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

BETWEEN

APOTEX, INC.,	
Claimant/Investor,	
and	
UNITED STATES OF AMERICA,	
Respondent/Party.	AMENDED
	Volume 2

FIRST SESSION OF THE ARBITRAL TRIBUNAL

Thursday, February 16, 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 9:32 a.m. before:

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

MR. CLIFFORD M. DAVIDSON, Arbitrator

HON. FERN M. SMITH, Arbitrator

Also Present:

MS. AURÉLIA ANTONIETTI,
Secretary to the Tribunal

Court Reporter:

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C O N T E N T S

CLOSING ARGUMENTS: PAGE
ON BEHALF OF THE RESPONDENT:
By Mr. Sharpe 296
By Mr. Kovar 312
By Ms. McLeod 329
ON BEHALF OF THE CLAIMANT:
By Mr. Rakoczy 334
QUESTIONS FROM THE TRIBUNAL 381

P R O C E E D I N G S

PRESIDENT LANDAU: Good morning, ladies and gentlemen. Welcome to the second day of the hearing on preliminary issues in Apotex, Incorporated, and the United States of America.

The schedule for today, as agreed, is that we will have closing arguments on behalf of the Respondent, first of all, and that was planned for about an hour and a quarter. We'll then have a break, and then we'll have Closing Arguments on behalf of the Claimant, and then we have, I think, in the program a further break, and then an opportunity for any last questions or remaining issuing to be raised by the Tribunal.

Are there any preliminary matters that anybody wants to raise before we head into that? For the Claimant?

MR. RAKOCZY: Nothing for Claimant.

PRESIDENT LANDAU: And for the Respondent?

I just put on record that I now understand the issue about Slide 41 of the Claimant's presentation from yesterday, which referred to

09:34:58 materials that were not so far in the record has been resolved, and the United States is not objecting to that material going into the record, so Slide 41 is now part of the record.

And with that, I then give the floor to the Respondent.

CLOSING ARGUMENT BY COUNSEL FOR RESPONDENT

MR. SHARPE: Thank you, Mr. President, Members of the Tribunal.

I will address the question of whether Apotex has made an investment--is an Investor that made an investment in the United States.

As you know, we framed the key jurisdictional issue before this Tribunal as follows: Has Apotex established that the mere filing of an application with the U.S. Government for revocable permission to allow it to export--not to export, but 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?

Apotex argues that it has met its burden, because its ANDAs are property under Article 1139(g).

09:36:09 That provision states: "Investment means, (g), real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes."

In making its argument, Apotex invites the Tribunal to apply the ordinary meaning of Article 1139(g) in context and in light of the NAFTA's object and purpose. We agree that's the proper standard for interpreting a treaty, but as the Tribunal's questions have highlighted, that standard doesn't get us very far in this case, for three reasons:

First, it's not clear that the words "intangible property" in the NAFTA have an ordinary meaning. We might all agree that the term covers, for instance, patents, but it is far from clear that it covers mere applications for revocable permission to market a product.

Second, there's no ready definition of intangible property under international law that would allow this Tribunal simply to point to and conclude that Apotex's applications meet that definition.

PAGE 298

298

09:37:24 Third, the NAFTA does not, on its face, protect as property mere applications or anything remotely resembling applications. Apotex, citing to Black's Law Dictionary, asks this Tribunal to adopt for Article 1139 a typical common law definition of property. But presumably our civil law neighbors in Mexico and Quebec would not wish to have a common law definition of property foisted upon them as the ordinary meaning of the term under our common international agreement.

We necessarily look to U.S. law, as the law of the host state for purposes of defining alleged property--that property--alleged property interests in this case. The Tribunal has asked whether it can simply apply U.S. law as pleaded by the Parties, rather than determining whether Apotex has established, by evidence, a property right in the ANDAs. Either approach, we think, would lead the Tribunal to the same place. There is, we submit, nothing in the pleadings or the Legal Authorities cited by Apotex that would allow this Tribunal to determine that pending ANDAs are property under U.S.

PAGE 299

299

09:38:32 law or the NAFTA.

We encourage the Tribunal to adhere to the principle adopted by some other investment tribunals and remain within the confines of the debate between the Parties rendering a decision in the dispute as pleaded by them.

Citing Black's Law Dictionary, Apotex claims that it has the right to posses, use, and enjoy its ANDAs. That right, it argued, is not tied to FDA approval of the ANDA. Indeed, the right appears not to be tied to the FDA at all. Apotex states an ANDA can be purchased and sold by the applicant regardless of its approval status. That is, it claims that parties are free to sell an ANDA as they wish, even before the ANDA is filed with the FDA. These are the so-called "pipeline ANDAs" that Apotex's counsel referred to yesterday.

So, a company could prepare its draft ANDA in Canada and then sell it and all of the proprietary data in it to, say, a Chinese company for a substantial sum. That transaction might be governed by, say, English law and have nothing whatsoever to do

PAGE 300

300

09:39:38 with the United States. There would appear to be no property rights at issue in the scenario at all.

Once the foreign company hits the "send" button and transmits its application to its agent for filing with the FDA, what happens? Under 21 CFR 314.101, FDA then has 60 days to determine whether the application is sufficiently complete even to be filed. But what additional property rights are acquired once the Applicant hits the "send" button? Here Apotex's arguments are in conflict. On the one hand Apotex concedes that, without FDA approval, it could not use its ANDAs for its intended purpose, which is to allow for the sale of the underlying drug. But, on the other hand, Apotex claims that, "ANDA applicants have the exclusive right to enjoy, use, and posses the respective ANDA."

So, what exactly is the use, enjoyment, and possession? It's precisely the same use, possession, and enjoyment that Apotex enjoyed the day before it was filed. And at that time an applicant might still be in Canada or China or elsewhere in the world and not yet have any property rights connected to the

PAGE 301

301

09:40:48 United States.

But even if Apotex had argued that it had property tentatively approved or even finally approved ANDAs, its argument still would fail. The principal reason that Apotex can't claim any property rights is because Apotex lacks exclusivity in its ANDAs vis-à-vis the Government. Apotex does not dispute that FDA has, by law, discretion to decline to approve or revoke approval of ANDAs, even finally approved ANDAs, for any number of reasons. The American Pelagic case, which was at issue in Glamis Gold is instructive here. In that case the Federal circuit found that the Claimant did not have a right to a fishery permit because, among other reasons, the Government had the right to suspend, revoke, or modify the Claimant's license. As such, the applicant could not claim exclusivity which is the key stick in the bundle of rights comprising the claimed property interest.

We don't believe that Apotex has established or that this Tribunal could find in applying U.S. law that Apotex has the necessary bundle of rights in its

PAGE 302

302

09:41:49 1 ANDA to constitute property.
2 Instead, on Apotex's own terms, its alleged
3 property right is merely the right to use, enjoy, and
4 posses its ANDAs. That's without with regard to
5 whether those ANDAs ever are filed with the FDA, or,
6 at the relevant time, have any property right
7 connection to the United States.
8 But let's assume for the sake of argument
9 that Apotex has a property right in its unapproved
10 ANDAs. That leaves three additional problems with
11 Apotex's claims.
12 First, as we discussed yesterday, Apotex does
13 not have property acquired in the expectation or used
14 for the purpose of economic benefit or other business
15 purposes. The economic benefit Apotex claims it was
16 seeking through its ANDAs was the right to sell drugs
17 in the United States, but that right was not acquired
18 or enjoyed in its unapproved ANDAs.
19 Apotex suggests, instead, that the definition
20 of "investment" in Article 1139 covers both existing
21 and future investments. It is true that NAFTA allows
22 so-called "pre-establishment claims," so that an

PAGE 303

303

09:43:01 1 Investor who is seeking to make an investment and who
2 is discriminated against can bring a national
3 treatment or a most favorite nation treatment claim.
4 But Apotex, of course, does not claim that it was
5 seeking to make an investment. It claims that it made
6 investments, and it claims that those investments were
7 expropriated and denied the minimum standard of
8 treatment required under international law. A State
9 obviously cannot expropriate or provide substandard
10 treatment to an investment that has not yet been made.
11 It's clear that Apotex is not making a
12 pre-establishment claim in this case.
13 Alternatively, Apotex suggests that it would
14 have acquired or used its investments at the time of
15 the alleged breaches but for the wrongful acts
16 complained of in this arbitration. Apotex, however,
17 claims that its investments were made the moment it
18 filed its ANDAs with the FDA, years before the alleged
19 NAFTA breaches. Apotex must establish the existence
20 of property acquired or used for economic benefit or
21 other business purposes in the United States, and it
22 has not done so.

PAGE 304

304

09:44:04 1 Second, even assuming Apotex's applications
2 were property acquired or used, those Applications
3 would still not be investments. Property is not a
4 free-standing concept in this context. It's part of
5 the definition of "investment" in the Investment
6 Chapter of the NAFTA. It has to be understood in the
7 context of an international Treaty that is designed in
8 the words of the Gallo Tribunal discussed yesterday:
9 "To stimulate flows of private capital into the
10 economies of contracting States." Or as the Grand
11 River Tribunal correctly concluded, the property
12 acquired or used in the United States must, "rise to
13 the level of an investment." Property is not an
14 investment if, as here, it merely supports
15 cross-border sales.
16 It's clear on the face of the NAFTA that
17 certain property that is acquired or used nonetheless
18 is excluded from the definition of "investment."
19 Contract rights, for instance, have been recognized as
20 a species of intangible property by the U.S. Supreme
21 Court for decades. But under the NAFTA, only
22 certainly contract rights, even if they are property

PAGE 305

305

09:45:14 1 acquired or used, are investments under
2 Article 1139(h). Commercial contracts for the sale of
3 goods or services are expressly excluded from the
4 definition of "investment" by Article 1139(i).
5 Apotex reads the NAFTA differently. It
6 quotes an article by a Mr. Porterfield from
7 Environmental Law Journal concluding that, "The
8 definition of "investment" that is protected under
9 Chapter Eleven is much broader than the real property
10 rights and other specific interests in property that
11 are protected under the Takings Clause," but that is
12 plainly wrong, as evidenced by the fact that property
13 rights in contract may be protected under U.S. law but
14 may not be protected under the NAFTA. If the Tribunal
15 is interested, we are happy to send a recently
16 published 96-page book chapter for Parvan Parvanov and
17 Mark Kantor for the Yearbook on International
18 Investment Law and Policy, which is called, "Comparing
19 Law and Recent U.S. Investment Agreements." Much more
20 similar than you might expect. They compare the
21 definition of "investment" and property under U.S. law
22 and recent U.S. investment agreements, such as the

09:46:24 NAFTA's investment chapter and conclude that, "Protection under U.S. investment agreements is in general not more favorable to foreign Investors and U.S. domestic protections in the areas we investigated including the scope of property protected. In all of these areas, the scope of protection for foreign investors under investment treaties is similar to and in some cases less favorable than the treatment afforded domestic Investors under comparable provisions of U.S. domestic law."

They then add, "The scope of property, protected property for expropriations under recent U.S. investment agreements and NAFTA Chapter Eleven awards is substantially narrower than the comparable scope of protections under the U.S. Constitution. The property right or interest must also be in an investment of an Investor. U.S. domestic law does not limit the protections of the Fifth Amendment solely to investments or Investors."

The third problem with Apotex's argument is that, even if its ANDAs were property acquired or used as investments, they're not investments in the

09:47:27 territory of the United States. Apotex admits that everything associated with the preparation of its ANDAs occurs in Canada: The developing, testing, manufacturing, labeling of its drugs and the compiling of the ANDAs themselves. If Apotex sold that ANDA before submitting to the FDA, clearly it could not claim to have made an investment in the United States.

So, why has Apotex become an Investor with an investment simply by transmitting that application to a U.S. Agent which then files that application with the FDA? Apotex claims that an ANDA is a uniquely U.S. investment because Apotex never would have prepared the ANDA or the ANDA products except to enter the U.S. market because rights under an ANDA can't be used outside of the United States.

But this is precisely the argument that Claimants unsuccessfully made in the Grand River Case. Grand River claimed to have created a proprietary blend of tobacco solely for the U.S. market, to have invested in state-of-the-art equipment solely for the U.S. market, and to have paid $29 million in escrow payments in the United States solely to enter the U.S.

09:48:40 market. But even that cumulatively was not enough to constitute an investment in the United States.

Now, Members of the Tribunal, we would leave you with this consideration: Apotex sells its drugs in more than 115 countries around the world, including the United States, and we assume that Apotex complies with the legal requirements for selling its drugs in every country in which it markets those drugs. Is Apotex, by that fact, a foreign investor in all 115 countries from which it's marketing and in which it sells its drugs? Could Apotex bring investment arbitration in every country in which Canada has an investment agreement?

Or, more pertinently, what would it mean for the NAFTA Parties if this Tribunal were to break new ground and find that there's an investment where a foreign company has simply filed an application with the U.S. Government for revocable permission to allow it to export its products to the United States for sale by others? What would be left of the distinction between trade and investment?

Every exporter is required to comply with the

09:49:46 laws of the host State. Some of those regulations are expensive and time-consuming, but that's the price of foreign trade. It's not an admission ticket for investment arbitration.

So, Mr. President, Members of the Tribunal, we submit that Apotex is not an Investor with an investment in the United States as those terms are defined in Article 1139. As such, we ask you to dismiss Apotex's claims in their entirety.

Thank you.

PRESIDENT LANDAU: Thank you very much.

I have one question which I wonder if I can pose now, just out of what you've just presented.

You point us to the statement which we see perhaps more recently in the Gallo-Canada case, but it crops up in many other cases which talks about the stated objective of investment treaties as stimulating flows of private capital into the economies of the contracting States. The question I've got is where in the analysis does one apply that criterion? There are different stages of the analysis that the Tribunal may go through in analyzing what is an investment. And in

particular there are three stages when one looks at 1139(g). One can apply that in the course of treaty interpretation to the notion of "investment," full stop. That's the first possibility.

The second possibility is you apply it when you get to the notion of property under 1139(g).

And the third possibility is you apply it when you get to the following words in 1139(g), acquired for--acquired in the expectation or used for the purpose of economic benefit.

Just thinking about that, it may not matter in the end because you may come to the same result, but as a question of methodology, these are distinct approaches.

Just to elaborate slightly further, the first one has a body of learning behind it where one looks at, for example, the writings of Zack Douglas and various others who say that when you look at the word "investment," you don't look at it in the abstract. It's got to have some inherent meaning, and that inherent meaning brings with it various qualities, whether they're legal or economic realizations of what

an investment is.

The second possibility is somehow it's confining the notion of "property" so that the universe that would come within 1139(g) is limited. And I'm not sure that's what you were pointing at when you were talking about intangible property being defined or not defined.

And the third possibility is that you apply--you have to have presumably some kind of meaning or restriction to the words, "acquired in the expectation or used for the purpose of economic benefit," because those words themselves could be very, very broad, could include, for example, any purchase of a commodity that you're going to sell on that would be an economic benefit.

MR. SHARPE: Yes. I'm afraid my answer is not going to be very satisfactory because the United States, in preparing these submissions speaks on behalf of the United States Government and requires interagency consensus on these views, and so I'm afraid the only consensus I have for purposes of today is with respect to the definition; that is, the term

itself, "property" has to be interpreted in context and in light of the Treaty's object and purpose. So, I'm afraid I can't answer your question precisely, but I would say at least it applies to that.

And I also would agree to you that it appears that it would not make a difference in this case at which level you applied it, but I'm afraid I can't speak further than that.

PRESIDENT LANDAU: That's understood.

So, the position that you're putting forward at the moment is the second of the three; is that correct? Which is the notion of property.

MR. SHARPE: Correct. Mr. President, I would ask that you call on my colleague, Mr. Kovar.

PRESIDENT LANDAU: Mr. Kovar.

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

Just one last point in response to your last question, the task of the Tribunal is to interpret the NAFTA; and, under the NAFTA, the task is to understand the intention of Parties in the text. And to do that you look at the test in the Vienna Convention on the

Law of Treaties and customary international law which we've set out and has been discussed over the last day and a half.

So, this is related to your question, but we would say that you do not look to external definitions or discussions of what "investment" might be in general or under other treaties, but rather the focus should be on what the intention of the Parties was in the NAFTA itself.

And, in that context, the object and purpose is parts of the--looking at the object and purpose is part of defining all of the terms of the NAFTA. Thank you.

If it's all right, then I will turn next to the issue of time bar in the Pravastatin Claim. The Tribunal has asked whether the time-bar objection was an objection to the jurisdiction of the Tribunal. We submit that it is. As stated in NAFTA Article 1122, the United States consented to investor-State arbitration under Chapter Eleven in accordance with the procedures set out in this agreement. The scope of the three NAFTA Parties' consent is thus limited by

the procedures contained within Chapter Eleven. In that regard and as discussed at length yesterday, Article 1116(2) prohibits an investor from making and the Tribunal from hearing, "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." Article 1116(2), thus, contains a temporal requirement for jurisdiction over the investor's claim. It's an jurisdictional objection ratione temporis. Just as the United States does not consent to be bound by obligations and treaties which are not in force, also an objection ratione temporis, the United States did not consent to arbitrate NAFTA Chapter Eleven claims that arise outside of the applicable three-year limitations period. We believe the plain language of Article 1116(2) makes this clear.

As further confirmation, the U.S. Statement of Administrative Action in briefly discussing Articles 1116 and Article 1117 states simply that those Articles require that, "all claims must be

brought within three years."

Now, considering that time bar in light of what we heard yesterday from opposing counsel, Apotex's Pravastatin Claim cannot survive Article 1116(2)'s jurisdictional hurdle because whatever form it takes, it is inextricably bound up with Apotex's challenge to the FDA Letter Decision in response to the Tribunal's specific query yesterday afternoon, we disagree with Apotex's argument that the separate judicial proceedings it brought challenging the final action of the FDA were so part and parcel of the FDA Award that they effectively extended the date by which it may challenge that underlying administrative decision.

We also disagree with Apotex's alternative argument that even if the FDA Letter Decision is time-barred, the Tribunal must consider its alleged errors as part of examining the subsequent court decisions, which are not time-barred.

The text of the NAFTA bases time bar on the date that the Claimant has knowledge of the breach and of the loss. If the FDA Decision is the core of

Apotex's claim that it knew of the alleged breach and loss when it was issued on April 11, 2006, any claim based on it is, therefore, barred.

Apotex tried to asserting yesterday that, "It didn't become aware of the harm until that judicial action was complete." That's at 250 at 11-13 in the transcript.

Similarly, Apotex stated in its slide presentation that it, "did not have knowledge of the breach and knowledge of the harm until it had exhausted its local remedies." That was Slide 71.

But this does not square with the facts or with Apotex's own previous statements to the Tribunal. I don't want to belabor the point because we made it in detail yesterday, but here again are a few of those statements:

In Apotex's Pravastatin--in a way, Apotex stated that it was, "prevented from obtaining approval and timely bringing its Pravastatin Sodium Tablets to market in April 2006 thus causing Apotex substantial injury, including, but not limited to, significant lost sales and lost market share." That's at

Paragraph 30 of their NOA.

Later it argues that, "The FDA's April 11, 2006, Administrative Ruling and the subsequent judicial actions each constitutes a violation of the NAFTA." That's at Paragraph 67 of the NOA.

And 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." That's at Paragraph 14 of the submission of Apotex in support of the stay.

Even yesterday, Apotex defined its Pravastatin Claim as follows, and I will quote from Slide 23 from Apotex's presentation yesterday: "Respondent's interpretation and application of the FFDCA against Apotex, and in particular the court decision-trigger provision, is unlawful and inconsistent with prior Agency and Federal Court decisions affecting different similarly situated U.S. Investors." Recall, it is only the FDA that issued an interpretation and application of the FFDCA, which is

PAGE 318

318

10:01:30 1 the Federal, Food, Drug and Cosmetic Act in this case.
2 Thus, because the gravamen of Apotex's
3 Pravastatin Claim is that the FDA measure interpreting
4 the court decision-trigger provision injured Apotex
5 and violated the NAFTA, Apotex's claim is time-barred
6 in its entirety. Seeking judicial review of the FDA
7 measure is not required under the NAFTA, and it cannot
8 extend the time for filing its claim.
9 Apotex's assertions that this rule undermines
10 U.S. courts, in our view, are nonsense. Three years
11 is enough time to pursue judicial remedies and to
12 bring a NAFTA claim challenging the underlying measure
13 if the Claimant is not satisfied with those remedies.
14 However, if Apotex's Pravastatin Claims are premised
15 solely on the judicial conduct itself, in other words
16 that Apotex suffered a legally distinct injury on
17 account of the nonfinal decisions of the District
18 Court and the Court of Appeals that denied Apotex's
19 request for preliminary injunction and re-hearing en
20 banc, then those claims would not be time-barred.
21 If this is Apotex's case, then the FDA
22 measure can only be considered by the Tribunal as a

PAGE 319

319

10:02:50 1 background factual predicate to the judicial conduct.
2 It cannot form the legal basis for finding a violation
3 of the NAFTA.
4 The Tribunal asked the Parties to elaborate
5 on this point and to describe the permissible limits
6 of its consideration of the time-barred FDA measure.
7 Here are two prior NAFTA tribunals' approaches that we
8 believe capture quite well these limits.
9 First, in Glamis Gold versus the United
10 States, both the Claimant and the United States agreed
11 that a claim brought on the basis of an event properly
12 within the NAFTA's limitations period may cite to
13 earlier events as, "background facts," or, "factual
14 predicates." The Tribunal agreed. The Glamis
15 Tribunal thus stated that, "It is necessary that any
16 action be preceded by other steps, but such factual
17 predicates are not, per se, the legal basis for the
18 claim."
19 Second, in the case of Mondev versus the
20 United States, the Tribunal considered this question
21 with respect to events that occurred prior to the
22 NAFTA's entry into force. "Entry into force" is a

PAGE 320

320

10:04:15 1 temporal limitation, like Article 1116(2)'s time bar.
2 The Mondev Tribunal stated that, "Events or conduct
3 prior to entry into force of an obligation for the
4 Respondent State may be relevant in determining
5 whether the State has subsequently committed a breach
6 of the obligation, but it must still be possible to
7 point to conduct of the State after that date, which
8 is itself a breach."
9 The Tribunal can only look at the underlying
10 FDA measure through the lens of the challenged
11 judicial conduct. As the President suggested
12 yesterday, the Tribunal would look at how the federal
13 courts assessed the FDA measure based on the claims
14 presented to them, including their application of the
15 appropriate standard under U.S. law for preliminary
16 injunctive relief. That standard, and we mentioned it
17 yesterday, is, one, the prospective irreparable harm
18 to the moving Party if the requested relief is denied;
19 two, the possibility of harm to other Parties if the
20 relief is granted; three, the likelihood that the
21 moving Party will succeed on the merits of its claim;
22 and, four, the public interest.

PAGE 321

321

10:05:36 1 With respect to that third factor regarding
2 the likelihood of success on the merits, it is
3 important to remember that a fundamental principle of
4 U.S. administrative Law is that the regulatory Agency
5 is given substantial discretion to interpret the
6 statute that it's charged to administer. Under the
7 principle announced by the Supreme Court in the
8 Chevron Case, as long as the Agency's interpretation
9 is reasonable and consistent with the statute, it must
10 be upheld; it is a highly deferential standard.
11 If Apotex is claiming that the courts
12 misapplied the law in such an egregious fashion that
13 their actions rise to the level of a breach of U.S.
14 obligations under the NAFTA, the FDA Decision would be
15 examined solely as part of the background in which the
16 courts applied U.S. law.
17 Finally, Apotex suggests that the United
18 States position on time bar is an implicit criticism
19 of Apotex for seeking judicial review under the
20 Administrative Procedure Act. Nothing could be
21 further from the truth. The United States is
22 criticizing Apotex for failing to challenge the FDA

measure in this proceeding within the three-year limitation prescribed in Article 1116(2) jurisdictional bar.

Let me now turn to the finality issue.

You asked the Parties to consider the finality rule and its relation to the rule of exhaustion of local remedies and how the finality rule should be characterized for purposes of its Award as a question of jurisdiction or a question of admissibility.

First, the United States agrees that the principle of finality in this case is distinct from the general international law rule of the exhaustion of local remedies, which the President has characterized as a procedural rule. The exhaustion rule does not apply as a precondition to bringing a claim under Chapter Eleven where the claim is based on a final Government act. In other words, a "measure" that has been, "adopted or maintained" pursuant to Article 1101.

Second, as we explained yesterday, the United States position is that under Article 1101, the act of

a domestic court cannot constitute a measure that has been adopted or maintained by the State, unless the Claimant has exhausted all his judicial appeals. This interpretation derives from the rule of finality in international law under which, "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." I quote from the Parties' submissions.

Thus, it is the United States's position that Apotex has no basis in the NAFTA for challenging nonfinal judicial acts as breaches of Articles 1102, 1105, and 1110, unless they can show that final appeal would have been obviously futile. To support a Chapter Eleven claim, the judicial acts complained of must be final. In our view, this is a question of jurisdiction ratione materiae, a question of subject-matter jurisdiction, because it goes to whether the Tribunal may consider a claim based on a nonfinal judicial act. But, whether the Tribunal chooses to characterize it as a question of ripeness,

of admissibility, or of jurisdiction, the outcome in this case is the same: The claim should be dismissed because Claimants failed to seek appeal to the Supreme Court.

In the United States's view, if the Tribunal characterizes the finality requirement as an issue of admissibility, this does not compel it to defer decision on it, as Claimant suggested yesterday. Even an authority such as Judge Fitzmaurice who considers finality a question related to the merits treats it as a "preliminary objection." Thus, it is entirely proper to consider finality as "a preliminary question," under Article 21(4) of the UNCITRAL Rules, along with the issues of investment and time bar. We believe there is no dispute about the nature of investment in time bar as jurisdictional questions.

In other words, whether characterized as admissibility or ripeness or jurisdiction, the question whether Apotex can properly state a claim that nonfinal judicial acts violated the NAFTA is a threshold issue. It should be decided by the Tribunal as a matter of sound judicial economy. Both Apotex

and the United States have presented rounds of briefs and evidence on the matter and have argued it before the Tribunal. The question is now ready for decision by the Tribunal.

The Tribunal also asked the Parties to address whether there would be a difference if it applied--

PRESIDENT LANDAU: Sorry to interpret, just before you move on, can you give me the reference to the Judge Fitzmaurice--

MR. KOVAR: Yes.

PRESIDENT LANDAU: Or where.

MR. KOVAR: It's the Respondent's Exhibit 135 at Page 59.

PRESIDENT LANDAU: Thank you.

MR. KOVAR: The Tribunal also asked the parties to address whether there would be a difference if it applied a finality test that looks at whether a remedy was available or a test that looks at whether a remedy was futile. We do not believe that there are two competing tests for excusing failure to seek final appeal of challenged judicial acts. Claimants agreed

PAGE 326

326

10:12:29 with the United States in their written Memorials that the rule of finality requires Claimants to exhaust judicial remedies unless they were obviously futile.

The United States argued, and we submitted numerous authorities for the proposition, that the Tribunal should look to the availability of a remedy, not the likelihood of success of an appeal, in determining whether further appeal would be obviously futile. We pointed to the decision in the Loewen Case where the Tribunal, without expressly stating that it was analyzing whether appeal would obviously be futile, looked to whether an adequate and effective remedy was available in an appeal to the Supreme Court, and the Tribunal determined there that it was.

The Loewen Tribunal then rejected the Claimant's argument that it had compelling business reasons not to seek appeal. The Tribunal concluded that Claimant's failure to bring the appeal was a complete bar to bringing the claim based on the alleged wrongful judicial acts. Loewen did not look at the likelihood of success.

Just like the Claimant in Loewen, Apotex has

PAGE 327

327

10:13:47 failed to seek review from the Supreme Court, despite the availability of that court to review the alleged errors of lower courts. And just like the Claimant in Loewen, Apotex offers justifications for its failure related to its litigation strategy and the likelihood of success rather than to the availability of the remedy.

But just like in Loewen, Apotex's failure to seek review from the Supreme Court bars Apotex from bringing before this Tribunal claims based on its nonfinal judicial acts.

In their argument yesterday, Claimant's counsel stated that the futility test goes to it, even if it was available, could you have gotten the relief you needed in the time you need today? Here, we definitely could not have. This is the transcript at 271:20 to 272:1.

Counsel remarked how statistically unlikely any single case will be granted certiorari by the Supreme Court. But as the authorities cited in our Slide 13 from yesterday underlined, this is not a ground for excusing a lack of final appeal. Indeed,

PAGE 328

328

10:15:12 echoing Judge Smith's expression of sympathy about the few cases that the Supreme Court takes every year, Judge Lauterpacht, a member on the International Court of Justice in the Norwegian Loans case stated, "I can appreciate the contention of the French Government that there are no effective remedies to be exhausted. Even if I must hold that, however contingent and theoretical these remedies may be, an attempt ought to have been made to exhaust them."

And judge Fitzmaurice, also on the International Court of Justice noted, "Wherever a possible remedy exists, recourse must be had to it, each if this is, in fact, highly unlikely to be successful." In other words, the probability or otherwise of success is quite different in principle from the question of effectiveness; and that to substitute one test for the other as the criterion for displacing the local remedies rule would be incorrect, and would also drastically alter the incidents of this rule.

To the extent Apotex is arguing that the futility test is distinct from an availability test

PAGE 329

329

10:16:30 because it requires the Tribunal to look at the question of likelihood of success, we strongly disagree. Apotex simply cannot sustain its argument that the test should be the likelihood of success. Where Apotex concedes that it could have sought certiorari from the Supreme Court or sought remedies in the District Court but did not, it's barred from bringing its claim.

Thank you, Mr. President.

PRESIDENT LANDAU: Thank you very much. That completes--

MR. KOVAR: We have one final word, if you don't have any more questions.

Mrs. McLeod.

MS. McLEOD: Mr. President, Judge Smith, Mr. Davidson, we would like to thank you for your preparation for this hearing and for your careful attention over these two days. As I noted yesterday, the United States views NAFTA Chapter Eleven as important both to ensure the international protection of foreign investors and their investments and to preserve the three NAFTA Governments' ability to

10:17:34 regulate in the public interest, to protect health and safety. Arbitrations such as this one are a key part of Chapter Eleven, and we appreciate your dedication to these proceedings.

Applying the plain terms of NAFTA Chapter Eleven requires the finding that Apotex's claims cannot proceed.

First, in NAFTA Chapter Eleven, the United States consented to arbitrate disputes only with Investors who seek to make, are making, or have made investments in the territory of the United States. Apotex is not such an Investor. Apotex is, by its own description, a Canadian generic pharmaceutical manufacturer that develops, tests, and produces its drugs entirely in Canada. Apotex exports its drugs from Canada to countries all over the world, including the United States. Apotex concedes that it has no place of business or operations in the United States.

In short, Apotex made no investment in the United States.

In the course of our arguments and in efforts to respond your questions, we have tried to focus on

10:18:44 the application of the text of the NAFTA in international law to the facts as presented in these proceedings. We've also tried to bring to your attention pertinent awards from previous NAFTA tribunals as well as other persuasive and relevant authorities. We ask that you find, based on this record, that Apotex's Abbreviated New Drug Applications do not qualify as investments under any of the provisions of NAFTA Article 1139, and both its Sertraline and Pravastatin Claims should therefore be dismissed.

To the extent the ANDA could be considered property rising to the level of an investment under Article 1139, which we do not think it could, that investment was made in Canada, where the ANDA was developed, not in the United States. As the Tribunal in Grand River made abundantly clear, the fact that Apotex made this investment in Canada in order to comply with U.S. regulation is irrelevant to this inquiry.

Apotex's Pravastatin Claim is time-barred in its entirety under NAFTA Article 1116(2) because that

10:19:48 claim seems to be based on the allegation that FDA's April 11, 2006, Letter Decision violated the NAFTA. Even if Apotex's challenge to the U.S. court decisions can be deemed a separate claim, the FDA letter cannot form the basis for a finding that the United States violated NAFTA Chapter Eleven.

To the extent Apotex's Pravastatin Claim is based on judicial acts, these acts were not adopted or maintained by the United States as required for a Chapter Eleven claim by NAFTA Article 1101 because they were not final.

At this hearing, Apotex readily conceded that it could have appealed its Pravastatin Case to the Supreme Court, and that the Supreme Court could have provided it with relief; therefore, the Pravastatin Claim, as it relates to the nonfinal judicial acts, must be dismissed.

Mr. President, Members of the Tribunal, in closing, let me thank you once more on behalf of the United States for your efforts in this case, including the very insightful questions you posed to the Parties. Let me also take this opportunity to thank

10:20:55 Ms. Antonietti for her assistance throughout these proceedings, our NAFTA partners Canada and Mexico for observing these proceedings, and Mr. Kasdan for his always excellent work.

This concludes the United States's presentation.

PRESIDENT LANDAU: Thank you very much.

At this stage, we have no further questions, and I thank the United States very much for their presentation.

We will now have a break before the Claimant's final argument. I think we have the luxury of time today, so do you want to have or suggest a particular amount of time in order to be fully prepared for your final presentation?

MR. RAKOCZY: Fifteen minutes is fine with the Claimant.

PRESIDENT LANDAU: All right. So, it's now 20 past 10:00. We will reconvene in 15 minutes' time. Thank you.

(Brief recess.)

PRESIDENT LANDAU: So, we will begin again.

PAGE 334

Mr. Rakoczy.

CLOSING ARGUMENT BY COUNSEL FOR CLAIMANT

MR. RAKOCZY: Thank you, Mr. President, Members of the Tribunal. William Rakoczy on behalf of the Claimant.

I will address each of the objections in turn beginning with the jurisdictional investment objection, followed by the timeliness and the finality.

Apotex respectfully submits that none of the objections can be sustained. They should all be rejected so that this case can proceed on the merits.

Now, on the investment issue, what is an investment under NAFTA, I think as an initial matter, we need to make sure the lines of analysis are clear here and that we're not blurring what the Tribunal needs to look at because there has to be both an investment itself, and then that investment has to be in the United States. And, for example, we can point back to the Bayview Tribunal which grappled with the latter question and the reason why was because the Tribunal in that decision was not disputing that, in

PAGE 335

fact, the Claimants had an investment. They had water rights in Texas. It was an investment. The issue was, was it an investment in Mexico? And that's the issue they grappled with and in that case or that matter, they came to the conclusion, yes, again, it was an investment, but not an investment in Mexico.

The same could be said of all the other Tribunal Awards that we've been talking about here: Grand River with cigarettes, cattlemen's with the cattle. There's no doubt that under NAFTA's expansive property definition of "investment", the cattle that was an investment, but it wasn't an investment in another State, and the same can be true with the cigarettes. Clearly an investment, clearly property acquired with the expectation of economic benefit, but not an investment in another State.

So, what I want to do is address first the investment definition itself, and then I'll go to the "in the other State" requirement.

Now, the Government wants to talk about how we need to focus on the intent of the Parties to NAFTA and what do they intend to subject themselves to. We

PAGE 336

completely agree with that, and we can go to the definition of itself of investment. And we don't have to guess what the Parties were talking about here. The Parties to NAFTA were not trying to limit investments to real estate or real estate interests or other interests that might implicate things like takings in the United States. This definition is much broader than that. It's real estate or other property, tangible or intangible. And in fact, we would submit that's a very broad definition. It's true, perhaps it's not as broad as some other investment or bilateral treaties that talk about all assets being an investment, but still a very broad definition: Any property, tangible or intangible.

And the fact of the matter is that is what the contracting Parties to NAFTA intended to protect.

So, two requirements. And again, I want to make sure we don't blur the lines of analysis here. The first is property, intangible or tangible; and the second is acquired in the expectation or used for the purpose of economic benefit or other business purposes.

PAGE 337

Now, from what we heard today, I don't think it's extremely clear, but I don't think the Government can seriously contend that an ANDA is not property. Now, yesterday we heard a lot from the Government about how this Tribunal can't determine on its own that an ANDA is property unless it finds some basis in U.S. law, domestic law, whether a case, a statute, a regulation, an act of Congress actually saying an ANDA is property. That's not the case. U.S. domestic law is clear what property is. Property can be interpreted using U.S. law. The Government admits that. We can use U.S. law as informative.

We know, as everyone acknowledges, that the NAFTA, it's implementation acts and other Tribunal Awards have not done anything to vary the definition of property from its plain and ordinary meaning.

Now, if the Parties to NAFTA had intended for property to mean something other than broadly all property, tangible or intangible, we would have to see it in there, and we don't, so we go to its plain and ordinary meaning.

Again, the Government has not given you, even

PAGE 338

338

10:40:47 as we sit here today, after all the papers, all the argument, we heard nothing from the Government. What is property? Black's Law Dictionary gives us the most common definition. It's a common law definition, probably common to the world: The right to posses, use, and enjoy a thing. And I don't think the Government has given you any reason not to use a basic definition of property to that effect.

And, in fact, again as we set forth in our papers, and it's not disputed, U.S. Courts, for example, have regularly used that definition of property.

Now, can an ANDA satisfy that definition? We would say it clearly can. We don't think there is a serious dispute that Apotex and only Apotex has the right to posses, use, and enjoy its ANDAs. Apotex and only Apotex can transfer ownership of those ANDAs. We know that right from the Government's mouth. FDA's own regulations say only the Applicant owns the application; only the application can transfer ownership of the application. That is all of the attributes and indicia of property. The Applicant has

PAGE 339

339

10:42:04 the right to possess, use, and dispose of it.

Also, FDA treats ANDAs and other drug applications as proprietary and confidential information, and for good reason, because it contains sensitive trade secret know-how and intellectual property information. Again, not a fact we believe is in dispute. All of these are the attributes and indicia of property.

While yesterday the Government mentioned that somehow there may be other bundles of rights involved with property that don't relate to an ANDA, they never identified any of them. The bundle of rights we're talking about is the right to use, posses, and enjoy the ANDA. The NAFTA gives us no indication that it's using any other type of different definition of property, other than any property, tangible or intangible.

Now, Judge Smith, I wanted to address a question that you raised yesterday, and I thought was an interesting one, when you asked, has anyone ever said they have a property interest in a New Drug Application, and that if you tried to take that away

PAGE 340

340

10:43:11 from me, could I assert a takings claim or some other type of claim for compensation? And what we did was we scoured the record here again to see if anyone had ever made such a claim, at least based on the submissions before this Tribunal, and we looked at Exhibit C-76, which was a case involving a company called Tri-Bio Labs versus the FDA. It went all the way to the Third Circuit Court of Appeals.

Interestingly enough, this was a case involving an animal New Drug Application. And like on the human side, FDA regulates animal drugs and you submit a very similar drug application. This case involves some generic companies that didn't want to do their own application. They asked the FDA, give us the application and the data of the brand-name animal drug because it makes no sense for us to go to the expense of repeating all of this. The FDA said we won't do it. And the reason the FDA said they won't do it is because it doesn't belong to you, it's a property interest of the drug applicant. And we can see right here, "the principal rationale the Agency offers in defense of its policy is that Pioneer

PAGE 341

341

10:44:23 Manufacturers posses a property interest in the test data they present to support their New Drug Applications. The FDA posits that this propriety interest may not be appropriated by the Government without just compensation."

So, here we have it right out of an Agency of the Respondent here, recognizing the property interest in the data, and the application.

PRESIDENT LANDAU: I have a question. Forgive me.

MR. RAKOCZY: Yes, sir.

PRESIDENT LANDAU: Isn't this referring to test data?

MR. RAKOCZY: Yes, Mr. President, this is referring to test data to present and support the New Drug Application. The way you see it, that test data is actually part of the drug application, just like an ANDA contains a plethora of test data, analytical data on the drug, bioequivalence testing and other data is actually submitted inside the application itself.

And all of these things are very proprietary, sensitive; and, as I said yesterday, technological

know-how. Much of it is trade secret.

So, yes, and I wasn't presenting this case as dispositive. I was just pointing out that in our record here we do have even the Government taking the position that there may be a property interest in some of the data and some of the things associated with these Drug Applications.

So, even the Government at one time has admitted that there can be property interest in these things. We don't have to rely solely on this case. We pointed it out only because yesterday the Government made much of the fact that they weren't able to find any U.S. authority talking about applications being property or having the--having anything associated with it like a property interest, and to Judge Smith's comment asking, has anyone asserted such interest in these things in the United States? And the fact is they have, and the FDA itself has recognized as much.

And as a matter of fact, those FDA regulations that prevent the FDA from disclosing and giving out ANDAs and drug applications, they have this

interest at their foundation. The reason the FDA has that is because the FDA recognizes that this is your proprietary interest, this application and everything in it.

So, we would submit this has all the indicia of property.

PRESIDENT LANDAU: Before we move on, since I've interrupted, I might as well exploit the situation. It leads me to one question I do want to ask which I think perhaps arises out of the Tri-Bio analysis. I understand the context in which you're putting--you're referring to this.

But might it be said that when analyzing an ANDA as an element of property, if one were to do that, there might be three distinct elements. One element could be proprietary data, of course, we would say data--that is the know-how and the technical information that might have been put together into the ANDA.

The second element might be the application itself being a pending process, which might be bought and sold or assigned.

And the third element might be the contingent drug, i.e., once it's approved it will be a commodity to be marketed. So, those might be three distinct elements of property although they all sort of sit together.

And if that analysis is correct, would this Tribunal have to consider each of those elements in applying NAFTA? Or do you just lump them together as one?

MR. RAKOCZY: As we discussed yesterday, Mr. President, we would agree that an ANDA investment, it does have connotations of all three of those. When you prepare it and you have the ANDA, you have all the test data and all the know-how and the intellectual property in it, that is a property interest that you own and you can sell it or dispose of it even before you file it.

When you file it with the FDA, obviously, yes, that application has additional intrinsic value now going forward into the future because it is clearly put on file with an expectation of obtaining economic benefit.

And then, lastly, yes, it has even additional future value because, if it's approved, hopefully you can manufacture and commercialize that drug in the United States, so we would submit the panel or the Tribunal can look at all three of those. What we would not agree is that you can so easily separate them because the ANDA investment itself or the ANDA property or A-N-D-A property, we would respectfully submit, is all of that bound up together, and that is why these things are so valuable and why ANDAs are bought and sold on a regular basis.

And to suggest as the Government did yesterday, that just because something is sold doesn't suggest that it's property, to us--it seems absurd. What else would an ANDA be if it's sold for incredible value both before it's approved and when it's approved or even before it's put on file when it's an existing pipeline ANDA.

Of course, these things have all the indicia of property, tangible and intangible.

PRESIDENT LANDAU: Forgive me, I won't keep you a bit, but further just on this tack, I've

understood your submission that we should not look at these separately. If, for the sake of argument, contrary to your submission, that we were to look at them separately, would your submission be that each of those three elements by themselves would constitute an investment for the purposes of NAFTA?

MR. RAKOCZY: For purposes of the broad NAFTA definition we're dealing with here, we would submit it would have to be a definition under NAFTA because if we look at that first element, when you have the application, let's say, for example, when it's first prepared and put together, that is the culmination of sometimes years of research and development, millions of dollars; and, then inside that ANDA, you have all that know-how, trade secrets, and intellectual property. Certainly that would satisfy the definition of "property" or an "investment" under NAFTA, which is just property, acquired, put together for the expectation of economic benefit. That's why you put it together.

But then, even if you wanted to move separately, then now you have the application put on

file with the FDA. Clearly it's still property. It's not lost any of its connotations of property just because it's been put on file with the regulator who may or may not approve it. In fact, it is still put on file with the expectation you would benefit from it.

So, even if you look at it solely and narrowly in that fashion, it's still an investment.

And we would submit that the third factor, the idea of a contingent future benefit that you may get approval and market that product, certainly that's a part of the investment as well because that, we submit, would perfectly satisfy the definition of "acquired" for the expectation of future benefit. And that expectation word I keep using, I think is an really important one under this definition.

And one that we're a little disturbed with the Government's argument today, because they never mentioned it. When they were making their arguments today about acquired, I listened very carefully. I don't ever remember the word "expectation" ever being used in their argument. They argued over and over it

can't be acquired because it's before a Regulatory Agency that may never approve it or could revoke approval or could change the conditions of approval.

Well, the definition just doesn't say acquired for use and enjoyment commercially now. It says acquired in the expectation of economic benefit.

As a matter of fact, that is the only reason, in the end, that you actually want to put an ANDA on file and maintain it and take it through to its final approval.

Respondent itself has conceded over and over in its submissions that Apotex put this ANDA on file. They prepared it, they put it on file. They maintained it because they wanted eventually to seek to enjoy the commercial sale of those goods in the United States.

So, clearly this is an ANDA or a property or an investment acquired with the expectation of economic benefit.

Again, that doesn't take away from the fact that the ANDA itself has intrinsic value even before it's finally approved. We know that's a fact because,

as the Government concedes, these things are regularly sold and disposed of for many millions of dollars.

So, we would submit that it satisfies the definition, again, which is very broad, property, tangible or tangible, and it definitely is acquired for the expectation of economic benefit or other business purposes.

Now the Government appears to want to make some very fine lines and cuts as to what it means to be acquired. Is it acquired when you first put it together. Is it acquired when you file it with the FDA, when you get final approval, we would submit that that really doesn't matter.

And in fact, an ANDA, in the strictest sense of the term, is acquired once you put it together, once you prepare it, and you have it. It has now become an asset in investment, and again with the future expectation of economic benefit.

So, no matter what definition of "acquired" you're using here, we submit it's satisfied.

What we really think the Government is getting at with this "acquired" issue is back to the

PAGE 350

350

same argument that they have been using over and over which is the approval status or the regulatory oversight of the FDA. I think in the end, that's their major argument. That's their point. I don't think the Government can seriously take away from the fact that ANDA is property. What else is it? It can't be anything else but property.

What their big, big argument here is, it can't really be property, it can't really be acquired for future economic benefit because the FDA could revoke approval, the FDA could change approval. The fact of the matter is I could point you back to the Tri-Bio Case, the FDA said nothing about that drug application and data not being a property interest because the data could be revoked and rejected which, as part of its mission to protect the public health, that's how the FDA regulates drugs. They're always free to reject data, reject applications, but that doesn't change the fact that it's still property that only the ANDA Applicant can use and enjoy and dispose of.

So, we would submit, by any measure, an ANDA

PAGE 351

351

is property, tangible or intangible and it's acquired in the expectation of economic benefit.

Now, that gets us again to the second part of the analysis because we believe there definitely is an investment here, but obviously the question becomes is it an investment in another State? The Government's position is it can't be.

Again, we believe that position in the Government is rooted in this real property idea they have because the Government basically wants to say, if you don't have a facility in the United States, if you didn't do your development in a factory or a lab in the United States, then this ANDA property can't be an investment in the United States.

Again, we think that that's parsing the definition too fine. The definition isn't just real property, real property interest. It's any property.

And as we know from other the Tribunal Awards, once we determine something is an investment, then how do we determine whether it's an investment in another State?

And this is something that the Bayview

PAGE 352

352

Tribunal again grappled with fairly seriously. And I think it's telling that again in their submissions and in their arguments the last two days, we don't have the Government giving any type of satisfactory explanation or addressing at all the Bayview Tribunal's concern with when we have something that's clearly a property interest or an investment like the water rights, how do we know if that's an investment in the other country or in the other State? Because, clearly, Bayview had interests. They had interests in the water rights, in the river, no one was disputing that. That was an investment. But is it an investment in the other country or in Mexico or, in this case, in the United States. And we respectfully submit the two factors or the tests that Bayview looked at should be dispositive here. The salient characteristic, according to the Bayview Tribunal, of whether an investment is an investment in another State is whether it is "primarily regulated by the law of a 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

PAGE 353

353

nationality."

Obviously, that's the case here. We have an ANDA created by U.S. law, it's filed under U.S. law. U.S. law controls and governs it, including all disputes regarding that ANDA. Here, you have an Investor, Apotex, who is making an investment in an ANDA that is protected only by the laws and created only by the laws of the foreign State. This isn't an investment that can be used in Canada. They're not protected by the Canadian regulatory laws. It's all about the law of the United States.

And we submit this goes back to the objective and policy of NAFTA. It's not just the objective that the Government pointed out today to encourage the infusion of capital. We want to encourage cross-border trade. We want Applicants or Investors to feel as though they could leave the protections of their own State and be satisfied that they will get the protections they need in the foreign State. Their investment will be governed by that foreign State. It's a textbook example of ANDA investment.

And we can look to the second test that

Bayview looked at, the legally significant connection. What is the State with the legally significant connection to the investment? In Bayview, they wanted to see that it was the foreign State, that it was legally connected to the State applying the measure at issue that was being challenged. And again, unlike Bayview, Apotex's ANDA investment satisfied that test because the only legally significant connection at all is to the law of the foreign State or here the United States. There is no connection to Canada whatsoever.

And that's very unlike what happened to the Bayview Claimant. The Bayview Claimant clearly had an investment. They clearly owned that water. They had property rights in it. No one disputed it, but they didn't have property rights, it wasn't governed by the law of the foreign State or Mexico. All their rights, all the law that created their rights, all the law that governed their rights was in Texas or their domestic state. So Bayview was comfortable saying that's not an investment in another State. That's an investment just in the United States.

But here again, Apotex's ANDAs? Yes. Were

they prepared in Canada? They were, but they were filed and maintained in the United States for the sole purpose of developing and marketing a product in the United States for the purpose of obtaining economic benefit in the United States. And again, they're regulated only by United States law, not Canada. We would submit this is exactly the type of investment that NAFTA was formed to protect and it wants to encourage.

So, we would submit Apotex is an Investor. It has made an investment in a foreign State, and that jurisdictional objection should be overruled.

I can quickly move on--

ARBITRATOR SMITH: Can I, before you, and since my question or statement is what started all of this, does it make a difference--I have a question about the application process versus the content of the information. The content of what went into the application, as far as I can tell, all was developed in Canada. Your data was collected, your testing was done, your expectations arose in Canada, and you were not deprived of any of that. In other words, that

underlying information/expectation, none of that was expropriated by the FDA or anybody, as far as I can tell. Apotex still has it.

And I understood your argument yesterday of well, Canada has a different regulatory system, probably Germany does, France does, but you're still left with that basic body of information that still has value, I would assume, probably can still be sold somewhere, not just to the United States, and so really the only thing that the United States did or the role it played was in the regulatory act of not approving how that data was presented.

So, can you address that for me?

MR. RAKOCZY: Yes, yes. Two points, Judge.

First, not all of the data and information came solely from Canada. It is true on the active ingredient, the sertraline drug itself, the pravastatin drug, that information was developed, tested, made in Canada. The fact of the matter is though, the inactive ingredients, the rest of the stuff that went into these drug products, that information and that physical product all originated

from the United States. Apotex purchased that from the United States. That included not just the physical inactive ingredients, but the data and the information on them came from the United States.

Then it was tested in Canada, put together in a finished drug product, and then that is all embodied inside of the ANDA.

Now, as to your second point, Apotex can't enjoy that ANDA under the laws of Canada or any other country. That ANDA investment, that product and everything bound up in the application it can only be used in the United States. And what happened here was, does the ANDA have intrinsic value? Yes, it does. But the value of that ANDA was significantly hindered if not decimated in the first instance when Apotex was not able to go to market when it believes Congress intended for it to go to market with the first-filers in this instance. And that's what happened to the ANDA. Apotex made this investment. It relied on United States law because, under United States law, in Apotex's view, it should have been able to launch those ANDA products as soon as those patents

PAGE 358

358

11:04:39 expired. It couldn't, and suffered serious damage, serious damage, to the ANDA here.

So, it's not the value, yes, there is value in investment wrapped up in what's in the ANDA, but it's also value wrapped up, as I said earlier, into what you can use it for, the future economic benefit.

And I apologize, there was an issue, if I could just go back real quick to the FDA approval revocation issue, and I apologize, I mentioned this yesterday a little. We think this is a bit of a red herring argument. It's nice for the Government to point out that there are all these reasons why an ANDA could be invoked or why it might not get approval, but those aren't our facts here. It's undisputed these ANDAs were approvable. These ANDAs had satisfied all the requirements for approval. The FDA had found these ANDAs were safe and effective in the United States. The only reason these didn't receive final approval was because of the 180-day exclusivity which Apotex has claimed was only there because of the breaches here.

So, again, we don't believe this panel should

PAGE 359

359

11:05:54 go off on what we call pure speculation as to what may or may not have happened to those ANDAs when the fact was they were tentatively approved. They were then finally approved as soon as those exclusivities expired.

So, there is no reason for this panel to look behind this FDA regulatory scheme and say, well, that ANDA approval could have been revoked. The fact of the matter was it wasn't. Apotex got timely tentative approval, they then got their final approval. So, there was no revocation, there were no issues here, so we don't think that that's a basis to say that somehow this is not property.

Yes, sir.

PRESIDENT LANDAU: Forgive me, before you move on to the second objection, there is one other question I wanted to ask, and again I'm afraid it's just going back one step. In your analysis, you set out a distinction between the two requirements: firstly, investment; and, secondly, in the territory of the United States. I just want to go, with apologies, back to investment rather than the second

PAGE 360

360

11:07:11 in the territory.

On the first one, you've taken us to the wording of 1139(g). And the way that I've understood your analysis is to look at the two different requirements; property, tangible or intangible; and then there are the words "acquired in the expectation" or "used for the purpose of economic benefit or other business purposes." I wanted just to focus on the second of those, that wording "acquired in the expectation" or "used for the purposes of economic benefit."

Following the analysis you've put forward, one applying Vienna Convention, customary international law and treaty interpretation, you've read those words for their ordinary meaning, plus in the light of object and purposes good faith, et cetera. But those words are very broad, if you simply read them as they're stated, and they would apply, arguably to a simple commodity that's being purchased for resale.

If I purchase a commodity, the commodity will be a property under the Requirement 1, and I'm only

PAGE 361

361

11:08:20 buying it in order to sell it onwards, then I seem to have met number two; is that right?

MR. RAKOCZY: I would say except for NAFTA does contain some express exclusions for things like just the sale of goods. I think you heard the Government talk about how NAFTA goes out of its way to exclude certain things, but we think that goes exactly to our point of interpretation, is we agree, that is an extremely broad definition, whether you parse it into the two requirements like we have or not, it's any property acquired for economic benefit.

We would say reading that in good faith and in context, that unless you find an exclusion somewhere else in the NAFTA or in the intent, then you have to read it broadly to include any investment acquired for the purpose of economic benefit. We would submit that's exactly how you read those words in context.

And I think it's important to note, Mr. President, as you noted, they are very broad. The Government has come in here saying that NAFTA wasn't intended to be broad, but let's look at the language.

11:09:30 What did Parties to the NAFTA agree to? Extremely broad language. If they didn't want investments to be anything but real property or real property like interests sitting in the foreign State, they could have said that. But they went on. They went on to say real property or other property acquired for economic benefit. Extremely broad language.

So, we would disagree with the Government that the Parties to NAFTA were expressing a narrow intent here because again, as I said earlier, while we might agree, this definition may be slightly narrower than other Treaties that say all assets, but it's still very broad language, and it's not limited to real property interests. It's not limited to interest like real property. They have to reside physically somewhere. It's any property, tangible or intangible.

And again that acquired limitation after that is broad. It's not limited to acquired and benefiting right at this moment. It's the expectation of benefit. Although, as we discussed earlier, we would submit an ANDA would satisfy having a benefit now or acquired for the expectation of a benefit in the

11:10:46 future.

PRESIDENT LANDAU: And wouldn't applying again, customary to international law as expressed in the Vienna Convention, wouldn't one have to look at this wording in the context of where it sits in NAFTA, i.e., Chapter Eleven? I mean, you have mentioned in the course of your previous argument, your argument earlier today, that the objective of NAFTA was cross-border trade, and I think you say that to take issue with the United States's suggested objective of NAFTA.

But it could be said, again for the sake of argument, the argument is there, that cross-border trade is a very broad notion, that NAFTA may have parts of it concerned with cross-border trade, but we are concerned with Chapter Eleven, which is investment. Isn't that a narrower objective or purpose that might feed into the interpretation of these words?

MR. RAKOCZY: You're correct, Mr. President. Cross-border trade could be construed as a very narrow--excuse me, a very broad objective, and we are

11:11:50 concerned with Chapter Eleven. But I think that that's why the Bayview Tribunal is so instructive here because the Bayview Tribunal was trying to grapple with precisely this issue, you know, what it meant--if the purpose is to promote this cross-border trade and if, as the Government says here, NAFTA wasn't for just any old, plain-old run-of-the-mill cross-border trade dispute, then how do we figure out if it's the investment in another Party, and that's why I think the tests in Bayview are very, very relevant here because they set out--again, we don't have any dispute or alternative construction or argument from the Government about what exactly does it mean, these salient characteristics, to put yourself in the hands, solely in the hands of the foreign State, which is what we believe Apotex did here, and that's the type of foreign trade and investment, we would submit, that object and policy is all about.

PRESIDENT LANDAU: Thank you.

MR. RAKOCZY: Now, very briefly, Members of the Tribunal, I will go into the timeliness issue first.

11:13:00 We still submit that when you're talking about a Party that is exercised its statutory rights to judicial review of Agency action, that that constitutes, in the words of the Government, a "single action" for purposes of the timeliness provisions of the NAFTA. And in fact, under our facts here, that's the only way you can reasonably interpret this because, in the end, by virtue of Apotex's seeking judicial review and allowing the courts of the United States to correct any supposed errors, Apotex did not gain knowledge of the breach and knowledge of the harm until after the judicial review was completed. And, in fact, the Government has not addressed the fact that Apotex actually obtained a temporary stay for a short period of time of the offending FDA Administrative Decision.

So, what happens, then, to their theory that somehow could have been a NAFTA arbitration claim? Because at that point in time Apotex did not have knowledge of harm or damage. It wasn't until after the stay was lifted and after Apotex lost in the courts that it obtained knowledge of the breach.

So, when--and we're not submitting that you are always required to exhaust administrative remedies, and in this instance we're not saying that you have to seek judicial review of final Agency action. What we're saying is under United States law it gives someone who has been aggrieved by final Agency action the right to do that; and, when they exercise those United States statutory rights, they should not be penalized for doing so, which is basically what the Respondent's position amounts to: Penalizing those who want to seek to exercise those local remedies which they're perfectly and lawfully entitled to do, and it provides a disincentive to pursue those local remedies.

So, we believe the Respondent's position is untenable. However, that said, even if we want to look at these issues as, Mr. President, you mentioned yesterday, is there a distinction between seeking review and basing the claim on an FDA Administrative Decision as opposed to judicial decisions, we would submit that when you're talking about APA or Administrative Procedure Act review in the United

States, there is no difference. There can't be. And this is something that you didn't hear from the Government. What happens when a court in the United States reviews final Agency action? It's de novo review.

Here we have a statement from one of the pravastatin courts itself. "In effect, we review directly the decision of the Agency under the familiar standards of the Administrative Procedure Act," they are conducting a de novo review whether the Agency has acted in accordance with law.

Now the Government mentioned for the first time today this Chevron I versus Chevron II issue. We dispute that. There is deference to the Agency by a reviewing court only when a statute is ambiguous and the Agency has been delegated gap-filling authority by the United States Congress under the primary thrust of Chevron I or the Chevron I prong, the Court is looking to see if the Agency has or has not violated law. Has it acted in accordance with Congressional intent and statutory law? That inquiry gets no deference from the courts. That inquiry is de novo, and again, the

Court is reviewing directly the Agency to see, has it or has it not acted in accordance with law.

Given that that's the analysis in the United States of so-called "APA review, it's impossible to distinguish or to separate the FDA Administrative Decision from the courts reviewing it.

And I think the answers you got from the Government about what you can do with the FDA Decision are wholly unsatisfactory. All they said is you can look at it as background. That just begs the question of, what does it mean to look at an FDA's Decision as background, when that decision forms the only legal and factual predicate for the judicial review.

In those circumstances, whether you're looking at a claim based solely on FDA Administrative Decisions or a claim challenging the judicial action reviewing them, the Tribunal has to be able to look at that FDA Decision for beyond just factual background or the fact that a decision occurred. The Tribunal, like the courts, has to be able to see what happened in that decision, what did the FDA do? What law were they following? Did it appear they were following the

strict letter of the law and strict Congressional intent? Because that's exactly the inquiry the court is doing under this so-called "Chevron I prong, the United States courts are putting themselves into the position of the Agency and saying, did what happened here comply with the United States law? How can you review that? How can you do meaningful review of whether the United States court has engaged in less than or has engaged in a denial of justice or some other minimum standards of international treatment, if you can't look at the legal predicate for what they were reviewing?

So, to us, it makes no difference whether you look at this as solely a claim based on judicial action or not. The fact of the matter is, you have to be able to look at the legal propriety of the FDA Decision because that's what the courts do. There would be no judicial review. There would be no APA case, were it not for that FDA Decision and the grounds for that decision and what the Agency did.

So, it's not just factual background. The Tribunal has to be able to look at that decision

11:19:33 through the eyes of the Court, and the Courts are not looking at it as solely background. They're looking at it, again, in the first instance de novo to see has the Agency acted in accordance with law.

So, we believe under any distinction again, looking at the FDA Decision alone or the judicial action, you have to be able to look at that decision, that administrative decision in toto.

Now, I think you heard today a much clearer statement from the Government about exactly what's going on here. They want to kick that FDA Decision out of this Tribunal so that they can then turn around and say, you can't engage in meaningful review of the court decisions. You can't look at whether there was a denial of justice. Well, that's exactly why their position is improper, and it's wrong. It's just a shortcut or back-handed way of attempting to prejudice the merits and undermine the merits from the git-go.

ARBITRATOR SMITH: Mr. Rakoczy, excuse me for interrupting you again, but let me ask this: You know generally what the standard of review is, I think, is one thing, but this is an unusual case in which, to my

11:20:47 recollection, the Court of Appeals specifically kicked it back to the FDA and said, "We're not going to decide this. We're not going to send it to the District Court. FDA, you're the ones that know what's going on. We want your expertise, your knowledge. Make a decision in light of what's happened."

I find it, frankly, puzzling that then your argument that under those facts and those circumstances that there would be no deference to that FDA Decision after the Court had specifically said this is the body we want to make the decision. Well, it would depend on the claim, Your Honor. And, as a matter of fact, I can get into more detail. That was the first appellate decision. You're right, the first appellate decision from the D.C. Circuit Court of Appeals remanded back to the Agency. They said to Judge Bates, the District Court, "We disagree with your analysis, but on top of that, we want the FDA to weigh in here, and for the first time give its reasoning," because remember this was a long running dispute, and the FDA had not been giving its reasoning for its decision, and--and this is very important, the

11:22:03 Court also told FDA, don't just bring your expertise and reasoning to bear. They specifically said you'd better tell us why this situation is different from those prior situations involving Granutech and the Ticlopidine decision, because there were serious allegations and claims of discriminatory treatment even at that early stage of the proceeding, and the D.C. Circuit was very concerned, were similarly situated applicants being treated alike, and they wanted a reasoned explanation under the statute why a certain court decision in Ticlopidine and why a certain court decision in a case called Granutech, why those were court decisions under the plain language of the statute and why necessarily this one might not be for pravastatin.

And so the Court was not just kicking it back for FDA to use its reasoned discretion and then to get utmost deference from the courts. The courts wanted to know also under the plain language of the statute, can these pravastatin orders be squared with the Granutech and the Ticlopidine orders under the plain language of the statute.

11:23:17 And that is not a deferential standard of review. As a matter of fact, the claim, it was later brought by Apotex in the Court raised a discriminatory treatment claim. One of Apotex's primary claims, not the only one, but one of several was that this was pure and simple discriminatory treatment by the Agency and the courts that there was no difference from the order that Apotex got in pravastatin or the ones in Granutech or Ticlopidine under the plain language of the statute.

So, one of the primary thrusts of Apotex's claims was a violation of the plain and ordinary language of the court-decision trigger statute itself. That analysis, Your Honor, we respectfully submit, gets no deference under Chevron I or any other administrative case, for example, like Skidmore or some of the other APA review cases. That analysis is based solely on the plain language of the statute, and no one gets any deference. The Court looks de novo in the first instance: Does this order satisfy the plain language or does it not? And it doesn't really matter in that inquiry what the Agency said or not because

11:24:29 the Agency can never vary from the plainly expressed intent of Congress and the plain text of the statute.

So we would submit here it doesn't make sense given the nature of what was going on in this APA review to separate and to say you can kick out the FDA Decision because it's all part and parcel of what the courts and the Agency were doing. They were all bound up together, and we think what the Government is doing is just a cute, albeit clever way to attempt to insulate those court decisions from review because they can kick out the predicate or the legal basis. Then they're just going to want to march back in here and argue, well, they can't have a claim now because you can't review the court decisions because you can't look at their legal predicate for their analysis, and we submit that's just wrong as a matter of law, regardless of any time limitations issue.

With that, I can get to the final issue here: Judicial finality.

And I think you heard the Government say that there are not two tests. Well, whether there are two tests or not, the fact of the matter is there are two

11:25:46 requirements. You have to look at would the remedies be both available, number one, and effective and adequate.

And, Mr. President, we went back and we looked at the authorities that you mentioned on Slide 13 of the Government's last presentation yesterday, and then we went back to the Loewen Tribunal. That Tribunal actually dealt with and grappled with all of the same authorities. As a matter of fact, the authorities in the Government Slide appeared to have been plucked right out of the Loewen discussion. And that Loewen Tribunal concluded, quote, "it is an obligation to exhaust remedies which are effective and adequate and are reasonably available." So, it's really a two-part test. Whether it's two tests or not, it clearly has two requirements.

And something that the Loewen Tribunal also said which we think is important here, "availability is not a standard to be determined or applied in the abstract. It means reasonably available to the Complainant in the light of its situation, including

11:26:49 its financial and economic circumstances as a foreign Investor, as they are affected by any conditions relating to the exercise of any local remedy."

What does that mean? We submit that means again you don't look at availability in a vacuum. You do not say, as the Government does here, that just because someone could have filed the cert petition that that takes care of the inquiry. No, you need to look further than that.

And the Government's argument basically subsumes the two requirements. They still are looking solely at availability. The Government wants to say, if you have an available remedy, we don't care what it is. If you have it, you didn't do it, then it's not final. But again that skips the big requirement here, which is, as we see here, from a very well-known treatise, it's at Exhibit R-132 in the record, "but even if there are remedies existing and available, the rule does not apply if these remedies are obviously 'futile' or 'manifestly ineffective.'"

So we don't just look at availability. We have to go to that second step: Are the remedies

11:28:00 adequate and effective or would they be futile? And here, we are not, contrary to the Government's assertions, making a likelihood of success argument. It is true I raise with Judge Smith yesterday the frustration of the fact that the Supreme Court, from what most people can tell, doesn't hear a lot of cases, less than 75 cases a year out of ten thousand cert petitions. That's not the basis of our argument. We're not arguing whether Apotex would or would not have had a likelihood of success in the Supreme Court. We're arguing would it have been effective and adequate to go to the Supreme Court.

On that point, we submit, no, it could not have been. No matter when you want to start the clock running here, whether you want to start it at the June 2006, D.C. Circuit Court of Appeals Decision or if you want to start at the later one in August, and we submit you have to start at the later one because Apotex should not be penalized for seeking re-hearing rights before the Court that issued the decision. We believe that was the appropriate route to take. We don't believe it's the Tribunal's position to question

PAGE 378

378

11:29:15 Apotex exercising what are allowed and statutorily authorized re-hearing rights.

But whether you're talking about June 2006, August 2006, or September 2006, the fact of the matter is the Government does not dispute a cert petition could barely have been briefed. It would not have been decided by October 23rd, 2006. We know that from first-hand experience that evidenced the Sertraline Cert Petition took eight months just to be briefed and denied. And even if we give the Government the benefit of the doubt and we go to the average decision times for Supreme Court cases that actually accept cert, nine months' average.

So, it's not whether the Supreme Court would have been likely to hear and grant Apotex's relief, it's whether that would have been effective in the time it took, and it could not have.

The same goes for the District Court, although it doesn't sound like the Government is relying on this as much. They did mention further proceedings in the District Court. We think that argument is even worse for them because the mandate or

PAGE 379

379

11:30:26 the jurisdiction for the Court didn't return until the mandate came down in September 2006, with a month to go, having already been denied emergency relief in the District Court, Apotex had no way to get adequate and effective relief from Judge Bates in the District Court.

So, that leaves one theory from the Government, and I'm going to call it the Government's flier theory, which is we should have, or Apotex should have in, say, August or September of 2006, they should have filed an emergency stay petition and their cert petition. The problem with that is emergency stay petitions are not granted in a vacuum. The Supreme Court just doesn't look at a stay petition and say, hey I'm going to stay this while I decide your cert petition. They also have to look at the cert petition itself and decide are they going to take the case. And we submit, even on a flyer like that, irrespective of the chances of success, there was not time to get that done to give Apotex the effective and adequate relief it needed.

So, we believe these decisions were

PAGE 380

380

11:31:39 sufficiently final, and that this objection should be overruled as well.

Unless the Tribunal has any questions, Apotex would like to thank you for your time, and we appreciate you letting us make our presentations and our arguments. We respectfully request that all of the objections be overruled, and that this matter be set down to proceed to a Hearing on the Merits.

Thank you.

PRESIDENT LANDAU: Thank you very much. We would like to thank the Claimant very much for all the presentations and assistance that we have been provided with.

I think at that point, in the agreed schedule, we will have another short break, so that we can simply pool our notes and see if there's anything else we want to raise before we close the proceedings.

It's now half past 11:00. We'll break for 10 minutes, on the understanding that we may apply for more time if we need it. Thank you very much.

(Brief recess.)

PRESIDENT LANDAU: Thank you very much.

PAGE 381

381

11:42:13 There's only one area of clarification that we wanted to raise.

I hand over to Mr. Davidson to articulate it.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR DAVIDSON: Thank you.

Mr. Rakoczy, I have one question that I would like to have some clarification on. It goes back to your Slide 19 where you were talking about the FDA Decision and court decisions equaling a single action where you said, in fact, Apotex obtained temporary stay in the challenge of the FDA Decision thus demonstrating that Apotex could not have had knowledge of the harm until its judicial remedies were exhausted.

Are you--in other words, is Apotex taking the position that it could not have taken arbitration directly from the FDA Decision Letter?

MR. RAKOCZY: I believe the Government's position is that we could have. We could have taken a direct claim from the FDA Decision, and I suppose in the abstract that would be correct if there was no judicial review, if we had not pursued judicial

PAGE 382

382

review.

Our position is that that's all fine and dandy for the Government to say you could have an FDA Decision, and don't worry about judicial review. If you want to take it right up to a NAFTA tribunal, you can do that.

ARBITRATOR DAVIDSON: Right.

MR. RAKOCZY: Do we have a major objection or problem with that? Well, again, in a vacuum or in the abstract, no. But our issue is, in a forum like the United States, where you have the right to seek judicial review under the Administrative Procedure Act, and when you exercise that right, at that time these things become bound up into a single action, and our point is you shouldn't be penalized for exercising that judicial review, which is what Apotex did here.

But do we take issue with the government's position? Again, in a vacuum, irrespective of the APA, if we just throw that out and say, could you take final Agency action up into a NAFTA arbitration, we would submit that would be a measure. And if you were adversely affected by it and affected your investment,

PAGE 383

383

then you should be able to do that. But again, that scenario changes when you exercise your right to judicial review.

And here, the judicial review actually--the judicial review, interestingly enough, actually broke the chain of this supposed knowledge of the harm and the damage here, which I find interesting and which the Government hasn't really addressed.

The only issue I would mention is, I'm not sure the Government's position on if we took a NAFTA arbitration up directly from the FDA Decision, ignored the APA, I'm not sure if we would have gotten a straight out of the government, that they wouldn't take issue with that from an exhaustion and a finality standpoint, in particular because this waiver provision that the Government was talking about yesterday, we're not so sure on its face applies to claims for declaratory injunctive relief, but I'm not sure that's relevant to what we're talking about here because again Apotex did exercise those rights.

ARBITRATOR DAVIDSON: Thank you.

ARBITRATOR SMITH: I'm sorry, I'm probably

PAGE 384

384

being more dense than usual.

Is it your position that it's one or the other, or can they go concurrently? I mean, that was something I was wondering. Could you take--file an arbitration on the FDA Decision, but at the same time go to the Courts and pursue judicial relief, or are you--or is it necessary to make an election of one or the other?

MR. RAKOCZY: Well, the Government's position, in my understanding, clearly is you can do both--

ARBITRATOR SMITH: But I want to know what your position is.

MR. RAKOCZY: --with parallel actions.

And I guess for purposes of our analysis here, Judge, I would have to say that we're not disputing that the FDA measure or the FDA action is final Agency action, and it is a measure, so I guess we would have to say that you could, but that still doesn't implicate the limitations analysis we're talking about here because our position is that once you do the review, then it's the one single action.

PAGE 385

385

So, again, if we're talking in a vacuum that no one ever wanted to do judicial review or you couldn't get judicial review, then, yes, the FDA measure is final in and of itself to take it up, but I don't think you can look at it in a vacuum, because you have to look at the rights to seek review.

And what the Government is suggesting here, again we think this is penalizing Apotex for doing that, and for giving the Government a chance or the courts a chance to take another look at it.

ARBITRATOR SMITH: Thank you.

PRESIDENT LANDAU: Thank you very much.

Unless anybody else would like to say anything in response on the substance to the exchanges that we've just had, I think that brings us to a close on the substantive part of the proceedings and takes into just a little bit of housekeeping before we complete our hearing.

There are a number of procedural matters that the Parties have agreed and we've been informed of, and which we are very grateful. Whilst we are all here and we have the transcript, I might as well just

PAGE 386

386

11:48:12 record them, but they will then be set out in an order through the ICSID Secretariat.

There is an agreement between the parties that there will be no Post-Hearing Briefs.

There is an agreement that submissions on costs, both as to the allocation of costs between the Parties and the assessment of the actual costs will be filed simultaneously in six weeks, a six weeks' time frame from today.

There is an agreement that within one week of today each Party submit any suggested corrections to the transcript.

And there is an agreement that for the purposes of NAFTA Article 1128, the non-disputing parties to NAFTA have a period of one month within which to make any written observations that they may have and thereafter there be a period of two weeks for each Party to respond to any such submissions so filed.

I think then for the sake of good order, I would like to refer both Parties firstly to Article 15 of the UNCITRAL Rules, which records that the Parties

PAGE 387

387

11:49:31 are to be treated with equality, and at any stage of the proceedings each Party is to be given a full opportunity of presenting its case, and I would ask each Party to confirm that they're content that that has been satisfied in this case. If I could ask the Claimants, first of all.

MR. RAKOCZY: Yes.

PRESIDENT LANDAU: Thank you very much.

And for the Respondents?

MS. McLEOD: Yes.

PRESIDENT LANDAU: Thank you very much. And if I can then, while we have them open, take you to the UNCITRAL Rules, Article 29(1), which says the Arbitral Tribunal may inquire of Parties if they have any further proof to offer or Witnesses to be heard or submissions to make; and, if there are none, it may declare the hearings closed. And I propose that we now formally close the hearing pursuant to that article, and ask for confirmation of that firstly from the Claimant.

MR. RAKOCZY: We have no further submissions, Mr. President, or Witnesses.

PAGE 388

388

11:50:33 PRESIDENT LANDAU: Thank you very much. And the Respondent?

MS. McLEOD: Nor do we.

PRESIDENT LANDAU: Thank you very much.

I think it's then just for me to thank on behalf of the Tribunal both Parties for their great assistance in the matter. I think I speak for all of us when I say that we have been extremely impressed not only with the quality of the written and oral submissions, but also with the cooperation between the Parties and the level of professionalism with which this case has been conducted, which has certainly made our lives extremely easy, at least so far, and we are very, very grateful to both Parties in that regard.

I would also like to thank our transcriber who has shown immense patience, sometimes under pressure, and the Secretariat for all her support.

Unless anybody else has anything else to say, I then formally draw these proceedings to a close.

Thank you very much.

MR. RAKOCZY: Thank you.

(Whereupon, at 11:51 a.m., the hearing was

PAGE 389

389

11:51:34 adjourned. 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