're not guaranteed to get the exclusivity.

And in fact, what's very important is Congress didn't want subsequent filing generics to be delayed indefinitely. Congress is actually very concerned about manipulation of the system, that somehow first-filers could bottleneck the market and stop all these subsequent filing generics from getting to market. As a matter of fact, Hatch-Waxman was amended in December of 2003 for the first time since its passage in 1984 to reaffirm Congress's concerns, because what had started to happen was this, and it's very counterintuitive, but basically brand companies learned that they could delay generic competition further by not asserting their patents. By delaying. And that's exactly what happened, for example, in sertraline.

Brand companies learned that if you settle with the first filing generic that has this 180-day exclusivity, settle with them and then insulate the patent from judgment, that might trigger that exclusivity, and in that way you could bottleneck the

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02:09:24 generic market and delay other generics from getting on much further.

So, for example, you might just have the brand company and the first filing generic competing together for the first six months, and then subsequent generics come on later. That could be a huge benefit to the brand company and that first filing generic company.

So, Congress in the MMA in December 2003, they recognized these problems, and they reaffirmed the right of a generic company to seek a declaratory judgment action to trigger exclusivity when they were not sued. Congress recognized these bottlenecks, and so they said, if you're a second filing generic or first filing for that matter, and you're not sued by the brand and you want to get patent certainty, because, again, some of these blockbuster drugs are worth billions of dollars, and you want to trigger the exclusivity of the first-filer, you can sue the brand company and seek a declaratory judgment that would trigger this exclusivity. And that's critical because Congress recognized that that was a very important

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02:10:26 issue for the generic industry. And, as a matter of fact, in the MMA, they directed the federal courts to exercise jurisdiction over those declaratory judgment actions to the maximum extent permitted by the United States Constitution, which again is limited only by Article 3 case or controversies; so, a very critical part of this statutory scheme, which forms the foundation of some of Apotex's claims here.

Now, what are--the factual background here. Just very quickly. You've heard a lot about this today, so I don't need to go into too much detail. But on Apotex's Sertraline Claim, that claim was brought exactly as Congress intended under the MMA. In this case involving sertraline and Zoloft, Pfizer cut a settlement deal with the first filing generic Ivax. They did it so that they could bottleneck the generic market, to stop other generics from getting on. Pfizer wanted to use the 180-day exclusivity as a sword so that as long as they settled with Ivax, Pfizer would not sue anyone else. And because of that, no other the generic could get final approval for their drug because they were blocked by the Ivax

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02:11:40 exclusivity.

And so Apotex filed its declaratory judgment action under Hatch-Waxman and under the MMA to seek to break open that bottleneck. The U.S. courts denied Apotex access and denied them the ability to get a decision that would trigger that exclusivity. And each of the courts said Apotex couldn't have jurisdiction--or the courts didn't have subject-matter jurisdiction because of this so-called "reasonable apprehension test."

And I don't need to get any--I don't want to pre-judge the merits or get into that too much. I did hear the Government. I know they can't help themselves sometimes to start previewing the merits here, but the fact of the matter is it's not true, that the reasonable apprehension test was the law of the land. It wasn't. The Supreme Court dating back decades had never applied any reasonable apprehension test. The highest court in the land. The reasonable apprehension test is not found in the United States Constitution. It is not found in the MMA or any other statute.

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02:12:40 The fact of the matter is all you need is a case or controversy that can be redressable by the court, and Apotex had exactly that in sertraline, and yet the court still denied it access. Apotex could not get its day in court. Even though other similarly situated U.S. applicants were able to get declaratory judgment jurisdiction, Apotex was not allowed to do so.

And interestingly enough, this should not come as a surprise to anyone in this room, least of all the Government, because the Government in a related case to Apotex's Sertraline Case actually filed an amicus brief where they actually admitted that the reasonable apprehension test was not the law, that it was improper, and that a company like Apotex should have jurisdiction to get its day in court so it could clear up these bottlenecks.

So, we believe that we can prove and that we will prove, respectfully, that Apotex was denied its day in court, that this dropped below minimum standards of international treatment at the very least, and was a denial of justice. And that is

basically the Sertraline Claim.

Now, the Pravastatin Claim, and I don't want to--again, I don't want to pre-judge the merits, just very briefly on the Pravastatin Claim, the Government gave you a lot of background on Apotex's Pravastatin Claim. Just a couple of tiny issues that were left out.

What the Government didn't mention was what was the prevailing law when Apotex was seeking its declaratory judgment in pravastatin. What was the law of the land at the time? Well, what the Government left out was, Apotex and Teva, the two Parties involved in this pravastatin dispute, sat in each other's shoes just several years before the pravastatin dispute broke out, and this involved a drug called Ticlopidine. And in that situation, Apotex was the first filing generic entitled to the 180-day generic exclusivity, and in that case it was Teva who sought to trigger Apotex's exclusivity, and Teva ran to court, and they got the dismissal and declaratory judgment action based on a disavowal of an intent to sue.

And what happened? FDA eventually and the courts determined that Apotex's exclusivity was triggered, that in fact a dismissal of a declaratory judgment action was a triggering court decision. As a result, Apotex's extremely valuable Ticlopidine exclusivity was triggered and ran and expired before Apotex ever got on the market. That was the law of the land when Apotex sought to get its pravastatin declaratory judgment action.

So, what happened to Apotex and pravastatin was what we would call in the United States a complete whip-sawing, flip-flopping by the Agency going the other way. They took away Apotex's exclusivity Ticlopidine, but FDA saw fit not to do it when the show was on the other foot and Apotex was the subsequent filing generic.

So again in pravastatin, Apotex believes again pravastatin we will prove, or respectfully should be able to prove and intend to prove, that it was not just a denial of justice but there was clear discrimination. Apotex was not accorded the same treatment as similarly situated Investors in the

United States, and that's the basics of the Pravastatin Claim, and I'll get more into the details of that when we reach the limitations in the finality arguments as well. But I want to start with the Government's big ticket item here which is obviously the investment or the investor issue which goes to the jurisdiction of this panel.

Obviously, we don't dispute that Article 1101 or Chapter Eleven applies to measures adopted or maintained by a Party relating to investments of Investors of another Party in the territory of the Party. So, basically two requirements, and I'll address them each separately in turn.

I'm sorry, Mr. President, I'm skipping some slides to try--I don't want to duplicate the prior facts and background.

PRESIDENT LANDAU: That's fine.

MR. RAKOCZY: This is Slide 30. So, two requirements. An investment of Investors of another Party and in the territory of the Party or here in the territory of the United States. Investment is expressly defined in NAFTA Article 1139. You heard

about some of this today already. We will focus on--largely on subpart (g), which relates to 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 then (h), interest arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory.

I'll address each of those in turn. But just first, a quick word on exactly what we're supposed to be doing here.

We're supposed to be interpreting NAFTA based on its plain and ordinary meaning and then in view of its object and purpose. The object and purpose I don't think anyone disagrees on: To promote and increase cross-border investment opportunities, and this is from the Metalclad arbitration Award. But however you want to phrase the objective and purpose, I think the Parties agree that that is a decent general statement of it.

Now, what I think you didn't hear today from the Government is how holding--that an ANDA is not an

02:18:22 investment, can at all be squared with that object and purpose. When an ANDA is created by U.S. law, it's regulated by U.S. law, all disputes of ANDAs are under U.S. law. And the fact of the matter is, no one can get into the U.S. pharmaceutical market without an ANDA; and the fact is, unlike the other arbitration awards that's been cited to you and described to you like Grand View or Bay--sorry--Grand River, or Bayview, or Cattlemen, nothing in the home State of Apotex regulates ANDAs. The only thing that regulates and controls ANDAs and the ANDA investment is United States law.

So, what you have is, you have a Canadian investor who is basically, in a leap of faith, relying on the law of another jurisdiction for everything about its investment. The ANDA has no use in Canada. If the ANDA can't be used in the United States, Apotex can't turn around and go to Canada and say, "Hey, I will try to exploit my ANDA here." They cannot because ANDAs are solely governed by United States law.

So, to say that an ANDA is not an investment

02:19:32 in such cavalier fashion, we believe, cannot be squared with the objectives of NAFTA, which should promote and encourage foreign investors to come into the home State--or the foreign State, United States, in order to make an investment and rely solely on United States law. That policy, we believe, can only be promoted by holding that in fact an ANDA is an investment.

Now, let's get down to the nitty-gritty, the actual definition here.

Now, much of the Government's arguments about 1139(g), focus, we believe, on the first two words: Real estate. No one here--excuse me.

Apotex has never contended--Apotex Inc., anyways, that it has real estate in the United States or like some of these other arbitration awards that has a factory in the United States or warehouse. That's not Apotex's point. That has never been Apotex's position or theory of jurisdiction here. Apotex has always relied on the second part of this definition: Other property, tangible or intangible.

And again, I would like to address the

02:20:50 property aspect first. Again, it's our position that the Government has never raised the second half of this definition. Now, we understand that, as the Claimant, ultimately on matters of--subject matter of jurisdiction, generally the Claimant must prove jurisdiction. At the same time, the movant on an objection carries in all jurisdictions to my knowledge some sort of burden of production and notice, to come forward with the basis for their jurisdictional defense or claim.

And the United States Government has never in any piece of paper filed before this Tribunal--and the papers are getting very thick--argued that an ANDA is not acquired in the expectation or used for the purpose of economic benefit or other business purposes in the United States. And again, we don't think arguing otherwise passes the straight-face test because the Government had conceded over and over the only reason that you prepare, submit, and file, and maintain an ANDA is so that you can commercially make and use a highly regulated pharmaceutical in the United States market to obtain an economic benefit.

02:21:53 So, we don't think that that is even at issue here. So, I'm going to first focus on the property, tangible or intangible.

Now, the Government's arguments basically are three. They basically just say it's not property. We're a little unclear on why it's not property. One of their main arguments also is that the approval status somehow affects status as property, and then again they have this permits, this export permit argument, and I would like to address each of those in turn.

Now, as I said earlier, under the NAFTA, we need to focus on the plain language as well as its objective and purpose. There is nothing in the NAFTA Implementation Act or in any of these arbitration decisions that have been cited by the Parties defining property tangible or intangible specifically. There is nothing. We will not find anything.

So, it's our position that we should use the plain and ordinary meanings of those terms. And to make this simple, we put forth the simplest definition that we could find. Black's Law Dictionary--all new

02:23:08 law students are familiar with it--talks about property as the right to possess, use, and enjoy a determinate thing, either a tract of land or a chattel, also the right of ownership.

We do not believe this is a U.S.-specific definition. To our knowledge, this is a common law definition which is common the worldwide. Property, something you have the right to use and possess and enjoy.

If we wanted, we could use the United States definition. In their papers, they point to a different part of Black's Law Dictionary. In the last bullet on Slide 36, they talk about property protected from public expropriation over which the owner that has exclusive and absolute rights. Under either definition, we believe an ANDA would satisfy it. And the fact of the matter is, it really doesn't matter which definition you use, but Apotex pointing to Black's Law Dictionary is perfectly appropriate in a proceeding like this where we need to look to the plain and ordinary meaning. U.S. courts have done it. Other NAFTA tribunals have looked at Black's Law

02:24:07 Dictionary. And again, I don't think we heard any disputes from the Government that defining property as the right to posses and use the thing is improper. We have not gotten any citations or authority to the contrary.

Now, does an ANDA satisfy that? Let's look at the attributes or the indicia of whether an ANDA is property. Clearly, ANDA Applicants have the exclusive right to use and enjoy their respective ANDAs. I don't think that's seriously in dispute here.

Now, FDA--I'm sorry--the Government tends to confuse this issue of exclusivity, and in their papers they actually connect it to some sort of idea that there must be some exclusivity in connection with the ANDA. That's not what it means for property, to have the exclusive use of something. The exclusive use of something just means that you own it. You're the only one that has the right to use and dispose of it. That's the exclusivity we're talking about when we're talking about basic property rights.

And here, there is no dispute. Apotex Inc. and Apotex Inc. alone, the ANDA Applicant, owns that

02:25:16 ANDA, the sertraline ANDA and the pravastatin ANDA, and only Apotex has the right to use it. FDA itself--excuse me. Let me back up a second.

There were some questions, Mr. President, you raised, as to are we talking about a purely legal issue here, are we talking about a matter of evidence? We don't believe the evidence or that facts here are in dispute. Apotex Inc. is ANDA Applicant. They own it. In our view, it's a legal question: Is that property or does that satisfy some rudimentary definition of property or not? The Government's only response to date that we've heard is they can't find a case or a statute or anything that just says an ANDA is property.

We submit this Tribunal does not need such a case to hold that an ANDA is something you own, have the right to possess, use and dispose of.

As a matter fact, FDA or an Agent of the Respondent here, treats ANDAs as property. They have regulations saying that an ANDA is owned by the Applicant, and that only ownership can only be transferred of the ANDA by the Applicant. That's from

02:26:33 the Respondent's own regulations. They recognize these things can be transferred like property, a huge indicia or attribute of what we would call "property" or a basic definition, tangible or intangible.

Now, what we also find interesting is no one on the Government's side has disputed the fact that ANDAs are bought and sold like stock. There are markets for ANDAs. They are constantly acquired, divested, and sold. And we gave you just a few examples in our papers, one of which is a company, Abraxis Bioscience, talking about having 29 ANDAs representing over $2.6 billion in Market Value.

We have another one, a company Zydus is paying $60 million in cash for both existing and pipeline ANDAs, and that's a very interesting distinction because companies buy and sell ANDAs even when they're pipeline, even when they're not filed yet. They're prepared, but not filed.

I'm sorry, sir.

PRESIDENT LANDAU: I hope I'm not interrupting your flow, but I have a question which I'm going to have to put now because I think it has an

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impact on the way that you're elaborating your case, and that is I would like more assistance from you as to exactly what the nature of the property is that we're talking about. You say in your presentation that the property is the ANDA. If one just tries to analyze that a little bit further, is it your position that the property is the right to apply to court, the court action or the application to the FDA, the actual chose in action we would call it in England, is the property in the application itself which may have in it a lot of preparatory work that's been done, a lot of proprietary information, et cetera, or is the property the actual drug at the end of the day, the rights to that drug if and when it is approved, or is it a combination of those?

MR. RAKOCZY: It would actually be both. The drug obviously is property. Clearly the drug is a chattel that is property, but the ANDA itself is also property because it is full of everything from trade secrets, protectable trade secrets to intellectual property to other confidential and sensitive business information.

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And it's difficult to separate the two because there is no drug product without the ANDA because the ANDA actually--it embodies the whole drug from beginning to end. If you have the ANDA as a competitor, you would be able to make the drug product from beginning to end without problem, so it's both. The drug obviously is property, but the ANDA itself is property and very, very valuable property.

And these things are sold because they're so valuable and property and investment, they're sold as tentatively approved ANDAs all the time before the drug has ever even been made. And that's how, I think, another indicia of the fact that they are property in and of themselves before you even have a commercialized drug product or a thing that you could sell. ANDAs are commercialized when they're only tentatively approved.

As a matter of fact, most ANDAs, I would say, we did a quick Internet search, we would find that they are generally sold when they are tentatively approved before anyone has ever made tablet one.

PRESIDENT LANDAU: Can I ask you, I read

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through the exhibits that you filed on these announcements or purchases. Would it be fair to analyze those purchases as not really a purchase of an application, but rather the purchase of a contingent drug, contingent because it's not yet approved, but there is a likelihood it will be approved, and when it is approved, it will have value. So, what actually is being bought is not a cause of action, but a potential product?

MR. RAKOCZY: Well, actually again, it would be both because when you sell an ANDA that's not tentatively approved, for example, and you don't have a commercialized actual drug to ship over to someone in a truck, for example, what you're doing is in the trade or in the industry you would call that a tech transfer. What you're selling is the technology and the know-how of how to make, use, and basically package and sell that drug, and that know-how, those trade secrets, that process information, has incredible valuable.

So, again, the answer to the question would be both. Clearly, yes, you are selling a contingency

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in that one day the company that buys that tentatively-approved ANDA does hope one day to be able to have an approved drug that they will sell, but at the same time they have bought your technology and your know-how which in and of itself has value, so there is both the projected future value to selling the drug, but there is also considerable intrinsic up-front value just to have that know-how and that technology transfer to you which again comes with a big bow around it in the form of the ANDA.

PRESIDENT LANDAU: Forgive me for asking another question, but just at the conceptual level, you've answered my questions by saying it's a bit of both, so there is an element which is concerned with the end product, and there is an element which is concerned with the process, the application process itself.

Just thinking about the second of those for a moment, the application process, conceptually, is it any different when you talk about purchasing an ANDA, is it any different from assigning any other cause of action? You may have any kind of litigation in court,

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which might get assigned insofar as it's permitted to be assigned. There may be money paid to take on an action or take on a debt, for example. Conceptually, is it the same thing? And if it's not, why is it different?

MR. RAKOCZY: Well, it can be. It can be the same thing. And I will give you an example with--and I apologize I don't have the press release from this example, but I can easily get it for the Tribunal. It was a couple of years ago where there was an ANDA product. The ANDA was on file. It hadn't been approved by the FDA yet. There had been ongoing litigation, however. The ANDA applicant had notified the brand company. They had been sued. They were busy litigating the brand dispute. And then a deal was struck with another company who wanted that ANDA and that product and that litigation. Everything was sold in one big package, so the ANDA and the know-how and the technology, everything wrapped up in the application itself was sold and transferred to the other Party. The other Party took an assignment obviously and substituted in to all the patent

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litigation that was going on.

And then obviously, there was additional monies paid for the future, if you call it, contingent or hope that that drug would be commercialized one day and what might it eventually sell for.

And so, the purchase price involved, basically involved three heads of the purchase price. The application and the know-how in it, money for the litigation, and then extra money with the hope projecting forward what that drug might sell when it was eventually approved.

So, I know that's somewhat of a complex answer, but it's--these are complex--overall I don't know what else to say, complex investments which involve a lot of different issues.

ARBITRATOR SMITH: Does the FDA have any regulations about the selling of ANDAs? Do they get involved? Or are the Parties simply free to go ahead and sell as they wish?

MR. RAKOCZY: The Parties are free to sell as they wish. The FDA regulations which we cited to you merely require the Parties to inform FDA that a

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transfer and sale has happened, so that the FDA now knows who the new Applicant is because they need to know for review purposes who they're going to be working with.

ARBITRATOR SMITH: Okay. Thank you.

MR. RAKOCZY: Now, relatedly, and I don't have--these are just another couple press releases of ANDAs being sold--and again on Slide 41, these are relating to unapproved ANDAs being sold for substantial sums.

MR. KOVAR: Point of order. I'm not sure if these press releases are in the record.

MR. RAKOCZY: I don't believe these two are. I was just citing them as examples. I don't need them. It's not a disputed point from the Government.

PRESIDENT LANDAU: Are you objecting to them being here?

MR. KOVAR: Yes.

PRESIDENT LANDAU: Well, for now, why don't you not refer to them, and you can give copies to the other side, and then if there is an objection, perhaps you can just have a moment to look at them, and then

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later on we can come back to that and see if there is still an objection for them going in the record. So, at the moment they're not in the record and we won't look at them for the time being.

MR. RAKOCZY: Understood.

And the other thing I would mention is, again, I don't believe the Government is disputing ANDAs are bought and sold, and I think it's important to mention, too. And I think the Government didn't mention this in its papers or today is that the United States Government regularly instructs Parties to divest ANDAs. It happens all the time. The Federal Trade Commission, the Department of Justice, who may be represented here, when they review mergers and acquisitions in the pharmaceutical industry, they actually line up the assets. They line up the ANDAs of each company, and they look to see do any of them match up.

For example, if they see two sertraline ANDAs, they're not going to let that happen, and they actually order, they go to court and they get a consent judgment or they litigate and force the

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companies to sell the duplicate ANDAs to other companies to increase competition in the industry. So, this is not something that's surprising to the Government. It happens all the time. Again, as I said, these things are bought and sold like stock.

Now, other indicia or attributes of ANDAs, and I don't need to repeat this, but again chock full of sensitive development process manufacturing information, so much so that the FDA actually has somewhat unique regulations in our Government here in the United States. It doesn't even allow the FDA to acknowledge the existence of an ANDA until it's approved. They can't even confirm or deny it's there, which is unique in our Government that these things are so sensitive and confidential that they, in fact, can't even reveal their existence.

And even once they're approved, you cannot get at the sensitive trade secret information in these ANDAs. Those will always be protected from disclosure to third parties or to someone who doesn't own the ANDA. Again, we would say a major indicia or attribute of property.

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Now, very quickly, this import permit argument, and I think I addressed this already. I would just add, you can search the statute that creates ANDAs, 21 U.S.C. 355(j). You can research regulations. You have seen them in the Government's presentations today. You will never find an ANDA equated with an export permit or an import permit, and that's because it's not. Anyone who wants to engage in the pharmaceutical market in the United States, whether domestic or foreign, regardless of what borders that drug or product may have to cross, they have to do an ANDA. There is no exception. So, it's not an import or export permit.

PRESIDENT LANDAU: Forgive me for coming here. I think, as I understand it, one of the United States's arguments on this is not to say that the ANDA itself is an import or export permit, but rather that in the case of Apotex the ANDA is a step which Apotex needs to get through in order to effect an export import. It's not taking the place of some export/import license specifically, but what it is is simply facilitating what Apotex's business is, which

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is import/export.

Do you have a reaction to that?

MR. RAKOCZY: Obviously, Apotex, Inc., is a Canadian company, and, yes, it has to move product into the country. We're not disputing that. But we took the Government's argument a little further to the extent they were suggesting that an ANDA is nothing more than export permit or permission to export, and our point is that's simply not true because domestic United States companies have to do ANDAs, and they don't export anything.

So, our point is that ANDA is much more than that. It is--as we said, it's the gateway to competing in the pharmaceutical market. Regardless of borders, if you want to be in the United States market and make and sell a generic drug, you have to do an ANDA or a brand drug, you have to do an NDA. So, it's got nothing to do with export or import.

But again, we're not disputing Apotex, Inc., is a Canadian company in that they export or transfer drugs from their Canadian facility to their U.S. affiliate here for sale in the United States. We're

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not disputing that. That is how it works factually.

PRESIDENT LANDAU: Forgive me for continuing, but I just want to ask just another question on that related to that. What is your position if you just take as a hypothetical, assume that there is no ANDA process and Apotex is a company producing drugs in Canada, and it exports them to the United States, and has them sold by other distributors in the U.S. In that scenario, that mythical scenario, would that be, in your view, an investment qualifying under NAFTA?

MR. RAKOCZY: It's interesting, that mythical scenario sounds fairly similar to some of the arbitration awards we have seen. And I would say the facts you're describing, Mr. President, would be more close to the cattle or commodity analogy that we have seen in some of these awards where you have cattle, for example, in Canada which probably are regulated by Canadian law that may or may not be regulated by U.S. law, and you want to move them across the border and sell them here, a measure comes down and you can't.

But the difference is, while that may not be an investment, that is in stark contrast to the fact

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of an ANDA because an ANDA--and this gets back to kind of the policy objectives of NAFTA, and what I'm going to get a little further to the point that is it an investment in the United States--an ANDA is only regulated by United States law, which we believe brings it outside of those commodity examples, for example, the cigarettes that may or may not be sold on both sides of the border, the cattle, even the water rights case in Bayview. We believe the fact that an ANDA that is created by U.S. law, regulated and governed by U.S. law, all disputes have to be resolved pursuant to U.S. law.

And the fact there is no redress in Canada or under Canadian law we think brings it well outside of those I will just call them the commodity cases under your hypothetical.

PRESIDENT LANDAU: So my hypothetical, as I understand it, you would accept it's not an investment, it's a so-called "commodity case."

MR. RAKOCZY: I would call that like the cattlemen commodity case.

PRESIDENT LANDAU: That falls on the side of

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the line.

If you then take that hypothetical one stage further, and let's say you've got a company in Canada and it's in the business of producing commodities for export to the United States for sale in the United States by others, and let's change the hypothetical one step and say that, in order to do that, you need to get an import license from a U.S. Agency, an import permit, and that process of getting an import permit from a U.S. Agency is governed by U.S. law, have we now crossed the line? Is that then an investment at that point? Again, I'm taking out the complexities of the ANDA and taking out a lot of what the characteristics of the ANDA. I'm just trying to drill down to the absolute basics to understand at what point you then say we crossed the line and it becomes an investment.

MR. RAKOCZY: Two things. As a preliminary matter, I've been told I amend my answer slightly, and I apologize that it was a little unclear.

In the prior hypothetical it would be an investment, and the tribunal awards even in

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cattlemen's, I think these other tribunals recognized that it's a two-part question. Is it an investment, and then is it an investment in the United States or in the opposite country.

PRESIDENT LANDAU: Just to simplify, forget what the other--those other fact scenarios. Just take a very simple fact scenario. Company X is producing widgets in Canada for transportation across the border and sale in the U.S. Is that scenario, in your analysis, would that be an investment in the U.S.?

MR. RAKOCZY: I would say that under the so-called "salient characteristics" of a foreign investment or the so-called "legally significant connection test" that other tribunals under NAFTA had discussed, that probably would not qualify. That would be more similar to, for example, the water rights in Bayview.

PRESIDENT LANDAU: All right. So then the question is, you take that Scenario one step further. In order to get the widgets sold in the U.S., you need to get an import permit from a U.S. Agency, and that process is governed by U.S. law. Does that change

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anything?

MR. RAKOCZY: But the widgets are still subject to Canadian law?

PRESIDENT LANDAU: Well, I mean, subject to. The widgets are being manufactured in Canada for sale in the U.S., but in order to get across the border, you need to get an import permit?

MR. RAKOCZY: Yes.

PRESIDENT LANDAU: Does that change things?

MR. RAKOCZY: If the manufacturer of the widgets can still rely on the law of his home State, if he's still protected, if his widgets are still subject to the law in Canada--

PRESIDENT LANDAU: Of what? The law of what? For what? The Canadian law relevant to what?

MR. RAKOCZY: For anything, commerce, widgets, the law of widgets.

And that's the distinction I'm trying to get at here is, in your example, I'm making widgets in Canada, and arguably I can sell them in Canada. The widgets I have redress to Canadian law for contractual or other disputes in Canada for my widgets, but I also

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can sell them in the United States if I get an import or export permit.

In that situation I am not--I have an investment, but I'm not necessarily an investment in another State because I'm not relying on, I'm not drawing the impetus for my investment on the law of another State necessarily, and I think that's the distinction that the Bayview Tribunal was trying to get at is what are the salient characteristics of an investment in another State.

And in your example, I would liken that more to the water rights in Bayview, where I had water that was governed by Texas law. When it was in front of me, it was governed by Mexican law. When it was upriver in the Rio Bravo, that's not an investment in another State.

So in your widget example I would say it's closer to that, but I would take, again to add the ANDA complexity back in, I think that is a completely different animal, and I think if you look at that legally significant connection factor test from Bayview or the salient characteristic factor they

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looked at in Bayview, is under NAFTA if you have a Party with something like an ANDA investment that can't be used in Canada, it can't be regulated in Canada, it's not subject to Canadian law and you're going to rely completely on the law of the foreign State for that entire investment like you do with an ANDA, then that is an investment in another State and makes it different from your widget example.

And again I would add, I can't--I can't do anything with my ANDA in Canada. It's useless to me there. It's solely a creature of the United States.

PRESIDENT LANDAU: Thank you.

ARBITRATOR SMITH: I'm sorry, I need to follow up on this a little.

I have to assume that if Apotex starts manufacturing this drug whatever, which I pick a drug, drug A, it's going to want to sell it in Canada as well, isn't it? It's not going to just--

MR. RAKOCZY: It can't, Your Honor. It cannot. You cannot sell an ANDA drug in Canada. If Apotex wants to sell a generic drug in Canada, Canada has an entirely--I don't have this in our submissions,

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but to answer your question, they have an entirely separate regulatory system for their pharmaceuticals. They would have to file what is known as a special Canadian drug submission which is different from an ANDA and has different requirements, different regulatory requirements, different regulatory review, a completely different statutory scheme.

So, to take your example to its logical end, if, say, I take my ANDA product and all of a sudden something happens in the United States and I can't sell it there, I can't turn around and dump that product on the Canadian market.

ARBITRATOR SMITH: So, if you were given the generic rights in the United States, you're limited to selling that drug only in the United States?

MR. RAKOCZY: That is correct. The ANDA rights in investment are limited solely to commercial--making--using and commercializing a generic drug in the United States. That gives me no rights in Canada or Mexico or any other country.

ARBITRATOR SMITH: Okay.

MR. RAKOCZY: Did I interrupt you,

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Mr. President?

PRESIDENT LANDAU: No.

MR. RAKOCZY: So again, we don't believe that the export permit example is the right analogy here.

I want to end on this particular topic with this approval status argument that the Government has made, that somehow the approval status takes away from the quality or the nature of an ANDA as property. We would submit that's not the case for a couple of reasons.

First off, if you look at these tentative approval letters--and let me back up a second. The Government gave you a lot of pie in the sky reasons about why an ANDA could be revoked. Obviously there are statutes in place for when an ANDA can't be approved, and the FDA has continuing regulatory authority which, in our view, just goes all the more to the fact that this is a uniquely U.S. investment. But the fact of the matter is it's all theoretical in this case because these drugs sertraline and pravastatin were, in fact, tentatively approved, and the FDA determined that based on review of the ANDA

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that the drug was safe and effective for use as recommended in the labeling. The only reason these drugs didn't get final approval to be marketed in the United States was because of blocking 180-day exclusivity.

And something the Government forgets to mention here is, but for the Government's breaches, as Apotex is asserting here, Apotex would have had final approval.

So, for the Government to march in here and say this is not property because you were only tentatively approved doesn't make any sense. But for their breaches, but for their denying Apotex access to the courts, Apotex would have had a final approval and would have been on the market.

So, we don't believe this tentative approval argument even gets off the ground.

And again, just because FDA has continuing regulatory oversight, the fact that they can ask for additional information as part of their public health mission doesn't mean this is not property. It doesn't mean that Apotex doesn't own it or have the exclusive

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right to use and enjoy it. It just means it's a highly regulated investment, just like any other investment. Just because the Securities and Exchange Commission regulates the issuance of stock, equities, and bonds in the United States doesn't mean those are not investments. That would be astonishing if someone held that very high regulatory oversight somehow took away from the aspect of something as property, so we don't believe that this approval argument goes anywhere.

The other thing we would mention here, a couple of arguments, this whole idea that the Government, we believe, is suggesting for the first time that a tentatively-approved ANDA means you don't have an investment or it's not acquired for use or obtaining economic benefit in the future, the fact of the matter is under NAFTA, the Implementation Act, it's clear that investment is broadly defined. It includes existing and future investments.

So, whether you want to call it a tentatively-approved ANDA, as, Mr. President, you mentioned a contingent or future investment or an

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existing investment, that doesn't matter. It's still an investment. It's still property, tangible or intangible.

And the last point on this issue is this whole idea of protected property rights in the United States. In their papers, in their presentations today, the Government makes much of the fact that they can't find any authority or cases talking about what happens if someone takes away your ANDA or revokes your approval or steals it, I don't know, you name it. They can't find a case talking about are there any takings principles involved or can you take that without just or due compensation? The problem with that argument is twofold. Number one, that goes to the real property interest in the definition that we are not proceeding under here; and, number two, as commentators have recognized under NAFTA, the definition of "investment" under NAFTA that is protected under Chapter Eleven is much broader than the real property rights and other specific interests in property that are protected under the Takings Clause.

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So, we do not have to establish here by case law or otherwise that somehow revoking an ANDA would invoke constitutional protections under the takings clause.

Again, investment is much broader than that under NAFTA. It is any property, tangible or intangible, regardless of whether it invokes the Takings Clause.

Now, very quickly--I'm sorry.

ARBITRATOR SMITH: Put NAFTA aside for the moment. Would the revoking of an NDA violate the Takings Clause potentially under United States law?

MR. RAKOCZY: I represent most of the generic industry, but I could tell you that the pharmaceutical industry believes absolutely yes, and that's one of the reasons, by the way, we find this Government position, for lack of a better word, astonishing because you saw the value of some of the ANDAs. ANDAs are bought and sold for the tens of millions of dollars or more. NDAs are bought and sold literally for billions of U.S. dollars, and foreign companies like AstraZeneca in the U.K. or Glaxo, they have NDAs

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that are literally worth billions in profit. Billions. If you were to tell these companies all of a sudden, you know what, FDA is going to take your New Drug Application, and they're going to expropriate it and give it to the National Institute of Health because we think it's a great drug, and we would like to have the application. Of course that would be a taking. That would be a taking in the extreme worst sense, we would submit not just under the U.S. Constitution, but under international law as well, which is why we find again this whole Government position, I don't know what else to say other than astonishing. The entire pharmaceutical industry branded and new drugs, their investments founded upon New Drug Applications and Abbreviated New Drug Applications. That's their business. And all of their know-how, their secrets, their technology are bound up in these applications.

So, we would submit, yes, we do believe it would be a Takings Clause. And again I'm sorry, Your Honor, we don't have this in our submission, but I could point you in a supplementary submission where

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the brand pharmaceutical industry has taken the position that anyone that looks sideways at their new drug applications is committing a taking without just compensation under the U.S. Constitution.

ARBITRATOR SMITH: And that's regardless of whether it's final or tentative?

MR. RAKOCZY: Yes, ma'am.

ARBITRATOR SMITH: Thank you.

MR. RAKOCZY: Now, very quickly, I won't spend a ton of time on 1139(h).

Apotex also believes that it's made or has interests from the commitment of capital in the United States. That is ancillary to or arises out of its ANDA investment.

Now, when you're looking at this subpart (h) or 1139(h), other tribunals have said that you shouldn't just focus on one element. You should look at the totality of the activities in the commitment of capital. And here, I have to mention here we have confidential information just for a couple of slides, and we need the feed cut for the slides and the oral.

(End of open session. Confidential business

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information redacted.)

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[redacted]

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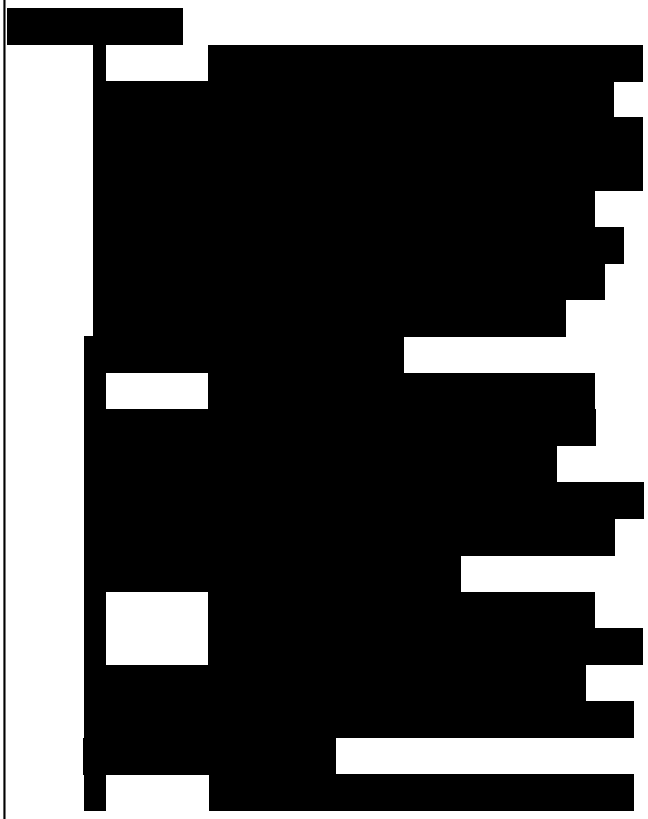

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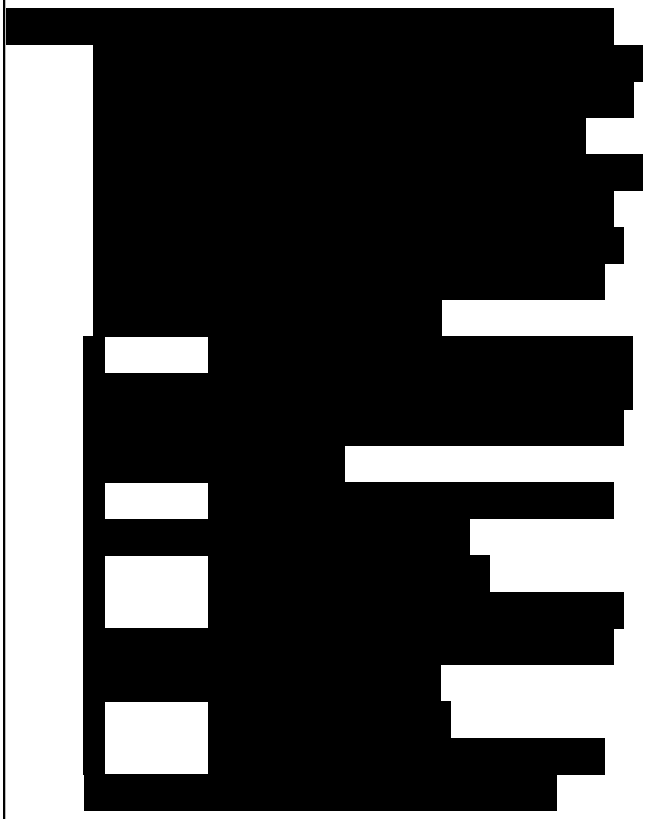

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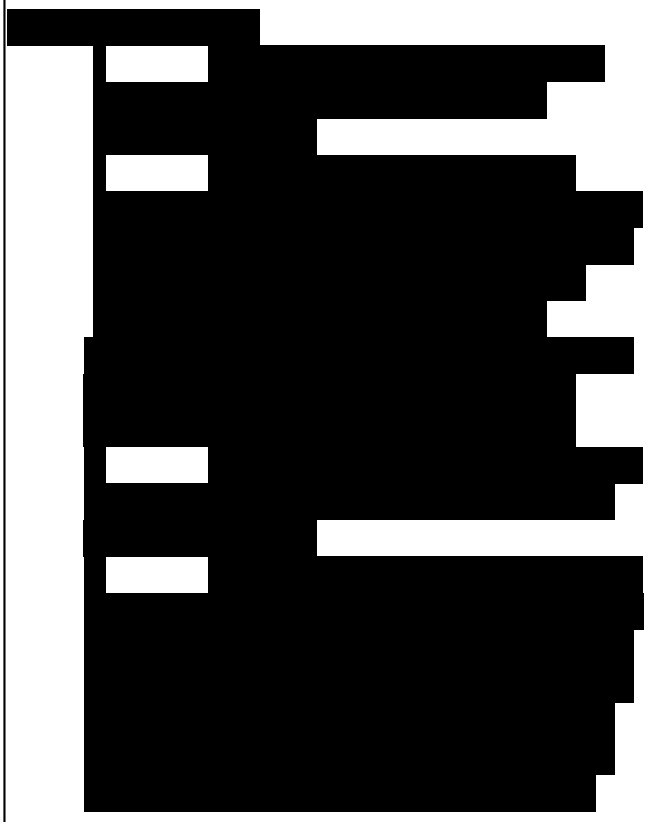

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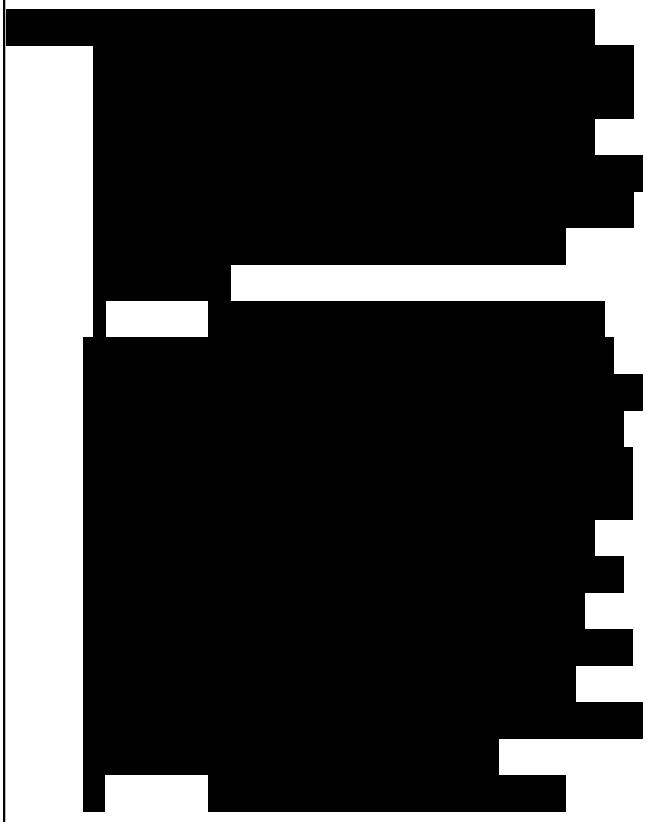

(End of confidential session.)

OPEN SESSION

MR. RAKOCZY: All right, I would like to move to the second requirement, and that is the investment, again--well, just to sum up again, Apotex's position is the ANDA is an investment in and of itself. It is property. It belongs to Apotex. It is a creature of United States law, and we believe a uniquely United States investment. On top of that, again we believe it is investment in the territory of the United States.

And I think it's very helpful when discussing what it means to have an investment in the territory of another country to look at what the Bayview and actually the I believe the Grand River tribunal awards discussed, and that is what are the characteristics of an investment under NAFTA in the country of another or a foreign investment.

And there are several parts of Bayview, which again the Government conspicuously didn't want to talk about, and I'd like just to spend a little bit of time on them here, and the first one is on Slide 60 here from the Bayview Award where they were trying to

grapple with what does it mean to be a foreign investment, what are the characteristics you're looking for because again I think as the Government acknowledges, this is not an issue that was addressed a lot in the very few NAFTA awards we actually have out there.

And here we had the Bayview Tribunal stating, "An Investor of one NAFTA State Party wishing to make an investment in the economy of another NAFTA State is necessarily concerned with the law and the governmental authorities who are making the law, applying the law and solving the conflicts in a State other than its own."

And we would submit that an ANDA investment is actually a textbook or classic example of that because a foreign investor who wants to invest in the United States pharmaceutical market, he is, as I said earlier, taking a leap of faith. He's putting his hands solely into the law of a foreign State, and that's exactly what Apotex did here.

And if we look to the continuing comments of the Bayview Tribunal, again here they weren't

purporting to lay down a comprehensive test, but again to describe what they believe were the salient characteristics of a foreign investment, and here they say, and I can quote, "It is evident that a salient characteristic will be that the investment is primarily regulated by the law of the State other than the State of the investor's nationality, and that this law is created and applied by that state which is not the State of the investor's nationality."

Again, that's exactly what is happening here. We have Apotex, which has made an investment in an ANDA, submitted it to the FDA, and that investment is not just governed solely by the law of the United States. That investment was actually created by the law of the United States. There is no other law--no other law than the United States which governs that ANDA.

So, again we don't have that situation, again I will call it the commodity situation, where I may have cattle that I can sell on either side of the border and that may be subject to Canadian law, may be subject to U.S. law. Here, we have an Investor who is

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stepping out of their own country and relying solely on the law of another State. And we would submit that that is exactly the type of objective and purpose that the NAFTA was trying to incentivize.

PRESIDENT LANDAU: You can see, as I go to my microphone, forgive me for interrupting again.

MR. RAKOCZY: Yes, sir.

PRESIDENT LANDAU: There may be an argument looking at the Bayview analysis as to whether this notion of the law of a foreign State, being governed by law of foreign State is a necessary but not a sufficient characteristic of investment; i.e., that it won't be enough just to say that, but at the same time you would have to show that it is the law of the host country that's applied.

What's puzzling me a little bit at the moment is why wouldn't you say the same thing about any sale and purchase across a border in terms of governing law? If I'm making products in Canada and I sell them in the United States, and I'm entering into sales and purchase contracts in United States which are governed by United States law, why is that different? Why does

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that matter if in fact I could also, if I wanted to, take those products to a different country and sell under their law?

MR. RAKOCZY: But I can't. That's the problem and the difference here, it takes it outside of our widget or our cattle or our cigarette example is, I, speaking as if I'm the foreign investor with an ANDA or an NDA for that matter, it doesn't matter. I can't exploit that investment anywhere except the foreign State, here the United States, and that's the problem, and the difference is in Grand River, for example, there was no dispute. He could sell his cigarettes anywhere he wanted, but here I cannot, if I'm the foreign investor, with an ANDA or NDA. I can only exploit it in the United States.

PRESIDENT LANDAU: How does that difference bear upon the definition of investment? Okay, I can understand there's a difference between Case A, you can sell your widgets anywhere, and Case B you can only sell them in the United States. Why does the fact that you cannot sell them anywhere else tell you it's an investment?

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MR. RAKOCZY: Well, first off, it goes to the investment in the United States part, not necessarily--irrespective of whether you believe this is a foreign investment or not, we believe an ANDA is an investment. So, there are two requirements. Is it an investment, is it an investment in another country? So, we believe this factor is going to is it an investment in another country.

And clearly, we believe it is because it's not an investment in Canada, I guess for lack of a better term or lack of a better way to say it. An ANDA or an NDA is not an investment in your home State of Canada or Mexico for that matter. It is only an investment in the United States where it's the only place that it can be freely used and enjoyed.

PRESIDENT LANDAU: Okay.

MR. RAKOCZY: And as far as the argument, Mr. President, that this salient characteristic is one test but maybe not sufficient or the only test, we're not suggesting it's the only test, but we find it interesting that in the piles of paper we've gotten and all the presentations we've gotten from the

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Government here, we have not gotten any other test from them, no suggestion, nothing of what we're supposed to look at, is this a foreign investment.

And I think the Bayview case or the Tribunal Award actually went beyond the salient characteristic test, and they also talked about another test or factor. They called it the legally significant connection test or factor with the State trading and applying the measures, and they said, quote, it is necessary that the Measures of which complaint is made should affect an investment that has a legally significant connection with the State creating and applying those measures. It is the relationship, the legally significant connection, with the State taking those measures that establishes the right to protection, not the bare fact that the enterprise is affected by the measures.

Here, again we think that this is a picture perfect case because when you look at the ANDA investment, unlike, for example, the cattle or the cigarettes or the widgets or the water, it isn't just a legally significant connection with the law of the

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03:12:16 foreign State, the United States. That is the only connection with the ANDA. It is the only State with which it has a connection or a legally significant connection, is the United States where the ANDA procedure was created, where the ANDAs are governed, and where they can only be exploited and used.

So, we would say under any measure, whether you're talking about the salient characteristic factor that the Bayview Tribunal wanted to talk about or the legally significant connection factor or test, we believe the ANDA would satisfy it. And so, it's not just property, not just investment, but it's an investment in another State.

So, in sum, Members of the Tribunal Apotex submits that its ANDAs obviously were investments in the State of another, and so this panel or this Tribunal would, in fact, have jurisdiction.

Now, I would like just to briefly address the--oh, I'm sorry, Mr. President, would you like to take the afternoon break?

PRESIDENT LANDAU: I was thinking we would go until about 3:30, but I'm in your hands, whenever is a

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03:13:28 convenient time.

MR. RAKOCZY: This would be actually pretty good for us.

PRESIDENT LANDAU: Shall we take 15 minutes from now?

MR. RAKOCZY: Thank you, sir.

PRESIDENT LANDAU: Fine.

(Brief recess.)

PRESIDENT LANDAU: Please go ahead.

MR. RAKOCZY: Thank you, Mr. President. I will continue briefly with the timeliness objections to Apotex's claim, in particular the Pravastatin Claim, and this argument, in a nutshell, by the Government is the FDA administrative decision that admittedly forms the only context and basis for the later judicial actions somehow is time-barred and can't be considered by this Tribunal for purposes of Apotex's claim under the NAFTA.

The standard of the limitations period is undisputed, and we don't need to spend any time on that. I think the key thing here is it's a two-part test. It's knowledge of the breach, and it's

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03:26:02 knowledge of the ensuing damage or harm. And here--again, it's undisputed--the Government admits that judicial action is a single action from beginning to end so the State has not spoken until all the appeals have been exhausted.

Now, their position seems to be that you need to separate FDA administrative action from the judicial action reviewing it. We would submit that doesn't make any sense when, under U.S. law, there is no dispute that anyone suffering a legal harm from Agency action has a statutory right to seek judicial review of that action. And when a Party that's aggrieved by final Agency action does seek that judicial review, it's our position they shouldn't be punished or penalized for it, basically; that when they do, that all becomes part and parcel of the same single continuous judicial action. So, as a legal matter, we would submit, Apotex didn't become aware of the harm until that judicial action was complete.

Now, an interesting thing about the Government's theory here is they're saying Federal Agency action, hard stop, that could give rise to a

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03:27:22 NAFTA claim; judicial action later, supposedly, could give rise to a whole separate NAFTA claim. We take, Mr. President, your comments to heart, is that really what we want to encourage, dual-track litigations under NAFTA. The Government has accused us of trying to turn this Tribunal into a super-national appellate court, yet at the same time they're criticizing Apotex for exercising its U.S. statutory right to seek APA review of final Agency action under the Administrative Procedure Act, which is what they did.

So, again, we would submit, as a legal matter, because Apotex was entitled to do that, that its claims did not ripen until they got knowledge of the harm when the judicial action they realized it had all failed.

Now, the interesting little tidbit in all this is if you look at the actual facts here, is--remember, Apotex did all it could in the District Court and the D.C. Circuit to challenge this judicial--or this Agency action, and at one point, remember, as the Government took you through the facts, Apotex was actually able to get a stay of the

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03:28:35 1 FDA administrative decision for a very short period of
2 time by the D.C. Circuit Court of Appeals here in
3 Washington.
4 Now, what type of wrinkle did that throw into
5 the Government's theory here? Because, according to
6 the Government, Apotex knew about its harm, and then
7 that NAFTA claim based on the Agency action ripened,
8 and they should have run into NAFTA to arbitrate, but
9 at the same time Apotex exercised its statutory rights
10 to judicial review and gets a short stay of that
11 Agency action. So, at that point in time, under the
12 Government's theory, are we to believe all of a sudden
13 now Apotex isn't harmed, its NAFTA claim isn't ripe
14 anymore? That doesn't make any sense.
15 What makes more sense is legally to treat
16 this as the Government has treated all claims like
17 this, that when you seek judicial review, as you're
18 entitled to do, it is a single continuous act that
19 doesn't ripen, and the limitations doesn't start until
20 that judicial action is finished. So, again, we would
21 submit, as a legal matter, this is timely, and this
22 Tribunal can consider the FDA action.

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03:29:47 1 But even putting that aside--put aside the
2 two-part test--as a practical matter, it doesn't make
3 sense to say that this Tribunal can review the
4 judicial actions of those courts, the D.C. Circuit and
5 the District Court, who were reviewing a Federal
6 Agency's administrative decision, but yet you can't
7 look at that decision, and you can't decide the
8 proprietary (sic) of that decision, when that's what
9 the courts were doing. In our view, that's just a
10 back-handed way of the Government to try and insulate
11 all of this from review because basically what they're
12 suggesting is that, as the Tribunal, go ahead and look
13 at what the D.C. Circuit looked at, but you're not
14 allowed to look behind what they're looking at and
15 say, Hey, was this FDA decision correct or not?
16 Because they're saying that's time-barred and that's
17 out, so basically you have to consider that that was
18 correct. Well, that insulates everything from review
19 because you can't then look at the Court and say did
20 they do right or not under minimum standards of
21 international treatment or was there denial of justice
22 if you can't look at the FDA Decision itself.

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03:30:59 1 And it's not just background and context.
2 The D.C. Circuit and the District Court are not
3 looking at an Agency decision in a vacuum as
4 background information. They're reviewing de novo the
5 Agency's decision and what they did here. That's what
6 the court decisions are about. So, we would say, not
7 just legally but as a practical matter, it makes no
8 sense, and you can't have meaningful review of this
9 judicial action unless you could look at what they
10 were reviewing, because otherwise again it's just a
11 back-handed way to insulate all of it from review,
12 which we don't think is proper. And again, it's not
13 just background and context. You have to be able to
14 look at what FDA did because that's what the courts
15 were doing de novo.
16 So, we would submit, no matter how you slice
17 this issue, the FDA Decision is, in fact, or should be
18 in play here. It should be reviewable. This Tribunal
19 should be able to look at it to determine when the
20 courts were looking at that, was their conduct falling
21 below the minimum standard of treatment? We think
22 that's proper and legally required here.

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03:32:10 1 PRESIDENT LANDAU: I will break in here;
2 forgive me.
3 Just again to be clear about the case that
4 you're putting on this, if one looks at this from the
5 perspective of a claim in respect to judicial conduct,
6 then one would look at the on your case, one would
7 look at the FDA Decision, but that would be the prism
8 of a denial-of-justice claim or some other claim which
9 is focusing on judicial conduct. So, as I understand
10 it, that wouldn't be the Tribunal assessing whether
11 the FDA fell above or below minimum standards of
12 international law. It would be whether the judges,
13 whether the court system fell above or below the
14 minimum standards. Isn't that a different inquiry?
15 MR. RAKOCZY: I would not--I would say not
16 necessarily, Mr. President, because you have to look
17 at this as to how United States courts review Agency
18 action under the Administrative Procedure Act, and
19 they are often reviewing de novo whether the Agency
20 action was arbitrary, capricious or contrary to law.
21 So, in our view, you can't separate these as to see
22 what's going on here.

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When a court is reviewing the United States, was the Agency action contrary to a statute, you have to look at what the FDA did. That's what the Court is doing. Only by doing that are you going to be able to see was the ultimate determination of the Court, was that a denial of justice or not? You can't separate what the Court's doing because there would be no judicial action to review but for the FDA Administrative Decision. I mean, they truly are--I mean, I hate to keep using the term "part and parcel" of the same thing, but in this case they really are. They're no different--I'm sorry--it's no different--and it's not the same thing that we see in it these other cases like Mondev and the other time-barred cases, where you had a city ordinance or you had a city acting in some way which diminished the contractual rights or breached contractual rights allegedly. That's different. That type of judicial review, it was admitted that that wouldn't even get the applicants all the relief that they were seeking.

You can't say that about an APA action. When an APA action is bound up in one action is what did

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the Agency do; and what they did, is it consistent with their statutory mandate, is it contrary to law, is it arbitrary, capricious, or otherwise unreasonable or abuse of discretion? And everything bound up in that APA action is the relief Apotex was seeking.

So, we would say you cannot separate that from the Tribunal's view of what the judicial action was.

PRESIDENT LANDAU: One difference, however, would be if you're looking at the claim through the prism of judicial conduct, then when you look at the FDA Decision, you would test it by reference to U.S. law, not international law, because you would be looking at how the judges have assessed the FDA Letter Decision, and the judges would be applying not international law but their own municipal law. So, you would be doing something slightly different, wouldn't you, if you bring the claim as a claim in respect of judicial conduct, you might then look at the FDA Decision, but you're looking at it not through the prism of international law at that point but through national law.

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MR. RAKOCZY: Well, I would agree it probably would be a two-part inquiry, then, because yes, originally you're looking at, yes, through the prism of what the U.S. courts and what judges are looking at, and obviously they are judging the conduct of the Agency through the prism of U.S. statutory law; here, Hatch-Waxman and the MMA. But then the second-part inquiry is, by doing that, was the Court falling below--was their conduct, then, and how they did that, and the judgments they made, was that falling below minimum standards of international treatment, or could it constitute a denial of justice?

So, yes, I think it would be a two-part inquiry, but if that first part of that inquiry, I would submit, you can't get away from being able to look at the FDA Decision and saying it's just background, to us, is again just a way to insulate everything from review, because to me that's just suggesting somehow that it's just background and the Agency did what it did, and we all have to assume it was correct and move on from there. Well, that's just a way to prejudice and pre-judge the merits of the

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claim before we even get started.

PRESIDENT LANDAU: The reason I'm pushing this is only because it strikes me that it may be that both sides are actually saying the same thing, surprisingly, on this, and obviously both sides are free to comment on this in a little bit, but as I understand it, what you're saying is that, what remains open to you is to bring a claim in respect of judicial conduct, and I'm not sure the United States would resist that because the judicial conduct in question is within the time period.

So, the question between the Parties is, what would a tribunal do in that situation when faced with assessing the FDA conduct through that prism?

And if you accept it's a two-stage test, in fact, when you look at judicial conduct, you apply it to national standards, but when you look at what they did with the FDA, you're applying national law standards, then that might not be a very controversial proposition.

MR. RAKOCZY: It might not be, but perhaps I didn't hear the Government's position correctly, but I

thought they were going a little further in saying that really you wouldn't be able to take a substantive look at all at the FDA Decision, and that's what troubles us because it's not possible to engage in any meaningful review at any level under anyone's law of an APA decision of a court when you can't look at the Agency action that that court was reviewing.

And you can't just say it's background or context because it forms the focal point of the entire court review. As a matter of fact, under United States law, there are no so-called "disputed issues of fact" when a court is reviewing under the APA Agency action. It literally is a question of law de novo, so the Court is taking an initial look of its own to see what happened there.

And we submit that if you just say that that's background and context and you can't dig into the Agency Decision, then that's problematic, and we think that the Government is trying to knock that out as time-barred precisely to do that because it will help, in their view, insulate the judicial action from review.

Now, I would like to move on to the last claim that the Government is raising here, and that the Pravastatin Claim somehow lacked judicial finality. I believe the Parties--I don't think there is a lot of dispute about what the finality requirement is. The major dispute seems to be, did Apotex meet it, and should they have, in the Government's view, either continued litigating in the District Court or petition the United States Supreme Court for cert. We would submit that neither of those avenues--let me back up.

We would submit that those would have been objectively futile, for several reasons. Apotex proceeded with dispatch throughout this. The Government wants to take issue with the fact that Apotex waited a certain number of days before taking certain actions such as filing a pre-hearing petition, but the fact of the matter is it is undisputed before this Tribunal Apotex never missed a deadline, Apotex proceeded within the rules of every court that it was before. And, in fact, it moved with extreme dispatch from the beginning.

Apotex--once the FDA Decision came out, something the Government doesn't mention, Apotex had actually sued the Agency before they even issued their adverse decision. Because Apotex was so worried about moving with dispatch, they filed a preemptive action against the Agency even before their action came out. So, when they issued their decision, Apotex immediately moved for emergency TRO and preliminary injunctive relief before the District Court. The District Court obviously denied it on the ground that Apotex was not likely to establish success or likelihood of success on its claims.

Apotex, then, according to U.S. law, exhausted its remedies in the District Court by seeking a stay before going to the Appellate Court, as it's required to do under Rule 8. Once Apotex got to the Appellate Court, it asked for everything it possibly could, expedited relief, an injunction, a stay, and even managed to get a stay for a few days before the D.C. Circuit Court of Appeals then obviously denied Apotex's relief and eventually entered summary affirmance against Apotex again on the

ground that Apotex was not likely to succeed on the merits of its claims. Apotex then--and the Government criticized Apotex for this, exercised its re-hearing rights to go back before the full D.C. Circuit en banc.

Now, what we find interesting is the Government criticized Apotex for doing that, saying that they could have easily filed a cert petition to the Supreme Court. Again, it seems to be a little bit of the Government talking out of both sides of its mouth. They accuse Apotex of wanting to make this Tribunal a supernational Appellate Court, at the same time they criticize Apotex for going to the full D.C. Circuit, the Court whose job it was in the first instance to determine whether they should rehear the panel's decision. Apotex obviously had that relief denied as well.

And it wasn't until the mandate issued in September, which the mandate issued on September 18 of 2006 from the D.C. Circuit, which was the first time that Apotex was allowed to go back down to the District Court. That's when jurisdiction returned to

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the District Court. At that point, barely a month left of exclusivity when Apotex was in the District Court, the suggestion somehow that Apotex had available relief in the District Court with a month of exclusivity left, we submit, again does not pass the straight-face test.

Apotex could not move again to expedite consideration in the District Court. It had already lost the TRO in that same District Court, Judge Bates. Judge Bates had already denied their preliminary injunction saying they had no likelihood of success. Apotex had no basis to go in and ask Judge Bates to move along and move faster so that Apotex could try to get up on appeal again. No basis whatsoever.

Could Apotex have filed a summary judgment motion or some other filing in the District Court? Perhaps it could have when it got back there in September. The fact of the matter is exclusivity would have run and the case been mooted before that motion had even been briefed, much less decided.

So, we submit that any efforts in the District Court were objectively futile. That leaves

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this whole Supreme Court idea that somehow Apotex should have either skipped re-hearing before the D.C. Circuit, which we submit would have been improper, or just to go up after re-hearing was denied on a cert petition.

Now, again, could Apotex have filed the cert petition? We're not denying that Apotex could have served a cert petition. That would have been objectively futile. Apotex filed the cert petition in the Sertraline Case. What the Government forgets to mention is it took eight months for that cert petition to be briefed and denied. Eight months.

So, even if as the Government suggests Apotex could have run out, filed the cert petition in one day after re-hearing or after the initial decision, Apotex still could not possibly have obtained any relief before that exclusivity expired, whether there was a month left, 67 days or a hundred odd days as the Government is arguing now. They could not have done it.

Even if the Supreme Court would have accepted cert--and let's remember, the Supreme Court is a court

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of limited jurisdiction. It is not a general court of error like a Federal Circuit Court of Appeals. They hear very few cases. They get 10,000 cert petitions. They hear less than 75. Even if Apotex could have gotten the Supreme Court to accept cert, no one disputes, and the Government concedes, cert petitions from grant to decision in the Supreme Court take on average nine months or more.

So, again, whether we were talking about 30 days, 60 days or a hundred days, Apotex could not have gotten the relief it needed from a cert petition to the Supreme Court. It would have been futile.

Now, could Apotex have moved to the Supreme Court for emergency relief as we heard the Government argue today? Well, I suppose they could have, but that kind of skips an important part of the inquiry, which is you just don't run to the Supreme Court and say, "Give me a stay and emergency relief." You still have to establish that that is a case that the Court is willing to take and exercise its limited jurisdiction on. And again, we submit that would not have happened in a month or 60 days or a hundred days.

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Again, Apotex, it is true, they have moved cert in other cases, and sertraline is a picture-perfect example. It took months and months before that petition was decided and denied.

And here, I don't think any of the Parties are arguing that you're not required to exhaust remedies when it would be obviously or objectively futile. All of the commentators agree, and we submit here would have been objectively futile under any scenario, whether Apotex moved for re-hearing or not. And by the way, we submit it was the proper thing to do.

Again, is the Government really suggesting that we should just ignore the federal courts of appeals and don't seek re-hearing before the court in the first instance and run to the Supreme Court? We suggest that would be complete nonsense. Of course, you're going to the court of general error. The appeals courts must hear these cases. That's the court you need to go to first. That's who Apotex went to. They exhausted and achieved all of the finality they could get. Anything left would have been futile.

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ARBITRATOR SMITH: Mr. Rakoczy, I understand and sympathize with the frustration of trying to get to the Supreme Court, but in a sense aren't you really arguing the Supreme Court out of the exhaustion law and basically the reality--what you're saying is, well, nobody gets to the Supreme Court, or hardly anybody gets to the Supreme Court; therefore, why should we even consider those efforts and just inferentially we are going to say "exhaustion of remedies" means you stop at the Court of Appeals?

MR. RAKOCZY: Actually, you're not, Your Honor. I raised 10,000 cases and 75 cert petitions.

ARBITRATOR SMITH: I would have raised it if you hadn't, which is fine.

MR. RAKOCZY: It's one of the most frustrating things in the United States, but the fact of the matter is--let's assume that the Supreme Court was dying to get this cert petition and that Apotex--we mapped out in our papers if Apotex would have taken a day to do its cert petition and get it on file, it still would not have gotten that fully briefed, at best--best-case scenario until it was

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about a month left of the exclusivity, and then we know--we know the time it takes for them to grant cert and issue a decision.

So, it's not a matter of would they take it or not. We could assume they would have taken the case, which again, as unrealistic as that may be, but we assume for sake of argument they would have. The fact of the matter is there was no time to get it done, and that even factors in these days that the Government is accusing Apotex of delaying on, which, by the way, we find very interesting because again Apotex (sic) accuses us of wanting to turn the Tribunal into a supernational appellate court, yet they're asking you to make some type of reasonable determination on if you have a deadline to get a re-hearing petition in 45 days and you file it in 44, they're suggesting somehow that's unreasonable, we would suggest that's not a decision the Tribunal should be making. Apotex hit every deadline it had to hit. It followed every rule. It exhausted everything it could, and it moved with incredible dispatch under the circumstances.

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So, we would submit it's not a matter of whether the Court would have taken it to the Supreme Court. It was the matter there wasn't time to get the relief that we needed.

PRESIDENT LANDAU: If I could ask a follow-up on that.

Perhaps you could just help me on this, when you say there wasn't enough time to get the relief that you needed, focusing on the Supreme Court, focusing on what's been put to you on the other side what could have happened on the 6th of June 2006, presumably, theoretically there would be time because you could ask the Supreme Court for an expedited briefing schedule. Is that possible? If something was really urgent, if somebody was on death row, presumably, there are times when briefing is done very quickly.

MR. RAKOCZY: Yes, Mr. President, you are correct. As a matter of fact, if we wanted to go back and look--and I don't have this in our submission, but I would be happy to follow up with a supplement, if we wanted to go look and see when has the Supreme Court

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exercised that stay power that the Government has raised here, it is in the death row, life or death cases. The Supreme Court Justice of the United States don't go around issuing stays in other cases very often, so yes, could we have moved for a stay--but again, I think the Government's papers and their presentation proves the futility of that. Apotex had already lost at every level, both on the merits, whether they were likelihood to succeed on the merits, as well as whether they were entitled to expedited relief. They weren't getting it.

So, to suggest that Apotex could have in June or August or September, again we submit that re-hearing was the appropriate thing to do here, could Apotex have gotten that relief? No, we suspect it would have been futile because the clock would have kept ticking on the exclusivity, and no order from any of these courts would have stopped that, and the case would have mooted out before Apotex could ever get any relief.

PRESIDENT LANDAU: Are you going to make any comment on the test as a matter of law that we should

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apply--I know you have made comment already, but any further comment on the test that we should apply to the futility exception? And I'm thinking in particular of some of the international law or authorities that have been cited today by United States, or focused upon today. They're set out in Slide Number 13 of Section 7 of the United States presentation, in particular the Separate Opinion of Judge Lauterpacht in the Norwegian Loans Case. Judge Lauterpacht who put this in that case, 1957, in terms of however contingent and theoretical remedies may be an attempt ought to have been made to exhaust them.

MR. RAKOCZY: Our comment on that would be simply that what we don't want to do is confuse availability and futility. The fact that you can file papers, if there is some petition that you can file, left to file at the last second, goes to availability. Futility goes to, could you get the relief you needed, and why our case is--why the facts are important here is that we have this running clock, and we knew when that date would come and we could no longer get effective relief, whether it was available or not.

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We're not disputing we could not have--sorry.

We're not disputing Apotex could have filed a cert petition, but again that goes to availability, which is how we read some of these commentators and not futility. Futility test goes to, even if it was available, could you have gotten the relief you needed in the time you needed it, and here we definitely could not have. We have not heard the Government dispute any of the facts we put forth in our submissions about the fact that this time was going to run out regardless of what we filed.

And also we take exception, by the way, with the suggestion somehow that Apotex wasn't moving with dispatch or didn't do enough here. As a matter of fact, I kind of like the Government's timeline. Apotex made so many submissions here it wasn't even funny. We tried expediting an emergency relief at every court we could get, and it was denied, which wouldn't have made sense to file that again in front of Judge Bates or in the Supreme Court. In fact, I would suggest that the Government should spend more time in front of our Federal District Courts here.

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And had we filed a petition to expedite in front of Judge Bates for example, again, we probably would have been sanctioned because it had already been denied. I don't think he would have taken it kindly.

So the relief had been repeatedly denied, we had sought everything we could, and the clock was going to run out, and again that's not confusing availability and futility, which are separate legal concepts, in our view.

With that, I can close my presentation. I want to thank the Members of the Tribunal for your time. You gave us more than ample time, and I appreciate it, and we would respectfully request that the objections to jurisdiction be denied in their entirety, and that this case be set down for another scheduling or procedural hearing so that we can move to the merits.

And, obviously I will address any of the questions the panel has today or tomorrow.

PRESIDENT LANDAU: Thank you very much.

We are well ahead of the planned schedule, but what I propose is that we now break briefly so

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that the three of us can have a conversation between ourselves to pool any outstanding issues that we may have together, and then we will convene again perhaps in about 20 minutes or so, depending on how long we take, to set out anything we want to be addressed on specifically tomorrow, if that's acceptable.

So, shall we say we'll break for 20 minutes with no guarantee that we'll be back in 20 minutes?

MR. RAKOCZY: Absolutely.

(Off the record.)

PRESIDENT LANDAU: Thank you very much for giving us that time.

We have gone through our notes, and I think our general feeling is that the course for tomorrow is probably already pretty clear, actually, from the questions that we've asked in the course of today. We have been somewhat interventionists, and we are grateful for everybody's toleration of that, but I think you can see from the questions that we've already asked that there are a number of outstanding matters that could be further elaborated in the course of tomorrow, so I'm not going to repeat all of those.

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There are two points of procedure still to resolve. One is Slide 41 of the Apotex presentation, which was the material that's not in the record at the moment, to which the United States has so far objected. And what I suggest is that overnight you take the time to look at that and consider whether the objection stands or whether you are able to address what's in there, and we can see whether that's an objection tomorrow morning that still stands and whether we need to rule on that.

For the time being, that material is not in the record, but what I would suggest is that maybe the United States can take a view as to whether it can address it in the course of argument tomorrow, perhaps.

The second point is just to go back very briefly to the confidential information that was presented in the course of Apotex's submissions. The point I had raised was that we must be alive to any sensitivities with respect to the Award, and what I suggest is that we adopt a procedure whereby the Award, when it's issued, is issued in the first

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instance to the Parties before it's made public, simply to give everybody an opportunity to confirm that there's no difficulty with it being made public or just to make sure if there are any redactions that need to be made at that stage would probably be the simplest way of resolving that.

In terms of more substantive points, the Tribunal is looking for any further assistance on, specifically apart from everything else, specifically on the question of the definition of "property" and the definition of "investment". So, essentially the question which has been ventilated by both sides today, we think is an area which could be concentrated on further as to whether or not what is said to be property in this case is property; and, if it is, whether it is investment, and that I think takes us back to 1139(g), and it takes us to the two elements there, the first part and the second part. The Respondent would have heard the Claimant's position that the second part has not been addressed or has not been put in issue. That's something which the United States would probably want to address.

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And if I can go back to the exchange that I had with Respondent's counsel, that the Tribunal would be materially assisted if these points can be looked at as a matter of analysis beyond simply a matter of evidence. We have on board the Respondent's position that there is a burden of proof and that there's a question as to whether or not any evidence has been provided on the issue of whether something is property or not, and whether it's investment or not, but beyond that, there is still an area of simple analysis and submission as a matter of whatever law is said to govern. I mean, self-evidently that's a key point and that's something which we would like to hear more on.

There's another point which again arises out of the questions we asked which we would like to have more assistance on, and that is in the context of the time-bar issue, and in particular if the claim that is raised is one focused upon judicial conduct as opposed to administrative conduct--i.e., it's a claim for denial of justice or something focused upon judicial conduct, what are the limits in terms of the Tribunal's ability to then look at the underlying FDA

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Decision.

And I'm reminded that the issue between the Parties as to whether there is a distinction between a judicial claim and an administrative claim or whether it's all to be lumped together, whether one can't make that distinction fairly, which I think arises out of Apotex's submissions this afternoon. Is that clear, the way I have articulated that?

So, those points are emphasized but not to exclude the other points that we've raised, so I hope that's of some assistance, probably not massive assistance, but a little bit of guidance.

The other two issues, just to put in the pot for tomorrow, we will need to put together a schedule for--actually, let me back up.

One point is whether or not there should be Post-Hearing Briefs. I don't think that's something which we have decided so far, and I would think that's something which the Parties might want to confer on and see if there's any agreement on that, and we can then discuss that tomorrow.

And, secondly, we need to put together a

schedule for submissions on costs which would involve both obviously the allocation of costs and the assessment of costs, and that's something which perhaps the Parties could get together and see if there is any agreement possible on that, with a view to us then being able to render an award which includes costs and will be complete.

(Tribunal conferring.)

PRESIDENT LANDAU: One further issue, sorry, out of order, but another issue which came up in the course of this afternoon, which could also be addressed a little bit further perhaps is a distinction that's being drawn between a test in terms of the judicial finality objection between the considerations of the availability of recourse and the alleged futility of recourse.

Now, other than that, I think that's all that we are going to put on our list for homework, together with all the other points.

We've got through the things rather expeditiously today, and we're wondering whether perhaps whether we should give ourselves the luxury of

a 9:30 start tomorrow as opposed to a 9:00 a.m. start, if that's acceptable.

MR. RAKOCZY: Good for us.

PRESIDENT LANDAU: That time of the day every minute counts.

And we could also build in the schedule tomorrow at break perhaps between the two presentations, which I don't think we have at the moment. But other than that, I think, unless there's any point arising from either side, anything for the Claimant from today? Anything from Respondent's side? In which case, with thanks to everybody, we'll close the proceedings for today, and start again at 9:30 tomorrow. Thank you very much.

(Whereupon, at 4:40 p.m., the hearing was adjourned until 9:30 p.m. the following day.)

CERTIFICATE OF REPORTER

I, David A. Kasdan, RDR-CRR, Court Reporter, do hereby certify that the foregoing proceedings were stenographically recorded by me and thereafter reduced to typewritten form by computer-assisted transcription under my direction and supervision; and that the foregoing transcript is a true and accurate record of the proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in this proceeding, nor financially or otherwise interested in the outcome of this litigation.

_____
DAVID A. KASDAN