

THE INTERNATIONAL CENTRE FOR THE SETTLEMENT OF INVESTMENT DISPUTES

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 In the Matter of Arbitration :
 Between: :
 :
 APOTEX HOLDINGS INC. and APOTEX INC., :
 : Case No.
 Claimants, : ARB (AF) 12/1
 :
 and :
 :
 THE UNITED STATES OF AMERICA, :
 :
 Respondent. : (Revised)
 - - - - -x Volume 3

HEARING ON JURISDICTION AND THE MERITS

Wednesday, November 20, 2013

The World Bank
 1225 Connecticut Avenue, N.W.
 C Building
 Conference Room C8-150
 Washington, D.C. 20433

The hearing in the above-entitled matter came on, pursuant to notice, at 9:00 a.m. before:

MR. V.V. VEEDER, QC, President

MR. J. WILLIAM ROWLEY, QC, Arbitrator

MR. JOHN R. CROOK, Arbitrator

Also Present:

MR. MONTY TAYLOR
Secretary to the Tribunal

MS. MARTINA POLASEK
Alternate Secretary of the Tribunal

Court Reporter:

MS. DAWN K. LARSON
Registered Diplomate Reporter
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1 P R O C E E D I N G S
 2 PRESIDENT VEEDER: Good morning, ladies and
 3 gentlemen. We'll start Day 3 of this hearing; that
 4 is, Wednesday, the 20th of November.
 5 Some housekeeping on our part. We've just
 6 received a new Page 56 from the PowerPoint slide from
 7 yesterday, deleting the two Legal Authorities which
 8 were withdrawn by the Claimant on Day 1.
 9 And, secondly, we'd just like to go through
 10 with the Parties today and tomorrow's likely
 11 timetable. We're looking at the Parties' joint
 12 proposed time hearing timetable which now needs to be
 13 revised. We have part of this morning's session with
 14 the Claimants concluding Opening Submissions, and
 15 then, as we understand, we'll start with the
 16 Respondent's Case-in-Chief certainly before the lunch
 17 break.
 18 Could we also respond just how they see
 19 things proceeding now? Is it changed from before, or
 20 how will it proceed?
 21 MS. GROSH: Mr. President, we anticipate
 22 continuing as we had proposed before. We would have

09:01:35 1 two presentations this morning, and then the remainder
 2 of the day would likely be taken up with Witnesses,
 3 and when we finish depends largely on how much
 4 cross-examination there will be.
 5 PRESIDENT VEEDER: Yes. So the order of
 6 Witnesses remains the same; that is, Ms. Emerson,
 7 Payne, Goga, Dr. Rosa, and then finishing with the
 8 Expert Witness, Mr. Vodra?
 9 MS. GROSH: At this point, yes. And some
 10 would depend on where we end up breaking, with breaks
 11 and lunch and all of that.
 12 PRESIDENT VEEDER: Yes.
 13 MS. GROSH: But, yes, we anticipate that the
 14 order will remain the same at this point.
 15 PRESIDENT VEEDER: Yes. Any revisions on the
 16 Claimants' side?
 17 MR. LEGUM: None here, Mr. President.
 18 PRESIDENT VEEDER: I mean, not tying you down
 19 in any way at all, because we know what happens, but
 20 just for planning purposes, when do you think we might
 21 finish these Witnesses? I guess that's a question for
 22 the Claimant more than for the Respondent.

09:02:33 1 MR. LEGUM: It's--of course, as you observed,
 2 it's difficult to anticipate without starting the
 3 examination because you don't know how long an
 4 examination will take, sometimes, before you start it.
 5 That being said, I would imagine we'll be finished
 6 tomorrow morning.
 7 PRESIDENT VEEDER: So it looks as if we'll
 8 finish the Respondent's case when? By Friday morning?
 9 We seem to be gaining time. That's what I'm just
 10 looking at as the old timetable.
 11 MS. GROSH: Mr. President, we do seem to be
 12 gaining time, although there is a large kind of
 13 unknown concerning the cross-examination.
 14 PRESIDENT VEEDER: Of course.
 15 MS. GROSH: So I think we could say at this
 16 point that it's likely that we will wrap up our
 17 Presentation-in-Chief by Friday if we continue to go
 18 at the pace that we are right now.
 19 PRESIDENT VEEDER: This has some effect as to
 20 how we resolve the timing of the post-hearing--I'm
 21 sorry, the Closing Oral Submissions. So let's look at
 22 this again maybe tomorrow evening and then we'll see

09:03:38 1 where we stand, shall we? If you have a better idea
 2 beforehand, don't hesitate to raise it with us.
 3 Any more housekeeping on the Claimants' side?
 4 MR. LEGUM: None here.
 5 PRESIDENT VEEDER: On the Respondent's side?
 6 MS. GROSH: Nothing for us, Mr. President.
 7 PRESIDENT VEEDER: Then let's resume with the
 8 Claimant. They have the floor.
 9 OPENING STATEMENT BY COUNSEL FOR CLAIMANTS
 10 MR. LEGUM: Thank you, Mr. President.
 11 What we'd like to do this morning is to
 12 provide a more considered response to some of the
 13 questions that were posed during the first two days of
 14 this hearing. On other questions, we're, at this
 15 point, satisfied with the answers that we've given,
 16 although we'll continue to reflect upon them and
 17 perhaps also address them again in the Closing
 18 Submissions if we have anything new to say.
 19 I'd like to begin with the question posed by
 20 the President and Mr. Rowley on Day 1 concerning
 21 res judicata and the RSM versus Grenada case. And I'm
 22 not going recite the question in detail, but I'll give

09:04:45 1 the reference to the transcript, which is Day 1, Pages
 2 162-166.
 3 So having reviewed the RSM versus Grenada
 4 decision, the second one, Apotex would agree that
 5 privies are bound to the same extent as the Party with
 6 which they stand in privity. So we would accept that
 7 Apotex Holdings could not bring the claims asserted
 8 and decided in the Apotex II case. We note that the
 9 RSM case--that in the RSM case, the disputing Parties
 10 agreed on the applicability of collateral estoppel
 11 under the governing law.
 12 That obviously is not the case here, and it's
 13 our submission that under NAFTA Article 1136(1) and
 14 public international law jurisprudence construing the
 15 identical provision in Article 59 of the Statute of
 16 the International Court of Justice, the test for
 17 res judicata is a triple identity test.
 18 Finally, we would note that while the
 19 disputing Parties in the RSM case agreed that
 20 collateral estoppel was a general principle, Apotex
 21 disputes this point. Collateral estoppel, or "issue
 22 estoppel" as it's known in England, is unknown to the

09:06:20 1 civil law.
 2 PRESIDENT VEEDER: Let me stop you. Issue
 3 estoppel is not collateral estoppel in England. Very
 4 important difference.
 5 MR. LEGUM: Well, it's not the place of
 6 counsel to ask the Tribunal questions. I would be
 7 interested to know the distinction.
 8 PRESIDENT VEEDER: You'll find it's in the
 9 IIA Report, but it's not a common law animal outside
 10 the U.S.A. But maybe it's how you use the term. So
 11 if you mean issue estoppel, issue estoppel does exist
 12 in the common law system outside the U.S.A. But
 13 collateral estoppel, as I understand it, can affect
 14 nonprivies, and that's where the line is drawn.
 15 MR. LEGUM: Yes. No, there are certainly
 16 differences between the concept in the United States
 17 and the analogous concept under English law. The
 18 point that I was coming to, however, is that it is
 19 unknown in either form to civil law systems which make
 20 up the majority of legal systems--the majority of
 21 developed legal systems in the world.
 22 So, in short, our position is that Apotex I

09:07:26 1 and II is binding between the Parties to that case and
 2 to privies to those Parties--and we would accept that
 3 Apotex Holdings is one of those privies--but it is
 4 binding only in respect of that case. It is not
 5 binding in respect of this case.
 6 I'd like to now turn to--unless my answer to
 7 the question has given rise to more questions. I'd
 8 like to now turn to the question posed by Mr. Rowley
 9 again on Day 1 concerning--and this was in the context
 10 of a discussion of Apotex I and II--concerning whether
 11 investments should be defined or considered by looking
 12 at the asset or whether it should be considered by
 13 looking at the investor's use of the asset.
 14 Could we bring up that slide, please, the
 15 first slide?
 16 So what you have on the screen is the
 17 definition of "investment" under Article 1139 of the
 18 NAFTA. The definition sets out a list of different
 19 categories of assets. The question presented by the
 20 text is of whether the asset in question falls within
 21 one of the defined categories and does not fall within
 22 the excluded categories. The focus, however, is on

09:09:16 1 the investment--it's on the asset--and not on the
 2 investor. There are other provisions of the NAFTA
 3 that address the investor, which we'll come to in a
 4 moment.
 5 So our position is that it would be erroneous
 6 to focus on the investor in assessing whether or not a
 7 given asset amounts to an investment.
 8 We would note that even if one were to focus
 9 on the investor here, a different result would be
 10 compelled than in Apotex I and II. Apotex Holdings is
 11 a critical part of the picture in this case. It
 12 indirectly owns and controls not only the Marketing
 13 Authorizations at issue, but also one of the leading
 14 generic pharmaceutical sales and distribution
 15 companies in the U.S.--that is, Apotex-U.S.--as well
 16 as packaging, distributing, and manufacturing
 17 facilities in the U.S. The Marketing Authorizations
 18 are an integral part of Apotex Holdings' broader
 19 investment in the U.S. And given this difference
 20 between this case and Apotex I and II, that--if one
 21 were to look at the investor, one would see an
 22 investment here in a different light.

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09:10:43 1 I'll now turn to another question posed by
2 Mr. Rowley on Day 1. This was posed at pages
3 203-204--actually, did I mention the pages, when
4 I--okay. Excuse me for that. The second question for
5 Mr. Rowley that I addressed, that was at Pages
6 185-187.

7 So the one I'm turning to now is from Day 1,
8 again, Pages 203-204. And the question here was on
9 the definition of "investor of a Party" under
10 Article 1139 and the potential disconnect from
11 Apotex-Canada, the company that owns Marketing
12 Authorizations, and Apotex-U.S., the company that
13 commits resources--or at least commits some of the
14 resources at issue in the United States.

15 Perhaps we can have the next slide.

16 So what you have on the screen are now three
17 pertinent definitions from Article 1139. There's the
18 definition "investor of a Party," which means "an
19 enterprise of a Party that seeks to make, is making,
20 or has made an investment." There's the definition of
21 "investment" in Article 1139(h), which we're now all
22 quite familiar with. And then there's the definition

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09:12:30 1 of "investment of an investor of a Party." And
2 "investment of an investor of a Party" is defined to
3 mean "an investment owned or controlled directly or
4 indirectly by an investor of such Party."

5 Now, here in the form of Apotex Holdings,
6 Apotex Holdings is an investor of a Party. It
7 indirectly owns and controls both the Marketing
8 Authorizations and Apotex-U.S., which indisputably
9 provides resources supporting those Marketing
10 Authorizations.

11 Apotex Holdings, in light of the definition
12 of "investment of an investor of a Party," must be
13 understood as contributing the resources of its
14 indirectly controlled investment and subsidiary,
15 Apotex-U.S. So in the form of Apotex Holdings, our
16 submission is that there should be no doubt that
17 Apotex Holdings has committed the resources of the
18 investment that it owns and controls directly and
19 indirectly, Apotex-U.S., to the other investment that
20 it owns and controls directly or indirectly, the
21 Marketing Authorizations.

22 Now, I'd like to pause here for a moment and

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09:14:22 1 note that holding companies are a very common form of
2 structure for holding investments. Many of the
3 largest multinational enterprises that are significant
4 investors in the United States and economies around
5 the world use holding companies to hold their assets.
6 Many of their assets are operating companies. Now, a
7 holding company, by definition, is not an operating
8 company. It holds things. It holds shares in
9 companies typically, but most holding companies have
10 no employees, have officers or directors, but do not
11 have a staff. They don't have resources as such. The
12 resources that can be contributed to an investment are
13 held by operating companies in the group.

14 So reading Article 1139 to exclude a
15 contribution by an operating company indirectly owned
16 or controlled by a holding company would exclude from
17 the ambit of the Investment chapter a very significant
18 portion of the most important investors in the world.

19 So our submission is that Apotex Holdings
20 did, indeed, make the investments in the form of the
21 Marketing Authorizations because it, through its
22 operating company in the U.S., Apotex Holdings,

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09:16:26 1 committed resources to supporting those Marketing
2 Authorizations. Those resources obviously are in the
3 territory of the United States at the time of their
4 commitment.

5 Now, unless that answer has given rise to
6 more questions, I will turn to the next question.

7 I'd like to turn, now, to the President's
8 question on Day 1--the reference is Page 196--which
9 requested that we take a careful look at the Apotex I
10 and II cases' discussion of Article 1139 and explain
11 Apotex's position as to why it is inapposite. And for
12 this--I hope it is not inconvenient, but what I would
13 like to do is walk through the Apotex I and II
14 decision paragraph by paragraph. So it would be
15 helpful, if the Tribunal has a copy--I don't have a
16 copy here. If you had that in front of you, it would
17 be helpful.

18 PRESIDENT VEEDER: Are you saying don't have
19 a copy?

20 MR. LEGUM: I have a copy, but I don't have a
21 copy to give you.

22 PRESIDENT VEEDER: Oh, we have a copy. Don't

09:17:47 1 worry.
 2 ARBITRATOR CROOK: Maybe only a partial copy.
 3 PRESIDENT VEEDER: We can share.
 4 MR. LEGUM: Okay. So the discussion begins
 5 at Paragraph 226 of the Award. But it's essentially a
 6 discussion of the Parties' submissions until we get to
 7 the Tribunal's analysis that begins at Paragraph 230.
 8 The crux of the Tribunal's analysis really begins at
 9 Paragraph 235, and that's where I'll begin.
 10 And in Paragraph 235, the Tribunal addresses
 11 the proposition that it considers in that paragraph,
 12 which appears in the block quote from the Rejoinder in
 13 that case, where the assertion was "Apotex's
 14 investment interests lie in the submission,
 15 maintenance, and utilization of its sertraline and
 16 pravastatin ANDAs in achieving an economic benefit
 17 from the marketing and sales."
 18 That is not the assertion in this case. The
 19 assertion in this case is not that the interests lie
 20 in these different activities. The assertion in this
 21 case is that the interest is the Marketing
 22 Authorization, and those activities constitute

09:20:05 1 resources that are committed to those Marketing
 2 Authorizations. So our submission is that the
 3 analysis made in this paragraph is an interesting
 4 analysis, but it is not one that addresses the
 5 position put forward in this arbitration.
 6 Okay. I come to Paragraph 236. This
 7 paragraph addresses a designation of a "U.S.
 8 affiliate" as "agent for correspondence as an
 9 investment." That, again, is not a position that has
 10 been advanced in this arbitration. We do not contend
 11 that the designation of an employee of the U.S.
 12 subsidiary is an investment. That is not a position
 13 that we have taken. Our position, instead, is not the
 14 designation of the agent but, rather, the substantial
 15 resources brought to bear in supporting those
 16 Marketing Authorizations by the U.S. subsidiary that
 17 constitute not the investment, but resources committed
 18 to the economic activity in the territory of the U.S.
 19 I come to Paragraph 237. This paragraph
 20 deals with the use of Apotex-U.S. as a U.S.
 21 distributor. Again, this is not an assertion that has
 22 been made in this case. We have not asserted that the

09:21:58 1 fact that Apotex-U.S. distributes products
 2 manufactured by Apotex-Canada constitutes a commitment
 3 of resources by Apotex-Canada, nor have we asserted
 4 that that's an investment. Therefore, the distinction
 5 of SGS versus Philippines and SGS versus Pakistan is
 6 not pertinent to the arguments advanced in this case
 7 because it's an argument that we haven't advanced in
 8 this case.
 9 Paragraph 239, "Purchase of raw materials in
 10 the United States." Again, in this arbitration we
 11 have not asserted that the purchase of raw materials
 12 by Apotex-Canada constitutes a contribution of
 13 resources towards the Marketing Authorizations in the
 14 U.S. This is not an argument or position that has
 15 been advanced here. And the Tribunal's analysis of
 16 that position sheds no light on the positions that are
 17 advanced here.
 18 Paragraph 240, "Consent to U.S. jurisdiction
 19 and legal fees." The proposition that the Tribunal
 20 states in this paragraph is Apotex's submission to
 21 U.S. jurisdiction, its engagement of U.S. attorneys
 22 and expenditure on legal fees, again, neither amount

09:23:40 1 to investments nor change the nature of Apotex's
 2 activity. So, again, we do not contend in this case
 3 that the engagement of U.S. attorneys and the
 4 expenditure of legal fees amounts to an investment.
 5 We do, however, contend that the expenditure of legal
 6 fees amounts to a commitment of resources in the
 7 territory of the U.S. that gives substantial value to
 8 the Marketing Authorizations that Apotex-Canada and
 9 Apotex Holdings own. But that is not the proposition
 10 that is addressed here. And as for submission to U.S.
 11 jurisdiction, we have not asserted that that is of any
 12 relevance to the Article 1139(h) analysis.
 13 That's the meat of the Tribunal's analysis
 14 under Apotex I and II on Article 1139(h), and for
 15 these reasons we submit that it does not shed light
 16 the issues before this Tribunal.
 17 PRESIDENT VEEDER: Can I just take you back
 18 to the beginning, to Paragraph 226. This is a very
 19 distinguished Tribunal. I find this passage quite
 20 hard to follow, but you start off in Paragraph 226 in
 21 this Award with a clear reference to 1139(h) of NAFTA.
 22 So the argument being addressed is that this Apotex,

09:25:08 1 Apotex Inc., has an investment being "interest arising
 2 from the commitment of capital or other resources in
 3 the U.S.A."
 4 MR. LEGUM: Sorry; you're on Paragraph 226?
 5 PRESIDENT VEEDER: 226. Yeah. The reference
 6 to 1139(h).
 7 MR. LEGUM: Yes.
 8 PRESIDENT VEEDER: I'm just putting in
 9 context what the argument seems to be.
 10 MR. LEGUM: I'm sorry.
 11 PRESIDENT VEEDER: It then takes off in a
 12 funny direction in Paragraph 229, where the Tribunal
 13 poses a question trying to identify exactly what the
 14 case is that is being advanced under 1139(h). And the
 15 answer from counsel for the Claimant, "Our basic
 16 argument is it's part and parcel of the ANDA
 17 investment because of the commitments that have been
 18 made, the commitments of capital," which I would
 19 understand that as referring expressly back to
 20 1139(h).
 21 And then somehow the Tribunal, in the next
 22 question, get an answer from the Claimant that really

09:26:17 1 the case comes more under 1139(g), than 1139(h). And
 2 I think what follows has to be read in the context of
 3 that.
 4 But in this case, could Apotex Inc. have made
 5 the same argument that you're making to us in this
 6 arbitration in relation to the Marketing
 7 Authorizations? Could it have made a different case
 8 under 1139(h) as regards Apotex Inc.?
 9 MR. LEGUM: Well, I guess two responses: The
 10 first is that neither I personally nor my firm was
 11 counsel in that other case.
 12 PRESIDENT VEEDER: I know that. I'm not
 13 trying to put you in a difficult situation. Just as
 14 an outsider reading this Award, as we are, is this
 15 something that could have been said that wasn't said?
 16 I mean, is there a reason why the argument that you're
 17 making to us wasn't put to the Tribunal or couldn't
 18 have been put to the Tribunal in this other
 19 arbitration?
 20 MR. LEGUM: So--so, two things: So, first,
 21 I'm not as familiar with the record of that case,
 22 obviously, as I am with this one. My own reading of

09:27:35 1 the pleadings in that case is that the Article 1139(h)
 2 was not--the argument was not developed, that it was
 3 one of these things that was asserted in a--in a
 4 comprehensive approach at the beginning of the case,
 5 and then the debate focused on--really, on
 6 Article 1139(g).
 7 Could the arguments that have been advanced
 8 here been advanced in that case? I mean, there are
 9 some significant differences, both in the nature of
 10 the interests, in that here we have Marketing
 11 Authorizations that have been granted as opposed to
 12 applications that have only tentatively been approved.
 13 The other significant difference is that here
 14 Apotex Holdings is a Claimant and an investor, which
 15 brings in to bear a different perspective and a
 16 different series of assets that can be--and resources
 17 that I think could fairly be brought to bear.
 18 But I will--with your permission, I will
 19 reflect upon that, and if I have anything more to say,
 20 I'll come back to it.
 21 PRESIDENT VEEDER: Thank you. Please
 22 continue.

09:29:03 1 MR. LEGUM: Okay. So--I'm hesitating.
 2 Mr. Crook asked a question on the French version of
 3 Article 1139(h) and the approach of Article 33(4) of
 4 the Vienna Convention on the Law of Treaties. Now, I
 5 have that here in my notes as being Day 1, but I
 6 remember that--was that Day 1 or was that--
 7 PRESIDENT VEEDER: Past month sometime.
 8 MR. LEGUM: Right. So the reference I have
 9 is Day 1, Page 216. But it's now a bit of a blur.
 10 So we've looked at commentary on
 11 Article 33(4) of the Vienna Convention, and our
 12 reading of that commentary leads to the conclusion
 13 that Article 33(4) doesn't favor a numerical approach.
 14 It is not simply that there is--if there are three
 15 versions and two say the same thing, then that decides
 16 the question. Rather, Article 33(4) contains a
 17 reference to the object and purpose of the Treaty, and
 18 the tools of Article 31 of the Vienna Convention on
 19 the Law of Treaties. And, therefore, our reading is
 20 that it's not a question of two against one or three
 21 against one. The question is really what is the
 22 interpretation that best accords with the object and

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09:30:44 1 purpose of the Treaty and best reconciles the texts.
 2 PRESIDENT VEEDER: But doesn't that beg the
 3 question that you raised? Is there a French version
 4 of NAFTA?
 5 MR. LEGUM: Yes.
 6 PRESIDENT VEEDER: Translations are available
 7 in Canada, but is there a version under NAFTA?
 8 MR. LEGUM: And on that question, again, I'll
 9 have to defer to my colleagues at the State
 10 Department--my former colleagues at the State
 11 Department. My understanding, at least as a certain
 12 period of time ago, was that there had not been an
 13 agreement on an authentic version. It is possible
 14 that the Parties have devoted their ample resources to
 15 correcting the version that existed and now there is
 16 an authentic version, but at the time, there was not.
 17 PRESIDENT VEEDER: Do you mind if we just
 18 ask--
 19 MR. LEGUM: I do not.
 20 PRESIDENT VEEDER: --the Respondent if that
 21 is so?
 22 I mean, if you can tell us if there is an

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09:31:42 1 official French version as opposed to translations.
 2 MR. SHARPE: Mr. President, we have some
 3 comments on this, but in light of your question, if
 4 you don't mind, we'll reserve for the moment and
 5 return.
 6 PRESIDENT VEEDER: Absolutely.
 7 ARBITRATOR CROOK: Quick question: Where
 8 should I go to look for this? Sinclair? Or do you
 9 recall who you looked at?
 10 MR. LEGUM: Yes. It was Molmar Yaseen's
 11 (phonetic) Commentary in The Hague "Recueil des
 12 cours." What is it called in English? You know, the
 13 collection of Hague lectures.
 14 ARBITRATOR CROOK: Okay. Thank you.
 15 MR. LEGUM: I'd be happy to provide that.
 16 Obviously, you know, that's not an Authority that's in
 17 the record, and so we have not made copies. If it's a
 18 question that's of interest to the Tribunal, that may
 19 be something--
 20 PRESIDENT VEEDER: Subject to any protest
 21 from the Respondent, could you get ready to give that
 22 to us? We might want to look at it.

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09:32:42 1 MR. LEGUM: Certainly. It's in French.
 2 PRESIDENT VEEDER: Oh, then maybe an official
 3 translation is needed by your former colleagues of the
 4 State Department.
 5 MR. LEGUM: Thank you.
 6 Okay. I come from a question from Day 2.
 7 This was posed by Mr. Veeder and Mr. Rowley. The
 8 reference is Page 75. This was with respect to
 9 Exhibit C-424, which was the October 28, 2010, meeting
 10 between FDA and Teva Parenteral, and the question was:
 11 "Were the attachments to those minutes produced?"
 12 We've gone back and we've looked at the
 13 document production by the U.S., and we have been able
 14 to locate the PowerPoint presentation that was
 15 referenced in those minutes. So that has been
 16 produced. We have not been able to identify an
 17 attendees list that corresponds to it. I should note
 18 that in the U.S. productions, often there were e-mails
 19 that were produced and then the attachments were
 20 produced separately. And so it was an exercise to try
 21 to identify what went with what.
 22 The PowerPoint presentation is not an exhibit

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09:34:09 1 in this arbitration at this point. We have no
 2 objections to providing that to the Tribunal, but it's
 3 obviously a question also to pose to our colleagues.
 4 ARBITRATOR ROWLEY: Have you given a copy to
 5 your former colleagues?
 6 MR. LEGUM: No, but we're happy to do that.
 7 PRESIDENT VEEDER: The more important of the
 8 two attachments was the PowerPoint rather than the
 9 list of attendees. When you hand over a copy of the
 10 PowerPoint, and if it can be put in by consent, we'll
 11 do that. And, if not, we'll hear both Parties later.
 12 But we don't want to see it for the moment, but do
 13 give a copy to the Respondent.
 14 MR. LEGUM: Very good.
 15 ARBITRATOR CROOK: Before we move on, could
 16 you just check the page reference? It couldn't be
 17 Page 75 on Day 2.
 18 ARBITRATOR ROWLEY: Our transcripts have
 19 running numbers.
 20 MR. LEGUM: Perhaps it was the rough
 21 transcript. Can we come back to it?
 22 ARBITRATOR CROOK: Of course.

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09:35:25 1 MR. LEGUM: All right. So I come to the
2 question that was also posed by Mr. Crook yesterday.
3 Now, again, the reference that I have is to Page 207,
4 so we'll come up with a corrected reference for the
5 Tribunal since that doesn't correspond to the running
6 page numbers.

7 The question concerned the Cargill case and
8 why the investor was part of the Tribunal's discussion
9 and whether the Measure affected the enterprise. And
10 the answer to that question--we would refer the
11 Tribunal to Paragraph 120, where it is clear from that
12 paragraph of the Cargill Award that the application
13 for Import Permit was made by the Claimant, but
14 obviously it did have an impact on the enterprise
15 because the Import Permit in that case was for the
16 importation of supplies for the local subsidiary, and
17 the denial or the unavailability of the Import Permit
18 prevented those supplies from reaching the subsidiary.
19 And, therefore, there was an impact on the subsidiary,
20 just as we would say there is in this case.

21 Also yesterday, Mr. Rowley posed the question
22 of whether Apotex sought any of the remedies indicated

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09:36:55 1 by the U.S. and whether there was evidence in the
2 record that related to why. And so I confirm that
3 Apotex did not seek any of those four remedies, but I
4 would like to refer the Tribunal to the evidence of
5 record as to why.

6 If we could have the first slide.

7 So what you have on the screen are excerpts
8 from three Witness Statements that reflect the
9 company's understanding at the time that the only way
10 to address the Import Alert was through re-inspection.
11 So this is what FDA told Apotex was the only way to
12 address the Import Alert. This is what Apotex
13 understood at the time.

14 Could we have the next slide, please.

15 What you see on the screen here is a
16 reference to the Second Expert Report of Mr. Bradshaw
17 and Mr. Johnson, Paragraph 61, where, with respect to
18 the citizen petition, Mr. Bradshaw gives his opinion
19 that this was not an adequate or timely remedy that
20 one would consider.

21 Yes, please--I'm sorry; was that a question?

22 PRESIDENT VEEDER: May be a question if I can

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09:38:31 1 ask it now. You referred in this context to the
2 Loewen case, where there was advice from lawyers who
3 were advising Loewen about the possibilities of
4 proceeding upwards to the U.S. Supreme Court. We have
5 letters, obviously, amongst the exhibits from the
6 lawyers who were writing on behalf the Apotex. But
7 speaking for myself, I haven't seen any other material
8 recording legal advice to the Claimant as regards any
9 of these possible remedies.

10 Is that correct or I have missed something?

11 MR. LEGUM: There is nothing in the record,
12 Mr. President, because there was no such advice. It
13 was simply not something that anyone at the time
14 considered or considered to be available.

15 PRESIDENT VEEDER: Thank you.

16 MR. LEGUM: Just to continue. There's a few
17 more slides which I'll very quickly go through here.
18 These are other references to the record with
19 Mr. Bradshaw and Mr. Johnson's Expert Opinion on the
20 availability of a citizen petition.

21 Could we have the next slide, please.

22 This is the transcript from the Direct

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09:39:52 1 Examination of Mr. Bradshaw yesterday where he, again,
2 states that the only way to come off the Import Alert
3 was going to be through a re-inspection.

4 And then if we could have the next slide,
5 please, this is a reference to the evidence of record
6 on Detention Hearings and why those are not an
7 adequate or available remedy.

8 So, unless there are questions on that, I'll
9 go back to a question that I skipped over erroneously.
10 And this was the question posed by Mr. Crook yesterday
11 during the course of the discussion of
12 Article 1105(1), and the question of whether
13 investments of investors of another Party, the
14 reference in that provision encompassed the according
15 of treatment to investors with respect to their
16 investments when those investments were not legal
17 persons themselves.

18 And Mr. Crook asked whether there were
19 any--whether there was anything else that one should
20 consider in the way of evidence that the NAFTA Parties
21 intended to cover the denial of due process to
22 investors with respect to their investments as well as

09:41:52 1 the denial of due process to those investments that
 2 had a legal personality.
 3 And if we could go back to the slide on
 4 1117(1). So our submission, having thought about this
 5 a bit more, is that the NAFTA does contain examples of
 6 where the Parties intended a provision to only address
 7 investments that were legal persons. And an example
 8 is found in NAFTA Article 1117(1). There, the
 9 provision refers specifically to "an enterprise of
 10 another Party that is a juridical person that the
 11 Investor owns or controls directly or indirectly." So
 12 this is an example of a specific reference to an
 13 investment that is a legal personality, and our
 14 submission is that it shows that if the NAFTA Parties
 15 intended a provision to address only one specific
 16 category of investment, they knew how to do so and
 17 they did do so in Article 1117(1).
 18 The fact that in Article 1105(1) the NAFTA
 19 Parties did not limit that provision to enterprises of
 20 another Party that's a juridical person that an
 21 investor or person controls directly or indirectly
 22 demonstrates that they intended that provision to have

09:43:46 1 to have a broader ambit. Moreover, in the structure
 2 of NAFTA Chapter 11, the use of the term "investors"
 3 is intended principally to bring into the coverage of
 4 the chapter pre-establishment activity.
 5 So the NAFTA, like other U.S. Investment
 6 Treaties, is unusual in that it covers the activity of
 7 investment before the investment is made. And this is
 8 limited in NAFTA Chapter 11 to Articles 1102 and
 9 Article 1103. Those are the only two provisions in
 10 the chapter that contain dispositions, substantive
 11 dispositions, that are addressed to investors rather
 12 than investments.
 13 The mechanism by which the NAFTA covers
 14 pre-establishment acts is through the definition of
 15 "Investor of a Party" that we looked at a little bit
 16 earlier--and perhaps you can you go back. I think
 17 it's just one slide. The definition of "Investor of a
 18 Party" means a national or enterprise that "seeks to
 19 make." So it's the use of the terminology "seeks to
 20 make" that allows pre-establishment acts on the part
 21 of an Investor of a Party to be covered by the
 22 Investment Chapter. That, we submit, is the principal

09:45:35 1 part of distinction between "investor" and
 2 "investment" that appears in Section A of Chapter 11,
 3 which is the part that deals with the substantive
 4 obligations.
 5 So looking at the context and the intent of
 6 the Parties in having the substantive provisions of
 7 the Treaty apply to pre-establishment activity through
 8 the references to Investors, our submission is
 9 that--and also looking at the specific use in
 10 Article 1117(1) of a reference to an instance where
 11 the Parties intended to limit a provision to
 12 investments that were legal entities, our submission
 13 is that Article 1105(1) should be understood to
 14 encompass treatment of Investors with respect to their
 15 investments.
 16 I would like to underline, however, that
 17 interesting as though this question is, it is not one
 18 that is necessarily posed in this case, in that, in
 19 this case, Apotex-U.S. is a legal entity. It is an
 20 investment of Apotex Holdings, and it has, in Apotex's
 21 submission, been denied the basic due process required
 22 by international law.

09:47:41 1 So, I come now to the question posed by
 2 Mr. Rowley yesterday, and we'll get the corrected
 3 reference, but in the rough transcript it was
 4 Page 263. And the question was: "What do the U.S.
 5 courts say in response to the U.S.'s position that an
 6 Import Alert is a discretionary act not reviewable by
 7 the U.S. courts?" There are four Authorities in the
 8 record that address this topic--well, that don't
 9 necessarily address this topic, but at least address
 10 related topics. Two of them were discussed yesterday:
 11 The Smoking Everywhere and the KV Pharmaceutical
 12 courts. I'm very briefly going to go through those.
 13 The KV Pharmaceutical versus FDA case was a District
 14 Court decision, so a lower court decision, from 2012.
 15 It's found at CLA-539.
 16 So this is a decision that was not available
 17 in 2009, at the time of the relevant events. In this
 18 decision, part of the claims asserted by KV was to
 19 challenge FDA's failure to block shipments of certain
 20 active pharmaceutical ingredients into the United
 21 States. So the assertion here was not a challenge to
 22 an Import Alert. It was a challenge to FDA's failure

09:49:24 1 to take import action with respect to certain
 2 products. The Court found, in agreement with the FDA,
 3 that the challenged Agency action was not subject to
 4 judicial review because it was committed to Agency
 5 discretion. And the reference there is Page 16.
 6 In Smoking Everywhere, the plaintiff sought
 7 to enjoin FDA from regulating electronic cigarettes as
 8 a drug/device combination. And from denying entry of
 9 those products into the U.S. So Smoking Everywhere,
 10 again, is a District Court decision. It's in the
 11 record at CLA-184, and it is from 2010. So, again, it
 12 is from after the time of the Import Alert in 2009
 13 and, therefore, was not available at the time that the
 14 decisions--that any decision had to be made.
 15 The Smoking Everywhere Court involved, not a
 16 court's jurisdiction to hear a challenge to FDA's
 17 authority to issue an Import Alert or the decision to
 18 issue an Import Alert, but, rather, FDA's authority
 19 under the Food, Drug, and Cosmetic Act to regulate
 20 tobacco products, but as part of the Court's analysis,
 21 in a footnote, the Court expressed skepticism about
 22 FDA's sweeping statement that Import Alerts are

09:51:22 1 committed to Agency discretion. So in this District
 2 Court decision from 2010 at Page 68, Note 8, the Court
 3 expresses skepticism about that proposition.
 4 The next case is Cook vs. FDA. This is a
 5 District of Columbia Court of Appeals decision--or
 6 District of Columbia Circuit Court decision from 2013.
 7 So from this year. That Authority is RLA-214. Again,
 8 this was not available at the time of the relevant
 9 events. That case, again, did not involve a challenge
 10 to an Import Alert; rather, the question was whether
 11 products not authorized by FDA in the U.S. could
 12 lawfully be admitted into the U.S. for the purpose of
 13 use in execution of prisoners on death row. And the
 14 Court found that FDA did not have discretion to allow
 15 those products into the United States.
 16 The final case is from 1988. This is the
 17 Bellarno International vs. FDA case. It's a District
 18 Court case from New York, and the reference is
 19 RLA-212. This, again, did not directly involve a
 20 challenge to an Import Alert. Instead, the Plaintiff
 21 challenged FDA's adoption of a new Import Alert under
 22 the Administrative Procedure Act on the grounds that

09:53:07 1 FDA had adopted it without complying with the notice
 2 and comment rule-making requirements. The Court
 3 resolved the matter on this ground and did not address
 4 whether the Import Alert violated other provisions of
 5 the Administrative Procedure Act.
 6 ARBITRATOR CROOK: Sorry; I'll go look at
 7 this, but I didn't quite understand the gloss here.
 8 "They resolved it on this ground." What do we mean by
 9 that? That they upheld APA notice and hearing where
 10 notice was required?
 11 MR. LEGUM: Yes. They held that APA notice
 12 and hearing was required, not for adopting an Import
 13 Alert with respect to a specific product or a specific
 14 facility, but, rather, for adopting a new kind of
 15 Import Alert. So you'll remember in this case it is
 16 Import Alert 66-40 which addresses Import Alerts for
 17 drug cGMPs. This was a different kind of Import
 18 Alert.
 19 ARBITRATOR CROOK: I understand. Thank you.
 20 MR. LEGUM: And then there was a question by
 21 Mr. Veeder on whether the sale of a certain Apotex
 22 ANDA was a taxable event in the U.S. I have an answer

09:54:37 1 for that, but it is confidential and, therefore, we'll
 2 need to cut the feed.
 3 PRESIDENT VEEDER: We're cutting the feed.
 4 We'll just wait to have confirmation the feed is cut.
 5 ARBITRATOR CROOK: Does anybody know how many
 6 people are watching this event, if any?
 7 SECRETARY TAYLOR: First, I can confirm the
 8 feed is being cut. Yesterday there was one.
 9 (Discussion off microphone.)
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09:55:44 1 CONFIDENTIAL PORTION
 2 MR. LEGUM: So the ANDA sale that the U.S.
 3 has focused on in its document request and in its
 4 pleadings was one to a company called [REDACTED]
 5 [REDACTED] in 2006. This was--the transaction in
 6 this case was one that involved more than the sale of
 7 the ANDAs. Essentially, Apotex owed money at the time
 8 to [REDACTED]. Apotex paid
 9 that money to [REDACTED], minus the price of the ANDA. So,
 10 as a result, there was no capital gain on the sale of
 11 the ANDA.
 12 ARBITRATOR CROOK: Just to be clear, was this
 13 then a U.S. transaction or a Canadian transaction or
 14 was it both?
 15 MR. LEGUM: Neither Party was a U.S. entity.
 16 So [REDACTED] was not a U.S. company.
 17 Apotex-Canada was not a U.S. company, if that answers
 18 your question.
 19 Okay. We can go back on, if you would like.
 20 SECRETARY TAYLOR: Confirming the feed has
 21 now been resumed.
 22

09:57:40 1 NONCONFIDENTIAL PORTION
 2 MR. LEGUM: Okay. On Day 1, Page 247,
 3 Mr. Crook asked a question about the criteria for like
 4 circumstances and the role of a Warning Letter being
 5 part of that criteria. And Mr. Rowley immediately
 6 followed up with that with another question to the
 7 same effect on Page 248. So we stand by the answer
 8 that we gave. And I would simply note that Apotex's
 9 position is that there are many factors that are
 10 relevant to the like-circumstances analysis. Whether
 11 an entity has received a Warning Letter is an
 12 important part of the like-circumstances analysis in
 13 this case, but it is only one part. You will have
 14 appreciated from our submissions yesterday that there
 15 are many other criteria that we consider to be
 16 relevant.
 17 Mr. President, Members of the Tribunal,
 18 unless there are any further questions for us, this
 19 will conclude--we have a further question.
 20 ARBITRATOR ROWLEY: I have one question. I
 21 ought to have asked it yesterday, but I'll ask it now.
 22 You needn't answer it immediately, and it is also

09:59:16 1 pertinent for the United States. But yesterday my
 2 note--and I haven't got a correct transcript
 3 reference, but my note was that it was at Page 448,
 4 but that was not a finalized version.
 5 You were making your introduction, Mr. Legum,
 6 on 1105 and Effective Means, et cetera, and you
 7 started more or less by saying the Parties were agreed
 8 that basic due process must be provided to an alien.
 9 And I would like you to have--your former colleagues
 10 can say whether that was accurate or not, but I would
 11 like to know the basis on which you said that. Is
 12 there an agreement in the record? Is there something
 13 in Respondent's Pleading that you take that from?
 14 I've just-- there may well be. I just can't remember
 15 it.
 16 MR. LEGUM: We can come back to you with
 17 specific references, but our understanding of the
 18 state of play is that there is no dispute that the
 19 international minimum standard requires a basic due
 20 process to be provided to aliens. That is something
 21 that is reflected, not only in--
 22 ARBITRATOR ROWLEY: I'm not concerned about

10:00:45 1 your understanding.
 2 MR. LEGUM: Right.
 3 ARBITRATOR ROWLEY: I'm concerned that you
 4 said the United States had the same understanding.
 5 MR. LEGUM: Understood. Now, we may have
 6 differences as to its applicability to specific areas,
 7 such as administrative decision making. We may have
 8 disagreements as to its precise contours, but I do not
 9 think that it is the United States's position that the
 10 customary international law minimum standard of
 11 treatment does not include denial of process to
 12 aliens. But I'll be very interested to hear the
 13 presentations.
 14 PRESIDENT VEEDER: Please continue.
 15 MR. LEGUM: Thank you very much.
 16 PRESIDENT VEEDER: That's it.
 17 MR. LEGUM: The sentence that was going to
 18 follow was, "This concludes the presentation of our
 19 Case-in-Chief."
 20 PRESIDENT VEEDER: I see. We haven't worked
 21 through all the new slides.
 22 MR. LEGUM: I think we have. We kind of

10:01:48 1 skipped around a bit.
 2 PRESIDENT VEEDER: Thank you very much.
 3 We'll take a short break, and then we'll obviously
 4 switch over to the--before we do that--I'll turn my
 5 microphone on--because we're going to hear the timings
 6 from yesterday, which I forgot to deal with when we
 7 started this morning.
 8 SECRETARY TAYLOR: From Day 2, there were 10
 9 minutes and 34 seconds allocated to the Tribunal for
 10 housekeeping and procedural matters. For the
 11 Claimants' Case-in-Chief, there were 4 hours,
 12 42 minutes and 38 seconds, and--sorry; that was
 13 allocated to the Claimants. And for questions by the
 14 Tribunal, 29 minutes and 8 seconds.
 15 For the Examination of Mr. Sheldon Bradshaw,
 16 the Claimants had 18 minutes and 0 seconds; the
 17 Respondent, 37 minutes and 17 seconds; and the
 18 Tribunal, 1 minute and 37 seconds.
 19 To clarify, for the Examination of
 20 Mr. Sheldon Bradshaw, Direct Examination was
 21 18 minutes and 0 seconds for the Claimants.
 22 Cross-examination was 37 minutes and 17 seconds.

10:03:07 1 There was no Redirect Examination, and the Tribunal
 2 had 1 minute and 37 seconds for questions which brings
 3 us to a total for the Claimants, a count of 5 hours,
 4 0 minutes and 38 seconds for Day 2. For the
 5 Respondent, 37 minutes and 17 seconds. For the
 6 Tribunal, 41 minutes and 19 seconds, for a grand total
 7 of 6 hours, 19 minutes and 14 seconds.
 8 PRESIDENT VEEDER: Thank you very much.
 9 Unless that is disputed today, we'll take those
 10 figures as having been agreed.
 11 How long do the Respondents need for the
 12 changeover? Do you need 5 minutes or 15, or what
 13 would you prefer?
 14 MR. SHARPE: If we could have 10 minutes,
 15 that would be appreciated.
 16 PRESIDENT VEEDER: Let's have 10 minutes.
 17 We'll come back here at quarter past 10:00.
 18 (Brief recess.)
 19 PRESIDENT VEEDER: Let's resume. The
 20 Respondent has the floor.
 21 OPENING STATEMENT BY COUNSEL FOR RESPONDENT
 22 MS. GROSH: Mr. President, Members of the

10:17:50 1 Tribunal, my name is Lisa Grosh, and it's a pleasure
 2 for me to appear before you today to begin the United
 3 States's Presentation-in-Chief.
 4 I will discuss the importance of the
 5 Government's consent to arbitrate claims under NAFTA
 6 Chapter 11 and provide an overview of weaknesses of
 7 Apotex's claims. I will also address the burden of
 8 proof for both jurisdictional and Merits issues
 9 presented in this case. I will summarize the
 10 undisputed facts that are relevant to the Tribunal's
 11 consideration of Apotex's claims, and I will provide
 12 an overview of the arguments that my colleagues will
 13 discuss in greater detail over the course of the next
 14 couple of days.
 15 Now, let me begin again with the point that
 16 the acting legal adviser, Mary McLeod, raised on
 17 Monday. This arbitration is of critical importance to
 18 the United States, and the merits of this case deal
 19 with some of the cornerstone of U.S. law, regulations,
 20 and policies for protecting the public health and
 21 safety of U.S. citizens. These are laws that are
 22 aimed at protecting U.S. citizens from the threat

10:19:08 1 posed by adulterated drugs and ensuring that U.S.
 2 citizens have access to adequate supply of life-saving
 3 drugs.
 4 Putting aside for the moment the significant
 5 jurisdictional shortcomings of Apotex's claims for the
 6 moment, it is important to note up front that any
 7 Award on the Merits based on the kinds of allegations
 8 and Legal Arguments put forward by Apotex could have
 9 serious repercussions for the United States' ability
 10 to carry out this most basic sovereign function.
 11 Apotex's theory for this case essentially challenges
 12 the discretion the United States Government invested
 13 in the FDA to make complex and technical enforcement
 14 decisions regarding the importation of adulterated
 15 drugs into the United States.
 16 There is no indication, however, that the
 17 NAFTA was intended to curtail the enforcement
 18 discretion usually enjoyed by regulatory agencies in
 19 most systems of Government. To the contrary, the
 20 NAFTA Parties expressly sought to preserve flexibility
 21 in the area of public health and welfare.
 22 As the Tribunal in the Grand River case

10:20:31 1 observed, "NAFTA involves a balance of rights and
2 obligations and does not point unequivocally in a
3 single direction. While NAFTA's preamble speaks of
4 promoting investment, it also affirms the need to
5 preserve the NAFTA Parties' flexibility to safeguard
6 the public welfare."

7 Few cases could bring to a Tribunal's
8 attention that flexibility to safeguarded the public
9 welfare the way this one does. Apotex does not
10 dispute that FDA undertook all of the actions
11 underlying this case to protect the health and safety
12 of U.S. citizens from adulterated drugs. Apotex could
13 not allege otherwise. The evidence does not contain
14 any suggestion whatsoever of improper motive, action,
15 or inaction on the part of the FDA or any of its
16 personnel in carrying out their functions under
17 established law, regulations, and policy.

18 This case is also very important for the
19 United States because a finding for Apotex would
20 create jurisdiction where none exists. The three
21 NAFTA Parties consented to arbitration in Chapter 11
22 only for a very limited set of claims and with an

10:21:54 1 important set of preconditions. As the Tribunal in
2 the Methanex case made clear, in order to establish
3 the necessary consent to arbitration, a Claimant must
4 show that Chapter 11 applies in the first place.

5 As set out in Paragraph 120 of the Methanex
6 Award on Jurisdiction, that means that the
7 requirements of Article 1101 are met and that the
8 claim has been brought by a Claimant investor in
9 accordance with Articles 1116 or 1117 and that all
10 preconditions and formalities required under
11 Articles 1118-1121 are satisfied.

12 As this Tribunal well knows, consent is the
13 sine qua non of international adjudication. The
14 International Court of Justice requires "unequivocal
15 indication of a voluntary and indisputable acceptance"
16 of its jurisdiction. And the Iran-U.S. claims
17 Tribunal similarly requires "express language" of a
18 State's consent to arbitrate.

19 The Tribunal in Waste Management warned that
20 "the entire effectiveness of this institution depends"
21 on fulfillment of the prerequisites established as
22 conditions precedent to submission of a claim to

10:23:25 1 arbitration because those conditions pertain to the
2 States' consent to arbitrate.

3 Apotex has failed to establish that the
4 United States has consented to arbitrate Apotex's
5 claims. This case is, at its core, a trade case. It
6 is not an investment case, and the United States has
7 not consented to arbitrate it under Chapter 11.

8 Before I proceed any further, it is important
9 to remember that the two Claimants in this
10 case--Apotex Inc. and Apotex Holdings--allege that
11 they made two separate investments. And Apotex's
12 jurisdictional failures depend on which of the two
13 asserted investments we are talking about. Apotex
14 Inc. claims that its sole investment in the United
15 States is its Abbreviated New Drug Applications, or
16 ANDAs. Apotex Holdings, the other Claimant, also
17 alleges an investment in Apotex Corp., a U.S.
18 distribution company.

19 Mr. President, my colleagues tell me that
20 they've not distributed the slides yet to the Members
21 of the Tribunal, so we might take a moment for that.

22 PRESIDENT VEEDER: We're following it on the

10:24:50 1 screen, but hard copies would always be welcome.

2 MS. GROSH: Yes. Apologize for that.

3 PRESIDENT VEEDER: No trouble at all.

4 (Pause.)

5 MR. SHARPE: Mr. President, if I might
6 clarify, we handed out the binders on Day 1. Tab 1
7 included Ms. McLeod's slides, so you should have the
8 binder also with Tab 1 slides, and now I believe 2 and
9 3. Thank you.

10 PRESIDENT VEEDER: Never trust arbitrators.
11 (Discussion off microphone.)

12 MS. GROSH: All right. If we're all in order
13 with the paper, I will continue.

14 The Tribunal in Waste Management warned that
15 the entire effectiveness of this institution depends
16 on the fulfillment of the prerequisites established as
17 conditions precedent to submission of a claim to
18 arbitration--oh, I apologize. I think we've already
19 gone through this.

20 Although Apotex Inc. claims to be an
21 "investor" with "investments" in the territory of the
22 United States, there is no dispute that Apotex Inc. is

10:27:57 1 a pharmaceutical company based and incorporated in
 2 Canada; all of Apotex Inc.'s facilities or offices,
 3 manufacturing or otherwise, are located solely in
 4 Canada; Apotex Inc. does not reside or have a place of
 5 business in the United States; Apotex Inc. does not
 6 have any business operations in the United States;
 7 Apotex Inc. does not claim to share in the income or
 8 profits of any U.S. company; Apotex Inc. does not
 9 claim to have an equity or debt interest in any U.S.
 10 company; Apotex Inc. does not pay tax in the United
 11 States, including on the Transfer or sale of its
 12 alleged U.S. investments, its ANDAs; Apotex Inc. does
 13 not itself develop, test, or manufacture any products
 14 in the United States; Apotex Inc. does not directly
 15 sell any products of any kind in the United States;
 16 Apotex Inc. "has put nothing into the stream of
 17 commerce in the United States"; and Apotex Inc.
 18 prepares its ANDAs in Canada.
 19 The Apotex I and II Tribunal well recognized
 20 this basic reality emphasizing over and over that the
 21 dispute before it related to trade, not investment.
 22 The Import Alert, the only challenged measure in this

10:29:29 1 case, relates to Apotex's Canadian manufacturing
 2 facilities. It prevented Apotex Inc. from exporting
 3 products into the United States. This explains the
 4 strained arguments you have heard from Apotex's
 5 counsel over the last days to try to show that its
 6 trade claims are, in fact, investment claims that fall
 7 under Chapter 11 of the NAFTA.
 8 Of course, as we know, the Apotex I and II
 9 Tribunal dismissed many of these same arguments.
 10 That Tribunal noted: "Apotex's argument that an ANDA
 11 cannot be equated with an application for an export or
 12 import license is unconvincing... Whilst an ANDA
 13 itself may not be, in the strict technical terms, an
 14 export or import license, it operated--in this
 15 case--in precisely the same way. As already noted,
 16 all Apotex's operations were outside of the United
 17 States. Apotex wanted to export its goods to the
 18 United States to be marketed and sold there by other
 19 entities. In order to do this, Apotex was required to
 20 obtain permission, which was to be secured by the
 21 submission of an ANDA. The ANDA was thus a
 22 requirement in order to conduct an export business."

10:30:58 1 And I am quoting from Paragraphs 216 and 217
 2 of that Award.
 3 In the present case, Apotex continues to
 4 cling to the argument that its ANDAs are investments
 5 under the NAFTA. And I would like to make a brief
 6 note on language here. You have heard Apotex refer
 7 repeatedly to its ANDAs as "Marketing Authorizations."
 8 Apotex provides no authority for that term because
 9 there is none. Under U.S. law, ANDAs are "Abbreviated
 10 New Drugs Applications." Once they are approved, they
 11 are referred to as "Approved Abbreviated New Drug
 12 Applications." Apotex cannot make an investment where
 13 there is none simply by changing its name.
 14 The Tribunal will recall that Apotex Inc.
 15 initially claimed that its investments were both ANDAs
 16 that have already been approved by FDA, and ANDAs for
 17 which FDA approval was still pending. In January of
 18 this year, Apotex disclaimed any reliance on the
 19 unapproved ANDAs. Thus, Apotex Inc.'s sole claimed
 20 investments in the United States are the approved
 21 ANDAs.
 22 As my colleague, Ms. Thornton, will later

10:32:23 1 describe in more detail, these applications for
 2 regulatory permission to market drugs in the United
 3 States, whether they are approved or unapproved, do
 4 not constitute investments in the United States. This
 5 was the clear holding of the Tribunal in the previous
 6 NAFTA arbitration Apotex Inc. brought against the
 7 United States. That holding is binding on this
 8 Tribunal as res judicata. And even if it were not, we
 9 submit that Apotex has presented no basis for this
 10 Tribunal to depart from that Tribunal's thoughtful and
 11 carefully reasoned decision.
 12 The critical question with respect to Apotex
 13 Inc. is whether that company, an exporter of drugs
 14 manufactured in Canada, qualifies as an "investor of a
 15 Party" such that it may pursue arbitration against the
 16 United States. To make that determination, we have to
 17 turn to Article 1139, the definitions section of
 18 Chapter 11. "Investor of a Party" is defined as "a
 19 Party or State enterprise thereof, or a national or an
 20 enterprise of such Party, that seeks to make, is
 21 making, or has made an investment." So the key to
 22 determining whether Apotex Inc. is an "investor of a

10:33:46 1 Party" is whether it "seeks to make, is making, or has
2 made an investment" in the United States.

3 In claiming that its ANDAs qualify as
4 investments in the United States, Apotex Inc. points
5 to two provisions in Article 1139's definition of
6 "investment"--part (g) and part (h). Part (g) includes
7 as an "investment" "real estate or other property,
8 tangible or intangible, acquired in the expectation or
9 used for the purpose of economic benefit or other
10 business purposes."

11 In this case, Apotex Inc. claims that its
12 applications to the FDA were "intangible property."
13 As Ms. Thornton will demonstrate, the "inherent
14 nature" of Apotex Inc.'s ANDAs are mere applications
15 for permission to export drugs to the United States.
16 They, therefore, do not fall within NAFTA
17 Article 1139(g) as the Apotex I and II Tribunal has
18 already held.

19 Apotex Inc. also claims, under part (h) of
20 Article 1139's definition of "investment" that its
21 ANDAs constitute "interests arising from the
22 commitment of capital or other resources in the

10:35:17 1 territory of a Party to economic activity in such
2 territory." In the Apotex I and II case, Apotex Inc.
3 argued that it had an investment under Article 1139(h)
4 because it had committed significant capital and
5 resources in the United States towards the
6 preparation, filing, and maintenance of its ANDAs.

7 The Tribunal, however, was not persuaded and
8 found that "The 'interests' so identified amount to no
9 more than the ordinary conduct of a business for the
10 export and sale of goods. And as set out below, each
11 of the specific activities and expenses relied upon by
12 Apotex simply supported and facilitated its
13 Canadian-based manufacturing and export operations."
14 This is at Paragraph 239 of that Award.

15 PRESIDENT VEEDER: I'm sorry. I have 235,
16 but we'll come back to it.

17 MS. GROSH: I'm sorry. Okay.

18 Now, one would think that would be the end of
19 the matter. Instead, as further evidence that Apotex
20 Inc.'s claim in this case is, in fact, a trade claim
21 rather than an investment claim, Apotex has advanced
22 the extraordinary theory that the NAFTA Parties agreed

10:36:50 1 to protect, as investments, interests arising from the
2 commitment of capital made outside of the host State.
3 This, of course, is completely contrary to
4 Article 1101, which the Methanex Tribunal correctly
5 described as the "gateway leading to the dispute
6 resolution provision of NAFTA Chapter 11." As such,
7 "the powers of the Tribunal can only come into the
8 legal existence if the requirements of Article 1101(1)
9 are met."

10 Apotex Inc.'s argument that interests arising
11 from the commitment of capital made outside of the
12 host State constitute "investments of investors of
13 another Party in the territory of the Party" under
14 Article 1101 is simply not credible. Nor is it
15 consistent with one of the key purposes of the NAFTA
16 set out in Article 102, and that is "to increase
17 substantially investment opportunities in the
18 territories of the Parties," which, as the Metalclad
19 Tribunal held, evidences the Parties' specific intent
20 "to promote and increase cross-border investment
21 opportunities."

22 This morning, Mr. Legum attempted to lend

10:38:15 1 further support to his view. He said that reading
2 Article 1139 to exclude a contribution by an operating
3 company indirectly owned or controlled by a holding
4 company would exclude from the ambit of investment
5 chapter a very significant portion of the most
6 important investors in the world.

7 That may be Mr. Legum's view, but we would
8 submit, as my colleague Mr. Sharpe will demonstrate,
9 that the NAFTA draws the line as to what constitutes
10 an investment of an investor at a very different
11 place.

12 As I previously mentioned, under
13 Article 1139, investors are inextricably linked to
14 their investments. And Article 1101 makes clear that
15 Chapter 11 applies only to investments in a territory
16 other than the investor's own. As the Grand River
17 Tribunal summarized it, "Prior NAFTA Tribunals have
18 held, following extensive briefing and argument, that
19 they do not have jurisdiction over claims that are
20 based upon injury to investments located in one NAFTA
21 Party on account of actions taken by authorities in
22 another." Thus, Apotex's alleged commitment of

10:39:38 1 capital in Canada cannot establish an "investment" for
 2 purposes of Chapter 11.
 3 It is worth noticing that Dr. Desai testified
 4 that Apotex Inc. once operated a manufacturing
 5 facility in the United States, but it closed that
 6 facility in 2004. Apotex Inc. undoubtedly has its
 7 reasons for choosing to invest in Canada over the
 8 United States, presumably including a more favorable
 9 corporate tax rate in Ontario. But what is clear is
 10 that Apotex Inc. is not an investor in the United
 11 States. And, thus, this Tribunal has no jurisdiction
 12 over its claims.
 13 Apotex Holdings, on the other hand, has made
 14 an actual investment in the United States, a
 15 distribution company called Apotex Corp. Another
 16 quick note about terminology is needed here. Apotex's
 17 counsel consistently refers to Apotex Inc. as
 18 "Apotex-Canada" and to Apotex Corp. as "Apotex-U.S.,"
 19 as if to suggest that the only difference between them
 20 is territorial, that they are two prongs of the same
 21 operation separated only by a border. These companies
 22 were not referred to as "Apotex-Canada" and

10:41:09 1 "Apotex-U.S." in any Apotex documents other than in
 2 this arbitration. In fact, Apotex Inc. and
 3 Apotex Corp. are entirely distinct corporations that
 4 are indirectly owned by Apotex Holdings. As
 5 Ms. McLeod showed you on Monday, they are not even in
 6 the same branch of the Apotex family tree.
 7 While the United States concedes that
 8 Apotex Corp. is an investment of Apotex Holdings for
 9 purposes of the NAFTA, that does not mean that consent
 10 has been obtained and that the Tribunal has
 11 jurisdiction over this arbitration. That is because
 12 Apotex Corp. fails to cross another NAFTA
 13 jurisdictional threshold: That the challenged Measure
 14 "relates to" the investment, as required by
 15 Article 1101.
 16 1101 states that Chapter 11 only applies to
 17 Measures "relating to" an "investor" or investment.
 18 In this case, both Parties agree that the two relevant
 19 questions are: (1), whether the Import Alert "relates
 20 to" Apotex Corp., Apotex Holdings' only alleged
 21 investment; and, (2), whether the Import Alert relates
 22 to the ANDAs, Apotex Inc.'s sole claimed investment.

10:42:41 1 In conducting this analysis, both Parties
 2 have adopted the Methanex Tribunal's definition of
 3 "relating to"; that is, it has to have a "legally
 4 significant connection." But again, this is a trade
 5 dispute. The Import Alert applied only to Apotex
 6 Inc.'s Canadian facilities, not to Apotex Corp., and
 7 it did not prevent Apotex Corp. from carrying on its
 8 distribution business. Indeed, Apotex Corp. made up
 9 for the lost products from its supplier, Apotex Inc.,
 10 by making Contracts with non-Apotex companies to
 11 supply products, which it could unquestionably do
 12 regardless of the Import Alert. Under very similar
 13 circumstances, the Methanex Tribunal found that the
 14 "relating to" test was not met. There was no legally
 15 significant connection.
 16 In order to get around this basic fact,
 17 Apotex has to resort to circular legal reasoning.
 18 Apotex argues that if it has established a breach on
 19 the Merits, it meets the "legally significant"
 20 requirement, but this would eliminate the threshold
 21 jurisdictional question of whether the Measure
 22 "relates to" the investment in its entirety. This is

10:44:05 1 not how the NAFTA works. Apotex has to show that the
 2 Import Alert had a legally significant connection to
 3 Apotex Corp., not Apotex Inc. Apotex's circular
 4 reasoning does not meet this burden.
 5 As Mr. Sharpe will show, and as Apotex has
 6 conceded, the Import Alert applied only to drugs
 7 manufactured at Apotex Inc.'s facilities in Canada at
 8 Etobicoke and Signet. It did not affect
 9 Apotex Corp.'s ability to purchase drugs from those
 10 facilities, nor was the Import Alert a Measure that
 11 prevented Apotex Corp. (and any other company) from
 12 distributing drugs from those facilities in the United
 13 States. To the extent that one of Apotex Corp.'s
 14 several suppliers of drugs--in this case, two of
 15 Apotex Inc.'s facilities--was impacted by the Import
 16 Alert, Apotex Corp. is in no different position than
 17 any of the several unrelated companies that distribute
 18 Apotex Inc. drugs.
 19 The Tribunal in Methanex made abundantly
 20 clear that in such circumstances, where the alleged
 21 investment stands in no different position legally
 22 from any other unrelated supplier or distributor, it

10:45:34 1 cannot be said that the Measure "related" to that
 2 investment.
 3 In reviewing Apotex's jurisdictional
 4 arguments, it is important to remember that the
 5 Claimant bears the entire burden of establishing facts
 6 necessary to establish jurisdiction. As the Tribunal
 7 in the Rompetrol Arbitration recently confirmed, the
 8 Claimants' burden of proof in jurisdictional matters
 9 is "absolute" and, thus, never shifts to the
 10 Respondent. As that Tribunal explained, "a Claimant
 11 before an international Tribunal must establish the
 12 facts on which it bases its case or else it will lose
 13 the arbitration." The Respondent, by contrast, does
 14 not in that sense bear any burden of proof on its own.
 15 NAFTA Chapter 11 Tribunals have confirmed
 16 that Claimants bear the burden of proof on
 17 jurisdictional issues and that the burden never shifts
 18 to the Respondent. According to the NAFTA Tribunal in
 19 the Fireman's Fund case, a Claimant is not "entitled
 20 to the benefit of the doubt with respect to the
 21 existence and scope of an arbitration agreement." Or,
 22 as the Gallo Tribunal explained: "Both Parties submit

10:46:55 1 and, the Tribunal concurs, that the maxim 'who asserts
 2 must prove'--or actori incumbit probatio--applies also
 3 in the jurisdictional phase of this arbitration. A
 4 Claimant bears the burden of proving that he has
 5 standing and the Tribunal has jurisdiction to hear the
 6 claims submitted. If jurisdiction rests on the
 7 existence of certain facts, these facts must be proven
 8 at the jurisdictional phase.
 9 And perhaps the Tribunal in Apotex I and II
 10 put it best and most succinctly: "Apotex (as
 11 Claimant) bears the burden of proof with respect to
 12 the factual elements necessary to establish the
 13 Tribunal's jurisdiction in this regard." The Tribunal
 14 must hold Apotex to its burden. Apotex Inc. must
 15 prove that its ANDAs constitute "investments" for
 16 purposes of Article 1139. It has failed to do so.
 17 Similarly, Apotex must prove that the Import Alert
 18 "relates to" Apotex Holdings' investment, Apotex Corp.
 19 The burden is especially important here
 20 because there are concerns about Apotex's
 21 representations made through the presentation of its
 22 case, including how it presented the facts and law

10:48:22 1 related to the significant jurisdictional issues in
 2 this case. And I will highlight just a few examples.
 3 The Tribunal will recall from our written
 4 submissions the difference between Apotex's statements
 5 about its corporate activities in this arbitration and
 6 statements made when Apotex seeks to avoid
 7 jurisdiction of U.S. courts. Other examples abound,
 8 and, I regret, are not limited to the written
 9 pleadings. I will pause for a moment to explain what
 10 I mean.
 11 On Monday, Apotex's counsel stated that the
 12 Grand River Tribunal found that a U.S. trademark was a
 13 protected investment for purposes of the NAFTA. In
 14 support of this conclusion, Apotex placed an excerpt
 15 of Paragraph 79 of that Award on a slide, but it
 16 omitted critical text without ellipses to indicate the
 17 omission. That omission explained that the investment
 18 involved not only a trademark, but also ownership of a
 19 substantial business in the United States.
 20 Regrettably, we see the same pattern in the
 21 Merits arguments. For example, in its Memorial,
 22 Apotex claimed to rely on a law school working paper

10:49:43 1 that, according to Apotex, demonstrated the minimum
 2 standard of treatment under international law,
 3 omitting text from that document showing that it was,
 4 in fact, discussing the maximum treatment available
 5 under some common law jurisdictions.
 6 Time and again this week, Apotex put slides
 7 before the Tribunal that selectively quoted from the
 8 record. For example, you may recall Mr. Hay
 9 explaining that following the Import Alert, FDA found
 10 Apotex's "Protocols" to be adequate. Here is what
 11 Mr. Hay said at Pages 109-110 of the first day
 12 transcript:
 13 "Because FDA continued to express a
 14 misunderstanding about Apotex's batch rejections, on
 15 November 24, 2009, Apotex submitted another detailed
 16 analysis of the batch rejection list showing all
 17 rejections were well within normal limits. On the
 18 same day, the FDA case officer completed her review of
 19 Apotex's protocols and concluded that they adequately
 20 captured all of FDA's concerns."
 21 The exhibit Apotex flashed on the screen was
 22 Exhibit C-526. Let's see what that exhibit said.

10:51:10 1 In this document, Hidee Molina, an officer in
 2 CDER wrote, "Just to inform you that reviewed both the
 3 quality systems assessment of Apotex Inc. protocol and
 4 the revised Product Quality Assessment of Apotex Inc.
 5 drug product protocol. Based on my review, both
 6 protocols appear to be adequate to capture both cGMP
 7 systems gaps and product that may potentially fail
 8 quality attributes."
 9 In other words, Ms. Molina was reviewing
 10 whether Apotex consultant, Jeff Yuen, had devised a
 11 system to detect Apotex's cGMP systems gaps, of which
 12 there were many, as Apotex admitted, and whether
 13 Apotex's system would now capture product that "fail
 14 quality attributes." Neither of these protocols
 15 suggest that Apotex's cGMP problems were remedied at
 16 this point. FDA was merely approving of Apotex's plan
 17 to begin returning to cGMP compliance.
 18 With that said, I will return to the burden
 19 of proof.
 20 The Parties agree that each Party has the
 21 burden of proving facts supporting its legal claims.
 22 Thus, Apotex bears the burden of proving its claims

10:52:36 1 under 1102, 1103, and 1105. A fortiori, because the
 2 United States is making no affirmative defenses in
 3 this case, the burden remains at all times with the
 4 Claimant to prove its claims. In its presentation on
 5 the Merits, however, Apotex routinely sought to place
 6 the burden on the United States by claiming that it,
 7 as the Respondent, failed to produce this document or
 8 that document.
 9 The Tribunal will recall that at the
 10 procedural hearing in July 2012, Apotex's counsel
 11 surprised all of us by claiming that it was prepared
 12 to file its case in full, as it was required to do
 13 under the Procedural Order, that very week. Of
 14 course, that turned out not to be true. Its damages
 15 Expert, Howard Rosen, admitted that he was not able to
 16 fully quantify Apotex's supposed damages. But as it
 17 turns out, Apotex also did not have its case together
 18 on the Merits. Instead of presenting its case in full
 19 on Articles 1102 and 1103, it intended to build that
 20 case through discovery. This is not how this
 21 arbitration is supposed to work.
 22 This became clearer during the document

10:54:02 1 production phase of this case, when Apotex served over
 2 100 document requests on the United States, including
 3 requests for all documents related to the inspections
 4 of its comparators. The United States made clear that
 5 production of these documents would not be possible.
 6 First, the request was overbroad, and compliance with
 7 such a request would require review of tens of
 8 thousands of documents.
 9 But second, and more importantly, FDA is
 10 bound by law to withhold commercially sensitive
 11 information supplied by the companies it regulates.
 12 And it is ironic that Apotex has repeatedly sought to
 13 cut the feed in this arbitration to protect its own
 14 commercially sensitive information, but accuses the
 15 United States of wrongdoing in protecting the
 16 commercially sensitive information of its competitors.
 17 In any event, in response to Apotex's
 18 request, the United States agreed to supply what
 19 documents it could--namely, the Form 483s and
 20 Establishment Inspection Reports. It is striking that
 21 despite Apotex's repeated cry that the United States
 22 has not produced relevant documents, Apotex chose not

10:55:29 1 to address the documents that we could provide, which
 2 contain significant detail about these companies' cGMP
 3 violations.
 4 Moreover, the United States told Apotex that
 5 after it reviewed those documents, the United States
 6 was open to further discussion on documents Apotex
 7 thought it needed, if it could identify those
 8 documents with sufficient specificity. Apotex never
 9 took the United States up on its offer. In short,
 10 Apotex should not be heard now to complain that it
 11 does not have documents to establish its claim under
 12 1102 and 1103.
 13 Thankfully, the Tribunal's task in this case
 14 is greatly simplified because of the large number of
 15 undisputed facts. My colleague, Ms. Cate, will
 16 discuss the relevant facts in greater detail, most
 17 likely tomorrow, but I want to highlight some of the
 18 key facts and, to be clear, facts that are not
 19 disputed.
 20 There is no dispute that FDA inspected
 21 Apotex's Etobicoke facility again in December 2008 and
 22 that Apotex was cited for multiple cGMP violations.

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10:56:56 1 These citations included a recurring failure to file
 2 Field Alert Reports on time, a failure noted in an
 3 earlier inspection in 2006. In one instance, the FDA
 4 investigator found that Apotex filed the Field Alert
 5 Report a year and a half late.
 6 The inspection also revealed Apotex's failure
 7 to thoroughly investigate failed batches as required
 8 by cGMP. The lead investigator on that inspection was
 9 Debra Emerson, who provided a Witness Statement in
 10 this arbitration and who will testify later today.
 11 Ms. Emerson recommended OAI, or "Official Action
 12 Indicated," expressing her view that enforcement
 13 action was appropriate in light of the severity of the
 14 Apotex's cGMP violations.
 15 Although FDA considered adding Apotex's
 16 Etobicoke facility to the Import Alert at that time,
 17 the evidence shows that it refrained from doing so.
 18 Instead, FDA issued Apotex a Warning Letter on
 19 June 25, 2009. Apotex responded to this Warning
 20 Letter on July 17, 2009, which FDA duly considered.
 21 FDA inspected the Signet facility between
 22 July 27 and August 14, 2009. The Parties agree that

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10:58:30 1 the investigators at that facility listed 17 different
 2 cGMP violations. The first among these was that "The
 3 quality unit has failed to fulfill its
 4 responsibilities in that components and drug products
 5 are not rejected when components and/or drug products
 6 fail to conform to the qualities they are purported to
 7 possess."
 8 In other words, Apotex's quality control
 9 staff was failing to perform its most basic function,
 10 to reject drugs that had failed quality testing.
 11 Again, the lead investigator for that inspection,
 12 Mr. Lloyd Payne, who submitted a Witness Statement in
 13 this arbitration, will testify later today. He
 14 recommended OAI, reflecting Mr. Payne's view that
 15 enforcement action was warranted.
 16 It is undisputed that in 2009 Apotex did not
 17 challenge any of these cGMP findings. Rather, Apotex
 18 admitted that it had significant cGMP violations;
 19 recalled over 600 batches of products, amounting to
 20 millions of dosages, in the United States; and hired
 21 several third-party consultants to help it remediate
 22 the cGMP violations.

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11:00:04 1 It is also undisputed that in August 17,
 2 2009, teleconference, Apotex expressly vowed to keep
 3 manufacturing drugs from those facilities for the
 4 United States market while it labored to remedy its
 5 cGMP violations. That is, Apotex acknowledged major
 6 systematic manufacturing problems at Etobicoke and
 7 Signet, but vowed to continue exporting to the United
 8 States drugs that were legally deemed to be
 9 adulterated. Apotex's Etobicoke and Signet facilities
 10 were thereafter placed on Import Alert on August 28,
 11 2009.
 12 It's also undisputed that Apotex's primary
 13 regulator, Health Canada, similarly identified major
 14 cGMP violations at Etobicoke and Signet. The problems
 15 were so numerous and so serious that, under Canadian
 16 law, Health Canada could have stripped Apotex of its
 17 establishment license and shut its facilities down.
 18 Instead, Health Canada committed huge resources to
 19 monitoring Apotex's compliance efforts. These
 20 included monthly site visits by Health Canada,
 21 something that FDA was simply not in a position to do.
 22 Other national health authorities in

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11:01:33 1 Australia, New Zealand, and the Netherlands, on behalf
 2 of the EU, expressed grave concerns about Apotex's
 3 manufacturing violations. In fact, New Zealand's
 4 Medsafe stated that, if Apotex had been a New Zealand
 5 company, Medsafe would have shut them down.
 6 Apotex's admissions with respect to its cGMP
 7 deficiencies were not limited to FDA. In an internal
 8 e-mail exchange, Dr. Jeremy Desai, Apotex Inc.'s CEO,
 9 admitted to Bernard Sherman that "our quality systems
 10 lack quality."
 11 Apotex committed to fix its cGMP problems and
 12 invite FDA back for re-inspection. It is undisputed
 13 that Apotex undertook an overhaul of its entire
 14 quality assurance system and that it took Apotex over
 15 a year to feel comfortable enough with its quality
 16 system overhaul to invite FDA back for re-inspection.
 17 Apotex first asked FDA in August 2010 to
 18 re-inspect Etobicoke in October 2010, and Apotex first
 19 asked FDA to re-inspect Signet in September 2010,
 20 although Apotex did not propose a date for
 21 re-inspection.
 22 In the meantime, FDA inspected two other

11:03:03 1 Apotex facilities, at Richmond Hill in Canada and at
 2 Bangalore, India. Although FDA found cGMP violations
 3 at both of those facilities, it decided, in its
 4 discretion, not to add those facilities to the Import
 5 Alert.
 6 PRESIDENT VEEDER: Forgive me, but I think
 7 Slide 19 may have the word "not" omitted.
 8 MS. GROSH: We apologize for the error, a
 9 significant error.
 10 With respect to these two facilities, FDA's
 11 exercise of discretion benefited Apotex. Ironically,
 12 Apotex's proposed approach to enforcement, in which
 13 FDA would have no discretion to refrain from
 14 enforcement once cGMP violations were found, would
 15 presumably have forced FDA to add these two facilities
 16 to the Import Alert.
 17 FDA scheduled the re-inspection of Etobicoke
 18 and Signet in late January 2011. The contemporaneous
 19 documents show that FDA investigators found continuing
 20 and numerous cGMP violations during these inspections;
 21 many of these were problems that had been identified
 22 in one of the previous inspections.

11:04:32 1 The lead investigator of that inspection is
 2 Mr. Michael Goga, who provided a Witness Statement in
 3 this arbitration, and he, too, will testify later
 4 today. Mr. Goga once again recommended OAI, or
 5 Official Action Indicated, and expressly stated in his
 6 view that Apotex should remain on Import Alert.
 7 Nonetheless, after considering Apotex's
 8 existing Corrective Actions, a subsequent Health
 9 Canada inspection, and Apotex's remediation plan, CDER
 10 exercised its discretion to recommend removing
 11 Apotex's two facilities from the Import Alert.
 12 FDA's Division of Import Operations and
 13 Policy, or DIOP, concurred with CDER's recommendation.
 14 Again, Apotex's one-size-fits-all approach to
 15 enforcement would have forced FDA to keep these
 16 facilities on Import Alert. But FDA does not operate
 17 this way, which is sometimes to Apotex's benefit.
 18 Mr. President, Members of the Tribunal, these
 19 are undisputed facts. They demonstrate that FDA
 20 properly denied the importation of Apotex products for
 21 cGMP violations at Etobicoke and Signet. Apotex did
 22 not contemporaneously contest these serious,

11:05:59 1 systematic cGMP violations.
 2 However, Apotex claimed yesterday that
 3 Apotex-Canada rejected FDA's suggestion that its
 4 facilities were not compliant with cGMP. Apotex cited
 5 to its own Request for Arbitration for this
 6 proposition. It pointed to no actual evidence for
 7 this statement because it cannot. The evidentiary
 8 record shows, however, that through multiple meetings,
 9 calls, letter, and e-mails through 2009 and 2010,
 10 Apotex repeatedly admitted its cGMP violations. This
 11 is just a small sampling of the many contemporaneous
 12 admissions by Apotex on this point.
 13 During the closeout meetings for the Signet
 14 2009 inspection, management agreed with the
 15 deficiencies. This is the Signet 2009 EIR Page 38,
 16 document R-42.
 17 On the August 17, 2009, teleconference,
 18 Apotex "acknowledged that there are significant
 19 deficiencies." That is R-43 at Page 2.
 20 At the September 11, 2009, meeting between
 21 FDA and Apotex, "Mr. Kay said that Apotex understands
 22 that it is our job, not FDA's, to make sure that our

11:07:36 1 systems are acceptable." This is from Apotex's own
 2 minutes of the meeting. This is document C-94 at
 3 Page 4.
 4 From the Apotex Response to the Signet 483,
 5 "Apotex acknowledges that there are instances where
 6 components or drug products are not rejected when they
 7 fail to conform to the qualities they purport to
 8 possess." That is document C-81 at Page 1.
 9 Because the facts are undisputed, the United
 10 States did not feel compelled to cross-examine
 11 Apotex's fact witnesses. The only question facing
 12 this Tribunal on the Merits is whether these facts
 13 support Apotex's claim that the United States violated
 14 NAFTA Articles 1102, 1103, or 1105.
 15 Before closing my discussion of the facts, I
 16 need to emphasize that Apotex has presented a very
 17 different view in its discussion of the facts.
 18 Mr. Legum said dramatically at the top of the
 19 hearing that with respect to the actions FDA took
 20 against Apotex, "It has never happened before. It has
 21 not done it since." This is simply not true. Apotex
 22 only gets to this conclusion by, once again,

11:09:14 1 selectively quoting from documents and cherry-picking
 2 its examples.
 3 So let's start with the first part, "It never
 4 happened before." To get to this conclusion, Apotex
 5 cites--among other things--a statement by Dr. Margaret
 6 Hamburg, the FDA Commissioner appointed in 2009. This
 7 is C-51. And it was literally the very first thing
 8 Apotex's discussed at this hearing.
 9 Apotex suggests that Dr. Hamburg's statement
 10 instituted "a new enforcement policy." And I would
 11 refer you to Page 87 of the first day's transcript.
 12 But if you look at the statement, you'll see that
 13 Dr. Hamburg was not trying to impose a new strategy
 14 with no historical precedent; rather, Dr. Hamburg was
 15 trying to return to FDA's historical practice.
 16 As Dr. Hamburg states, "Reports have noted
 17 that there has been a steep decline in FDA's
 18 enforcement activity over the past several years. At
 19 the same time, many of the enforcement actions that
 20 the FDA has undertaken have been hampered by
 21 unreasonable delays." Dr. Hamburg thus proposed
 22 strengthening FDA's enforcement policies to bring

11:10:48 1 enforcement back to historic levels.
 2 Mr. Vodra, our Expert, has been in this
 3 industry since 1970s, and if the Tribunal is so
 4 inclined, Mr. Vodra could address the ebbs and flows
 5 in FDA's priorities, including enforcement, which
 6 often depend on resources and the pressing issues of
 7 the day.
 8 Critically, however, the basic Regulatory
 9 Framework giving rise to the action against Apotex was
 10 well established and is not challenged by Apotex in
 11 this case. Indeed, as Mr. Bigge will discuss after
 12 me, none of the relevant statutes, regulations, or
 13 practices were in any way new. In fact, they were,
 14 for the most part, many decades old.
 15 As for Mr. Legum's statement that the FDA
 16 "has not done it since," again, this is not true.
 17 Apotex has presented six companies that received
 18 Warning Letters, but were not subject to enforcement
 19 action and claims that Apotex was uniquely targeted.
 20 Apotex ignores the various companies
 21 mentioned in this very arbitration, companies whose
 22 names you have heard mentioned or read in an exhibit:

11:12:08 1 KV, Actavis, Caraco, Aurobindo, Claris, and Ranbaxy.
 2 Each of these companies was subject to significant
 3 enforcement action and, in some cases, placed on
 4 Import Alert 66-40. But there are many more.
 5 As we discussed in our Counter-Memorial at
 6 Paragraph 66 and 67, between 2002 and 2008, CDER
 7 issued, on average, only three Warning Letters per
 8 year. By contrast, CDER issued 13 Warning Letters in
 9 2009, including Apotex's Etobicoke facility; 18
 10 Warning Letters in 2010; and 20 Warning Letters in
 11 2011.
 12 Similarly, between 2003 and 2008 FDA added,
 13 on average, only one firm per year to the Import
 14 Alert. By contrast, FDA added 10 firms in 2009,
 15 including Apotex; 12 firms in 2010; and 19 firms in
 16 2011. Far from "never happening since," there are
 17 many companies in the exact same situation as Apotex.
 18 Apotex also falsely claims that it was not
 19 given an opportunity to provide information to FDA
 20 prior to the Import Alert and that this makes it
 21 unique. Apotex is wrong in both respects.
 22 Apotex had ample opportunity to explain

11:13:56 1 itself from the moment the 2008 Etobicoke inspection
 2 began and in the eight months that followed. But
 3 Apotex's second premise is untrue as well. Claris and
 4 Aurobindo, as discussed in our papers, were put on
 5 Import Alert before a Warning Letter was even issued.
 6 There was nothing unique about Apotex's treatment at
 7 all, we would submit.
 8 The truth of the matter is this: When
 9 pharmaceutical companies selling drugs in the United
 10 States market violate cGMPs, FDA must make enforcement
 11 decisions. It weighs various factors in making these
 12 decisions, including the risk to the consumers, the
 13 history of compliance by the company, the severity of
 14 the violations by the company, the risk of drug
 15 shortage in the United States, the quality of the
 16 evidence it collected during the inspection, and its
 17 own resources. Trained FDA personnel assess these
 18 factors, and the ultimate decision on what to do next
 19 is a matter of their experienced judgment.
 20 Apotex has presented no basis for
 21 second-guessing the good-faith judgments made by
 22 trained FDA personnel. Under Apotex's theory, where

11:15:35 1 two or more companies have similar cGMP violations,
 2 FDA must either take action against all of them or
 3 take no action against any of them. Apotex thus seeks
 4 to strip regulatory agencies of all enforcement
 5 discretion, creating a one-size-fits-all model of
 6 regulatory enforcement that could endanger the public
 7 health. The NAFTA does not require this approach to
 8 enforcement, which would undermine the NAFTA's goal of
 9 preserving the State's flexibility to protect public
 10 health.

11 In the International Thunderbird case, for
 12 example, the Tribunal rejected the Claimants'
 13 Article 1102 argument that it had been subject to
 14 discrimination because its illegal gambling activities
 15 were subject to enforcement, while other gambling
 16 operations continued to operate.

17 The Tribunal explained, "Even if Thunderbird
 18 had established without a doubt Mexico's line of
 19 conduct with respect to gambling operations was not
 20 uniform and consistent, one cannot overlook the fact
 21 that gambling is illegal in Mexico. In the Tribunal's
 22 view, it would be inappropriate for a NAFTA Tribunal

11:16:57 1 to allow a Party to rely on Article 1102 of the NAFTA
 2 to vindicate equality of nonenforcement within the
 3 sphere of an activity that a contracting Party deems
 4 illicit."

5 Mr. President, Members of the Tribunal, the
 6 remainder of our presentation will proceed as follows:

7 First, you will hear from my colleague,
 8 Mr. Bigge, who will present an overview of the
 9 relevant domestic regulatory structure. We will then
 10 present as Fact Witnesses the three lead investigators
 11 for the relevant inspections: Debra Emerson for the
 12 2008 Etobicoke inspection; Lloyd Payne for the 2009
 13 Signet inspection; and Michael Goga for the 2011
 14 inspection of both facilities. They can each tell you
 15 about the severity of the cGMP violations they
 16 recorded.

17 And you will also hear from Dr. Carmelo Rosa,
 18 the Director of the International Compliance Branch of
 19 FDA's Center for Drug Evaluation and Research, who was
 20 the team leader who oversaw the decision to recommend
 21 addition of Etobicoke and Signet to the Import Alert
 22 in 2009, and he was also the branch chief when CDER

11:18:16 1 recommended removing those facilities from the Import
 2 Alert in 2011. Dr. Rosa was in near constant
 3 communication with Apotex regarding its cGMP
 4 violations and its attempts to remedy those violations
 5 over the course of 2009 and 2010.

6 Finally, you will also hear from Mr. William
 7 Vodra, an attorney with over 30 years of experience
 8 advising clients on FDA regulations, including cGMP.
 9 Mr. Vodra will identify remaining areas of
 10 disagreement with Mr. Bradshaw and Mr. Johnson
 11 regarding the applicable Regulatory Framework.

12 Following the Witnesses, we will present our
 13 arguments on jurisdiction and the Merits. With
 14 respect to jurisdiction, Ms. Thornton will address the
 15 res judicata effect of the Award in Apotex I and II.
 16 Ms. Thornton will also explain why Apotex's ANDAs
 17 cannot be considered "investments" under
 18 Article 1139(g).

19 Mr. Sharpe will then address Apotex's
 20 arguments under Article 1139(h) with respect to the
 21 ANDAs and will also show how the Import Alert does not
 22 "relate to" any alleged investor or investment in this

11:19:37 1 arbitration.

2 Those presentations will demonstrate that the
 3 Tribunal has no jurisdiction to hear any of Apotex's
 4 claims. All claims, thus, should be dismissed for
 5 lack of jurisdiction.

6 You will then hear from Ms. Alicia Cate, who
 7 will present the facts as relate to the Merits. The
 8 story you will hear from Ms. Cate will sound quite
 9 different than the story you heard from Apotex.
 10 Apotex's quick recitation of the facts glossed over
 11 critical documents and events that show that Apotex
 12 had very serious cGMP violations, that it was made
 13 aware of these problems, that it was given an
 14 opportunity to address them, and that FDA was in
 15 regular communications with Apotex during the period
 16 of the Import Alert to assist in bringing it back into
 17 compliance.

18 Mr. Bergman will then present U.S. arguments
 19 on Articles 1102 and 1103 showing how Apotex has not
 20 met its burden to establish any of the three prongs of
 21 a National Treatment or Most-Favored-Nation Treatment
 22 claim; that is, treatment accorded to an investor or

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11:20:56 1 investment in like circumstances that is less
 2 favorable. Mr. Bergman will show that each of
 3 Apotex's comparators fails on at least one, and in
 4 most cases several, of these prongs.
 5 After Mr. Bergman's presentation on
 6 Articles 1102 and 1103, Mr. Blanck will address
 7 Apotex's failure to establish a breach of
 8 Article 1105. In particular, Mr. Blanck will
 9 demonstrate that customary international law minimum
 10 standard of treatment does not provide a rule of
 11 administrative due process that would require that
 12 States provide an oral hearing and the other
 13 procedural protections claimed by Apotex before
 14 detaining at the border drugs lawfully deemed to be
 15 adulterated under domestic law.
 16 Mr. Blanck also will discuss the many
 17 administrative and judicial remedies that were
 18 available to Apotex to challenge FDA's findings if
 19 Apotex had actually disputed those findings and the
 20 Measure at issue in this arbitration.
 21 Again, the real-world impact of Apotex's
 22 theory is untenable. Under Apotex's theory, the

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11:22:09 1 United States had to provide Apotex--or any foreign
 2 investor--with certain procedural rights before it
 3 makes any decision that would materially affect the
 4 alleged investment. This is the case, according to
 5 Apotex, even where there is ample due process
 6 available immediately after the decision is made, as
 7 was the case here.
 8 Such a procedure would grind the modern
 9 administrative State to a halt, put an incredible
 10 resource burden on governments and making it
 11 impossible to take any kind of swift, timely action to
 12 protect the public health. This will allow companies
 13 like Apotex to flood the market with adulterated
 14 product while that process is ongoing instead of
 15 permitting detention of that product to protect U.S.
 16 consumers.
 17 Following Mr. Blanck's presentation on
 18 Article 1105, Mr. Bigge will return to address
 19 Apotex's arguments under the U.S.-Jamaica BIT. The
 20 U.S.-Jamaica BIT provides Apotex with no better
 21 treatment than NAFTA Article 1105 because neither
 22 Treaty requires a procedural hearing prior to a State

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11:23:25 1 making a decision in a nonadjudicatory context.
 2 In any event, the "effective means" provision
 3 in the U.S.-Jamaica BIT could not apply in this case
 4 because Apotex did not make any attempt to utilize the
 5 means available to it to assert its claims and, in any
 6 event, Apotex had no claim to assert nor right to
 7 enforce.
 8 Thank you, Mr. President, and Members of the
 9 Tribunal for your patience. I would ask that you call
 10 on Mr. Bigge to address the Regulatory Framework
 11 underlying FDA's cGMP inspections of Apotex and the
 12 addition of Apotex to the Import Alert.
 13 ARBITRATOR CROOK: Thank you, Counsel.
 14 I think before we go to the next presenter, I
 15 may have misunderstood, but I thought I heard a
 16 resonance in your argument that Apotex was calling for
 17 one-size-fits-all enforcement Measures, that if a
 18 Warning Letter was issued, then everyone had to be
 19 treated similarly.
 20 Maybe that's not the position that you're
 21 arguing, but certainly it seems to me, over the course
 22 of the last couple of days, Apotex has indicated that,

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11:24:55 1 at least at this stage, that is not their position.
 2 So I'd invite you to look at the Monday
 3 transcript of Page 240, 247, and 248 where, in the
 4 first cite, Mr. Legum responded to a similar
 5 characterization in Ms. McLeod's introductory remarks.
 6 Then at 247 and 248 there was an exchange involving
 7 similar questions by me and Mr. Rowley. And then we
 8 had a further colloquy to similar effect this morning.
 9 So I'd just invite you to look at those and
 10 just make sure that we're dealing with the correct
 11 characterization of what the position is.
 12 MS. GROSH: Mr. Crook, thank you for those
 13 comments. We will go and review those portions of the
 14 transcript, and my colleagues who will address the
 15 arguments on 1102 and 1103 will provide further
 16 discussion of those.
 17 PRESIDENT VEEDER: Thank you very much for
 18 that. Do you want a five-minute break while you swap
 19 chairs, or would you like to continue straightaway?
 20 MR. SHARPE: Five minutes to swap chairs
 21 would be much appreciated.
 22 PRESIDENT VEEDER: Let's take five minutes.

11:26:16 1 (Brief recess.)
 2 PRESIDENT VEEDER: Let's resume. The
 3 Respondent has the floor.
 4 MR. BIGGE: Mr. President, Mr. Rowley,
 5 Mr. Crook, my name is David Bigge, and I will be
 6 explaining this morning the domestic legal background
 7 to this case. As I indicated to the President and to
 8 opposing counsel, my presentation will take
 9 approximately an hour, although I will beg opposing
 10 counsel's and the Tribunal's indulgence if I hold us
 11 back from lunch for an extra few minutes.
 12 The purpose of my presentation this morning
 13 is threefold. First, and most importantly, I will try
 14 to present the relevant legal background in a succinct
 15 manner for the Tribunal to draw on as it deliberates.
 16 Mr. Hay presented some of this information on Monday,
 17 but his short presentation skipped over key parts of
 18 the regulatory background, which I will provide this
 19 morning.
 20 Second, it is important to emphasize that the
 21 statutes, regulations, and practices at issue here are
 22 well established. As we detail in our

11:39:17 1 Counter-Memorial, U.S. regulation of pharmaceuticals
 2 dates back to at least 1848. In the Drug Importation
 3 Act of that year, Congress sought to prevent the
 4 importation of "adulterated and spurious drugs and
 5 medicines."
 6 Under that law, drugs found to be adulterated
 7 or deteriorated were not to pass the Customs House.
 8 The relevant statute in this case dates back to 1938
 9 and allows FDA to prevent drugs from crossing the
 10 border that appear to be adulterated.
 11 The cGMP requirements were added to that
 12 statute in 1962. Under that amendment,
 13 pharmaceuticals manufactured at non-cGMP compliant
 14 facilities are deemed to be "adulterated" and can be
 15 refused admission at the border. Furthermore, the
 16 procedures for cGMP inspection and enforcement are
 17 well publicized and were understood by Apotex.
 18 In this arbitration, Apotex challenges
 19 neither the appearance of adulteration standard in the
 20 1938 statute, nor the cGMP requirements in the 1962
 21 Amendments, nor the practices and procedures related
 22 to cGMP. The evidence shows that FDA precisely

11:40:44 1 followed those laws and procedures with respect to
 2 Apotex, and Apotex has not alleged otherwise.
 3 Third, there are critical legal differences
 4 in cGMP inspection and enforcement between domestic
 5 and foreign facilities. In particular, the Import
 6 Alert and detention and refusal actions for which FDA
 7 can rely on the appearance of adulteration standard
 8 are not available for domestic facilities. Similarly,
 9 inspections of domestic facilities are quite different
 10 than inspections of foreign facilities. As
 11 Mr. Bergman will explain in greater detail, these
 12 differences mean that Apotex's alleged U.S.
 13 comparators are inapt for purposes of Apotex's
 14 discrimination claims because they are not in like
 15 legal circumstances with Apotex's Canadian facilities.
 16 My presentation will be broken down into
 17 seven parts. First, I will discuss the Federal Food,
 18 Drug, and Cosmetic Act, the relevant statute which
 19 includes the cGMP requirements.
 20 Second, I will address the cGMP regulations
 21 themselves, including some of Apotex's more egregious
 22 violations.

11:41:59 1 Third, I will discuss how FDA conducts cGMP
 2 inspections, highlighting the differences between
 3 FDA's ability to inspect domestic pharmaceutical
 4 facilities and its ability to inspect foreign
 5 facilities.
 6 Fourth, I will discuss FDA's available
 7 enforcement mechanisms, again showing the differences
 8 between enforcement for domestic and foreign
 9 facilities.
 10 Fifth, I will briefly discuss how FDA's
 11 decision to take an enforcement action and what
 12 specific enforcement action to take are subject to FDA
 13 discretion and what--as recognized by both Apotex's
 14 and the United States's Experts.
 15 Sixth, I will discuss the statutory avenues
 16 available for a pharmaceutical company to challenge
 17 FDA's cGMP findings or enforcement actions.
 18 And, finally, I will discuss how this entire
 19 Statutory and Regulatory Framework impacts Apotex's
 20 arguments with respect to the challenged Measure in
 21 this arbitration, the Import Alert.
 22 The modern statute governing pharmaceutical

11:43:10 1 manufacturing--the Federal Food, Drug, and Cosmetic
 2 Act, which I will refer to as "the FDCA" or "the
 3 Act"--was first passed in 1938. It is included in
 4 U.S. Code at 21 USC, Section 301, et sequentia.
 5 Relevant excerpts are found in the exhibits at CLA-223
 6 through 240.

7 The statute, as originally drafted in 1938,
 8 authorized FDA to refuse to admit any drug into the
 9 United States that "appears" from examination or
 10 "otherwise," to be adulterated, misbranded, or in
 11 violation of other drug approval provisions in the
 12 Act.

13 The current version of the statute, which is
 14 on the screen, similarly states that FDA border agents
 15 may collect samples of pharmaceuticals offered for
 16 import into the United States, and if it appears from
 17 such samples or otherwise that such article is
 18 adulterated, misbranded, or in violation of
 19 Section 505, that such articles shall be refused
 20 admission except as provided in Subsection (b) of this
 21 section.

22 In other words, FDA can block the importation

11:44:29 1 of a drug into the United States on the basis of an
 2 appearance of adulteration. FDA does not have to
 3 establish actual adulteration. That appearance may be
 4 based on an examination of the product delivered to
 5 the border "or otherwise." Although the statute has
 6 been amended from time to time since 1938, the
 7 "appearance from the examination of such samples or
 8 otherwise" standard has remained consistent throughout
 9 the life of the statute, and Apotex does not challenge
 10 it here.

11 I should note also that the cite to this
 12 statute is 21 USC Section 381, because that's where it
 13 currently stands in the U.S. Code. However, by the
 14 numbering of the FDCA outside of the Code, it was
 15 Section 801. And those within the pharmaceutical
 16 industry refer to this section as Section 801. Thus,
 17 if you hear me or one of our Witnesses refer to
 18 Section 801, it is this statute that allows FDA to bar
 19 products from import based on the appearance of
 20 adulteration.

21 A 1962 Amendment to the Act passed following
 22 the well-known thalidomide disaster required FDA to

11:45:44 1 set Good Manufacturing Practices or, cGMP, for the
 2 pharmaceutical industry. These amendments included
 3 21 USC Section 351(a) (2) (B), which states that a drug
 4 shall be deemed adulterated--and if we could move to
 5 the next slide--"if methods used in or the facilities
 6 or controls used for its manufacturing, processing,
 7 packing or holding do not conform to or are not
 8 operated or administered in conformity with Current
 9 Good Manufacturing Practices, to assure that such drug
 10 meets the requirements of the Act as to safety and has
 11 the identity and strength and meets the quality and
 12 purity characteristics which it purports or is
 13 represented to possess."

14 There are two important points to highlight
 15 about the 1962 Amendment. First, as I mentioned a
 16 moment ago, the statute, from its enactment in 1938,
 17 made clear that FDA could refuse to admit drugs into
 18 the United States that "appeared" to be adulterated.
 19 The 1962 Amendment was added to a section of--the 1962
 20 Amendment was added to a section of products "deemed
 21 to be adulterated." Thus, the amendment made clear
 22 that a drug would be "deemed to be adulterated" if it

11:47:06 1 was not manufactured at a cGMP-compliant facility.
 2 Therefore, under the 1962 Amendment and Section 801 of
 3 the original statute, if it appears that a foreign
 4 facility is out of cGMP compliance, FDA could refuse
 5 to permit the importation of any drugs manufactured at
 6 that facility.

7 It is worth noting here that Canada and many
 8 other countries have similar provisions in their laws.
 9 It appears to be common practice among States to
 10 prevent products manufactured at foreign facilities
 11 that are not cGMP compliant from crossing the border.

12 In this very case, Apotex discussions
 13 discusses actions to block the importation of Apotex's
 14 products that were taken or contemplated by the
 15 European Union, New Zealand, and Australia. Evidence
 16 in the record also shows that Health Canada blocked
 17 the import of products made by a U.S. company called
 18 Ben Venue after Ben Venue's U.S. facilities failed a
 19 cGMP inspection. Ben Venue avoided a European import
 20 ban by agreeing to cease manufacturing while it
 21 remedied its cGMP violations, a step that Apotex
 22 refused to take in this case.

11:48:19 1 In fact, NAFTA Article 904 specifically
 2 states that where products offered for import do not
 3 meet standards like cGMP, the NAFTA Parties can block
 4 their importation.
 5 And the Article is on the screen. I will
 6 read it. "Each Party may, in accordance with this
 7 Agreement, adopt, maintain, or apply any
 8 standards-related Measure, including any such Measure
 9 relating to safety, the protection of human, animal,
 10 or plant life or health, the environment or consumers,
 11 and any Measure to ensure its enforcement or
 12 implementation. Such Measures include those to
 13 prohibit the importation of a good of another Party
 14 that fails to comply with the applicable requirements
 15 of those Measures."
 16 The second point to highlight about the 1962
 17 Amendment is its purpose, as stated explicitly in the
 18 statute itself. Products produced at
 19 non-cGMP-compliant facilities were "deemed to be
 20 adulterated" and, therefore, subject to refusal the
 21 border "to assure that" the drugs were safe and met
 22 the strength, quality, and purity characteristics they

11:49:26 1 purport to have.
 2 In other words, FDA did not have to prove
 3 that the drugs were actually unsafe or, even worse,
 4 they had injured someone before blocking import. The
 5 legislative history to the 1962 Amendment specified
 6 that cGMP violations would subject a firm to
 7 enforcement action "even though there is no deficiency
 8 in the product itself."
 9 And as a U.S. appellate court wrote just 10
 10 years after the 1962 Amendments, the "cGMP provision
 11 stems from congressional concern over the danger that
 12 dangerously impure drugs might escape detection under
 13 a system predicated only on seizure of drugs shown to
 14 be in fact adulterated."
 15 In other words, FDA takes a proactive
 16 approach to drug safety, and Apotex's insistence that
 17 its drugs did not injure anyone is, frankly,
 18 irrelevant. FDA requires that drugs intended for the
 19 U.S. market must be manufactured in accordance with
 20 Current Good Manufacturing Practices "to assure that"
 21 the millions and millions of dosages taken by U.S.
 22 consumers every day are safe and effective before

11:50:39 1 someone gets hurt.
 2 Thus, the components of the statute that led
 3 to the enforcement action against Apotex were in place
 4 by 1962, long before Apotex even existed, never mind
 5 before Apotex began exporting its drugs from Canada
 6 into the United States. The enforcement action
 7 actually taken against Apotex preventing the
 8 importation of drugs due to the cGMP violations at
 9 Etobicoke and Signet was clearly permissible under the
 10 statute.
 11 Again, Apotex does not challenge the statute
 12 itself as a violative measure. Apotex, instead,
 13 challenges only the Import Alert, FDA's memorandum
 14 informing its field offices of Apotex's cGMP
 15 violations.
 16 Turning now to the regulations themselves, in
 17 the U.S. federal system, statutes like the Federal
 18 Food, Drug, and Cosmetic Act are passed by Congress.
 19 Those statutes form the United States Code, which is
 20 why our citations to the statutes include the initials
 21 USC.
 22 Federal agencies responsible for implementing

11:51:46 1 those statutes can then establish regulations which
 2 are included in the Code of Federal Regulations or
 3 CFR. These regulations have the force of law. While
 4 the 1962 Amendment to the Act required pharmaceutical
 5 companies to comply with Current Good Manufacturing
 6 Practices, the Act itself does not state what those
 7 practices are. Therefore, starting in 1963, just a
 8 year later, FDA began publishing cGMP regulations.
 9 These cGMP regulations are currently found at
 10 21 CFR Section 210 and 211, and relevant portions of
 11 those regulations appear as exhibits at CLA-281-286
 12 and RLA-158-167.
 13 The GMP standards included in the U.S.
 14 regulations are not aspirational. Rather, as
 15 Mr. Bradshaw and Mr. Johnson acknowledge, they are
 16 minimum standards for the manufacturing of
 17 pharmaceutical products sold in the United States.
 18 Pharmaceutical manufacturers certainly understand what
 19 is expected of them to maintain this cGMP compliance.
 20 As Mr. Bradshaw and Mr. Johnson Report,
 21 "Pharmaceutical manufacturers can apprise themselves
 22 of the Agency's cGMP requirements and expectations by

11:53:05 1 reviewing cGMP regulations, the preamble to the
 2 proposed and final rules amending those regulations,
 3 relevant guidance documents, and FDA enforcement
 4 actions taken in response to alleged cGMP violations."
 5 Mr. Bradshaw and Mr. Johnson later write, at
 6 Paragraph 59, "FDA's interpretation of its cGMP
 7 regulatory requirements is expressed through guidance
 8 documents issued for industry and to the Agency's own
 9 investigators and compliance personnel. These
 10 guidance documents include numerous cGMP/compliance
 11 guidances for industry; guides to inspection, which
 12 are reference materials for FDA's inspectional
 13 personnel; and various other manuals and guides,
 14 including compliance program guidance manuals,
 15 compliance policy guides, the
 16 Investigations/Operations Manual and, the Regulatory
 17 Procedures Manual. These cGMP-related guidances and
 18 manuals are publicly available on FDA's Web site. In
 19 particular, they are collected on one of the Web pages
 20 that provides information about FDA's Office of
 21 Manufacturing and Product Quality."
 22 We also agree with Mr. Bradshaw and

11:54:18 1 Mr. Johnson's Statement in their Second Report that
 2 the cGMP requirements represent the "what" but do not
 3 describe the "how." As Mr. Bradshaw and Mr. Johnson
 4 suggest, generally speaking, there is a certain amount
 5 of flexibility built into many of the more technical
 6 cGMP requirements. To be absolutely clear, however,
 7 this flexibility is not at issue in this particular
 8 case. The cGMP requirements that Apotex violated
 9 repeatedly could not have been clearer and the
 10 violations more readily established.
 11 Ms. Cate will go into further detail about
 12 the specific findings at Apotex, but for now, it will
 13 suffice to walk through a few of the more significant
 14 cGMP requirements that Apotex violated to show the
 15 clarity of requirements.
 16 First, 21 CFR Section 211.22 part(d), "The
 17 responsibilities and procedures applicable to the
 18 Quality Control Unit shall be in writing. Such
 19 written procedures shall be followed."
 20 At Apotex's Signet facility, FDA found that
 21 while Apotex had some written quality procedures,
 22 those procedures were routinely ignored by its quality

11:55:36 1 control staff.
 2 Next, 21 CFR Section 211.67(a), "Equipment
 3 and utensils should be cleaned, maintained, and as
 4 appropriate for the nature of the drug, sanitized
 5 and/or sterilized at appropriate intervals to prevent
 6 malfunctions or contamination that would alter the
 7 safety, identity, strength, quality, or purity of the
 8 drug product beyond the official or other established
 9 requirements."
 10 FDA inspections of Apotex facilities in 2006
 11 and again in 2009 showed that Apotex was not
 12 maintaining and cleaning its equipment sufficiently to
 13 prevent cross-contamination of the drugs it
 14 manufactured. In other words, residue from the
 15 manufacture of one drug--
 16 -could make its way into other drugs.
 17 Next, 21 CFR Section 211.192, "The failure of
 18 a batch or any of its components to meet any of the
 19 specifications shall be thoroughly investigated,
 20 whether or not the batch has already been distributed.
 21 The investigation shall extend to other batches of the
 22 same drug product and other drug products that may

11:56:51 1 have been associated with the specific failure or
 2 discrepancy."
 3 In other words, all production failures must
 4 be fully investigated. Merely rejecting a failed
 5 batch and continuing on with production is
 6 insufficient. This was a key concern for FDA with
 7 respect to Apotex. FDA found that on numerous
 8 occasions, Apotex discovered a problem with one batch
 9 of its product but failed to conduct a proper
 10 investigation into the root causes of the problem.
 11 Instead, it appears that Apotex would merely test into
 12 compliance; that is, they would rework the batch and
 13 then retest it until it passed inspection.
 14 You heard Apotex in this hearing discuss
 15 FDA's supposed confusion about the number of rejected
 16 batches, but whether Apotex had or failed
 17 batches is not the issue. It is the fact that Apotex
 18 was willing to fail batches over and over again
 19 without investigation as to why it had so many
 20 failures.
 21 ARBITRATOR ROWLEY: Just a question here, if
 22 I may. A "batch." Is that a technical term that has

11:58:02 1 some particular number associated with it or is
 2 it--can it be anything? Can it be a large or small
 3 grouping of?
 4 MR. BIGGE: Thank you, Mr. Rowley. To adopt
 5 a practice of my opposing counsel, this may be a
 6 question better suited for the manufacturer, but in
 7 any event, if I can discuss it with our FDA counsel
 8 and get you an answer.
 9 The problems at Apotex that I've just
 10 outlined were all systemic problems that showed that
 11 Apotex did not have what Mr. Vodra describes in his
 12 Report as a "closed loop self-correcting process."
 13 That is, Apotex was tolerating breaches in its quality
 14 assurance and, even worse, was not taking actions to
 15 identify the root cause of the problems it did
 16 identify. Because Apotex was not taking appropriate
 17 corrective and preventative actions, Apotex's failures
 18 would continue to accrue.
 19 Finally, I should mention a completely
 20 different, but very important regulation, 21 CFR
 21 Section 314.81(b) relating to Field Alert Reports or
 22 FARs. This provision requires pharmaceutical

11:59:15 1 manufacturers to report certain problems with their
 2 products to FDA within three days of the discovery of
 3 the problem. Apotex has been surprisingly dismissive
 4 of this requirement in this arbitration, describing it
 5 as "paperwork violations." And that's in the Second
 6 Carey Statement at Paragraph 21.
 7 FDA, on the other hand, takes this
 8 requirement extremely seriously. The three-day time
 9 limit on FARs is critical for FDA. Without it, FDA
 10 cannot assess the problem for itself in a timely
 11 manner and take action, if necessary, to protect the
 12 health and safety of U.S. consumers. It also cannot
 13 compare one company's FARs against FARs received from
 14 other companies to ascertain whether there is a
 15 problem with a drug that goes beyond just one
 16 manufacturer.
 17 Apotex was routinely and repeatedly late in
 18 filing its FARs, often months late, and in at least
 19 one instance, a year and a half late. Apotex was
 20 cited for this in 2006, 2008, and again in 2009. I
 21 will not belabor the point any further. There were
 22 numerous cGMP violations found at Apotex's Etobicoke

12:00:27 1 and Signet facilities. The point here is that this
 2 was not a case where reasonable minds may differ about
 3 whether Apotex had violated the cGMP requirements
 4 because the regulations themselves were unclear.
 5 The particular cGMP requirements Apotex
 6 violated were quite clear and Apotex, just as clearly,
 7 violated them. Apotex admitted these violations in
 8 2009 and Health Canada and Apotex's own third-party
 9 Expert confirmed them several months later.
 10 Now, to determine whether a facility is cGMP
 11 compliant, FDA conducts inspections. In practice,
 12 these inspections cover what is referred to as the
 13 "Six Systems" for pharmaceutical manufacturing, and
 14 they are there on the screen: Materials, equipment
 15 and facilities, production, packaging and labeling,
 16 laboratory controls, and quality assurance. The Six
 17 Systems model was published by FDA in 2006 in a
 18 guidance document called Quality Systems Approach to
 19 Pharmaceutical cGMP Regulations. This document is in
 20 the record at Exhibit R-126.
 21 Although Apotex claims that its comparators'
 22 U.S.-based manufacturing facilities are in like

12:01:45 1 circumstances with Apotex, it is at the point of the
 2 Six Quality Systems that the similarities in
 3 inspection and enforcement procedures end. Apotex's
 4 pleadings have been inconsistent on this point. In
 5 the First Expert Report included with Apotex's
 6 Memorial, Mr. Bradshaw and Mr. Johnson made clear that
 7 domestic and foreign pharmaceutical facilities were
 8 governed by two different legal regimes for both
 9 inspection and enforcement. For example, pointing out
 10 the "sharp contrast," in their words, between the
 11 process of obtaining an injunction and the process for
 12 adding a company to the Import Alert.
 13 The United States agreed with Apotex and its
 14 Experts that there was such a difference under U.S.
 15 law and showed how this difference undercuts Apotex's
 16 discrimination claims. NAFTA Tribunals have
 17 consistently held that for comparators to be in like
 18 circumstances, they must be governed by the same legal
 19 regime.
 20 Having inadvertently undermined Apotex's
 21 claim, Apotex's Experts changed tack in their Second
 22 Report, arguing in Paragraph 34 that the differences

12:02:58 1 in inspections and enforcement for foreign and
 2 domestic facilities are "a distinction without a
 3 difference."
 4 This confusion extended into this hearing.
 5 Yesterday morning you heard Mr. Bradshaw explain his
 6 view of how the differences in legal regimes were
 7 insignificant because, in Mr. Bradshaw's view, they
 8 all somehow stopped the drugs from entering the
 9 market. But then Ms. Weil, in her presentation on
 10 Article 1105, emphasized that there were very
 11 different legal standards for enforcement actions
 12 against foreign and domestic facilities citing the
 13 United States' Expert on this point.
 14 PRESIDENT VEEDER: Excuse me for
 15 interrupting. If at some stage you can give us the
 16 reference when you refer to the transcript.
 17 MR. BIGGE: I apologize.
 18 PRESIDENT VEEDER: It makes it easier.
 19 MR. BIGGE: Sure.
 20 The truth is that the differences in
 21 regulation between domestic and foreign facilities are
 22 highly significant. Before explaining those

12:04:03 1 differences in more detail, it is important to make
 2 clear up front that U.S. law and practice does not
 3 discriminate on the basis of nationality of ownership.
 4 Rather, the differences in inspection and enforcement
 5 regimes are based on the location of the facility.
 6 Facilities within the United States that are owned by
 7 foreign companies are treated exactly the same as
 8 domestic facilities owned by U.S. companies. Had
 9 Apotex Inc. chosen to make an actual investment in the
 10 United States by building a manufacturing plant here,
 11 that facility would have been subject to the same
 12 inspection and enforcement regime that governs all
 13 facilities in the United States.
 14 By the same token, if a U.S. company builds a
 15 manufacturing facility outside the United States, that
 16 facility is subject to the inspection and enforcement
 17 regimes that govern all foreign facilities, regardless
 18 of the U.S. nationality of the plant's owner.
 19 There are several important distinctions
 20 between FDA's authority to inspect domestic facilities
 21 and its authority to inspect foreign facilities. The
 22 foremost of these is the element of surprise. Under

12:05:15 1 Section 704 of the Act, FDA may enter a domestic
 2 pharmaceutical facility at any reasonable time without
 3 advance notice to the owner. Thus, operators of
 4 domestic facilities have no time to prepare for an FDA
 5 inspection. If the operator of a domestic facility
 6 refuses to permit the inspection, FDA can obtain an
 7 administrative inspection warrant from a federal court
 8 with jurisdiction over the facility to obtain access
 9 without the owner's consent.
 10 For foreign facilities, by contrast, FDA does
 11 not generally conduct surprise inspections. Instead,
 12 FDA provides advance notice of the inspection. The
 13 operators of foreign facilities benefit from this
 14 advance notice and can prepare accordingly. There is
 15 ample evidence in the record of this advance notice
 16 with respect to Apotex. FDA and Apotex began
 17 negotiating over dates for the 2009 Signet inspection,
 18 for example, as early as January 2009, eight months
 19 before the inspection actually occurred.
 20 If the foreign facility operator refuses to
 21 allow FDA access for the inspection, the only remedy
 22 FDA had in 2009 was the authority to withdraw approval

12:06:41 1 of an ANDA or New Drug Application. Unlike domestic
 2 facilities, FDA does not have the power to go to a
 3 local court to obtain a warrant to compel the
 4 inspection.
 5 FDA's ability to conduct inspections outside
 6 the United States is also constrained by resources.
 7 FDA has district offices all over the United States,
 8 each of which is staffed by local investigators.
 9 Thus, for domestic facilities, the inspection usually
 10 entails little or no travel cost and can last for as
 11 long as the inspection takes, often weeks or even
 12 months.
 13 For foreign facilities, on the other hand,
 14 FDA has to dispatch investigators to the facility at
 15 significant cost both for airfare and lodging. For
 16 this reason, inspections of foreign facilities usually
 17 last only a matter of days and FDA usually attempts to
 18 schedule several back-to-back inspections on the same
 19 trip to save travel costs.
 20 The inability to conduct surprise foreign
 21 inspections and timing constraints of foreign
 22 inspections means that FDA has far more capacity to

12:07:50 1 investigate and compile evidence at a domestic
 2 facility than it does at a foreign facility. This
 3 difference underscores the need for the "appearance"
 4 standard regarding foreign facilities exporting their
 5 products into the United States. The "appearance"
 6 standard applies only to products from foreign
 7 facilities and is a lower enforcement standard than
 8 for products from domestic facilities.
 9 If an investigator finds cGMP violations at a
 10 facility, the investigator will fill out a Form 483.
 11 We put up an example of the first page of a Form 483
 12 that is in the record. This is Exhibit C-61, the Form
 13 483 for the 2009 Signet inspection. There are
 14 numerous Form 483s in the record from the 2006
 15 inspection, the 2008 inspection, the 2009 Signet
 16 inspection, the 2011 inspections of both facilities
 17 and others.
 18 The Form 483 lists inspectional observations
 19 and is provided to the inspected company at the close
 20 of the inspection. It is not a definitive finding
 21 that the firm violated the cGMP regulations, but
 22 nonetheless, the Form 483s from 2006, 2008, and

12:09:11 1 particularly 2009 all provided Apotex with notice of
 2 the cGMP violations as observed by the investigators.
 3 When the Form 483s are presented, the
 4 investigator will usually have a long discussion with
 5 firm management addressing not only the violations
 6 listed in the Form 483, but also other observations
 7 not included on the form. And, again, the minutes
 8 from those meetings or records of those meetings are
 9 in the record in this case, often recorded in the EIR.
 10 The Form 483s are also forwarded to the
 11 relevant FDA district office for domestic inspections
 12 or, for foreign inspections, to the International
 13 Compliance Branch of the Center for Drug Evaluation
 14 and Research, which goes by the acronym C-D-E-R or
 15 CDER. Those offices determine whether, in fact, the
 16 cGMP regulations have been violated. Thus, different
 17 FDA personnel in different offices make cGMP and
 18 enforcement recommendations for domestic and foreign
 19 facilities respectively. For domestic inspections,
 20 it's local district offices; for foreign facilities,
 21 it's CDER.
 22 The Form 483s are faxed to CDER with a cover

12:10:30 1 sheet that includes one of three recommendations by
 2 the investigator: NAI, VAI, or OAI. These stand for
 3 "No Action Indicated," "Voluntary Action Indicated,"
 4 or "Official Action Indicated."
 5 Even if the investigator made certain cGMP
 6 observations, the investigator may feel that the
 7 observations are minor or are so few in number that no
 8 action is needed. That would be NAI. For more
 9 significant observations that do not rise to the level
 10 of an enforcement action, the investigator may write
 11 VAI, or Voluntary Action Indicated. That is the
 12 investigator's suggestion that FDA work with the firm
 13 on a voluntary remedial plan, including possible
 14 recalls.
 15 OAI, or Official Action Indicated, is
 16 reserved for the most worrisome inspections. By
 17 forwarding the Form 483 with an OAI recommendation,
 18 the investigator is telling CDER that, in the
 19 investigator's view, the cGMP observations are serious
 20 and that CDER should take some kind of enforcement
 21 action. An example of a fax cover sheet with an OAI
 22 recommendation--this is from the 2011 Apotex

12:11:45 1 inspection--is in the record. As you can see in this
 2 document, the lead investigator of the 2011
 3 inspection, Michael Goga, is recommending OAI even
 4 after Apotex supposedly remedied its cGMP violations
 5 from 2009.
 6 The investigators can also indicate their
 7 recommendation in the Field Accomplishments and
 8 Compliance Tracking System, also called FACTS,
 9 F-A-C-T-S. In this slide, we see a FACTS form from
 10 the Signet 2011 inspection again, with a
 11 recommendation of OAI and continued IA, or Import
 12 Alert. Notably, the various investigators at Apotex's
 13 Etobicoke and Signet facilities in 2008--in 2008,
 14 2009, and 2011 all recommended OAI.
 15 The investigators then draft a document I
 16 referred to earlier as the EIR, the Establishment
 17 Inspection Report. EIRs are longer and much more
 18 detailed than the Form 483s and may contain more and
 19 different observations than were included in the
 20 Form 483.
 21 The EIRs for all of the relevant
 22 inspections--2008, 2009, and 2011--are in the record

12:13:06 1 at Exhibits R-26, R-42, R-71, and R-72. Again, in
 2 each these EIRs, the investigators recommended OAI for
 3 Apotex's facilities.
 4 Once the district office--I'm sorry. Did you
 5 have a question?
 6 ARBITRATOR CROOK: Could you give us the
 7 cites again? I may have not been entirely clear on
 8 the transcript.
 9 MR. BIGGE: I apologize. It is
 10 Exhibits R-26, R-42, R-71, and R72. Thank you.
 11 ARBITRATOR CROOK: Thank you.
 12 MR. BIGGE: Once the district office--or in
 13 this case CDER--received the observations and
 14 recommendation from the investigator, it determines
 15 whether any further action is warranted. It may make
 16 this determination quickly based on the Form 483, or
 17 it can wait until the EIR is filed. Either way, the
 18 district office or CDER will view the investigator's
 19 observations in light of the longer history of the
 20 compliance at the inspected firm and any other
 21 information that may have been gathered outside of the
 22 inspection, and then determine next steps. Such

12:14:19 1 additional information may be information like Field
 2 Alert Reports which we discussed, also Adverse Event
 3 Reports and consumer complaints.
 4 There are several immediate consequences of
 5 cGMP violations regardless of whether FDA takes an
 6 enforcement action. An OAI recommendation entered
 7 into the FACTS system will be accessible to many FDA
 8 employees. Thus, when a product from that facility
 9 arrives at the border, an FDA field officer can check
 10 on the facility and may detain the product under
 11 Section 801 of the Act on his or her own accord. FDA
 12 can also advise other federal agencies of the cGMP
 13 violations. For example, by advising the Department
 14 of Veteran Affairs not to purchase pharmaceuticals
 15 from the offending companies.
 16 Also, under 21 USC Section 355(j)(4), and
 17 21 CFR Section 314.127, FDA can withhold approval of
 18 new drug applications or, in the case of generics,
 19 Abbreviated New Drug Applications for facilities that
 20 are not cGMP compliant. This was clearly stated in
 21 the Warning Letter sent to Apotex following the
 22 Etobicoke inspection. "Until all corrections have

12:15:47 1 been completed and FDA has confirmed corrections of
 2 the deficiencies and your firm's compliance with
 3 cGMPs, this office may recommend withholding approval
 4 of any new applications or supplements listing your
 5 firm as a drug product manufacturer."
 6 Third, under 21 USC Section 355(j)(6) and
 7 21 CFR Section 314.150 and 151, FDA can revoke
 8 approved NDAs and ANDAs for drugs that are made at
 9 non-cGMP compliant facilities. This is one of several
 10 bases for revoking an ANDA, even an approved ANDA.
 11 FDA can also send a Warning Letter to the
 12 firm. According to Regulatory Procedures Manual
 13 Chapter 4, Warning Letters are issued only for
 14 violations of regulatory significance; that is, for
 15 violations that may lead to an enforcement action if
 16 not promptly and adequately corrected. Nonetheless,
 17 Warning Letters are not final agency action and are
 18 intended to persuade a company to voluntarily and
 19 swiftly bring itself into cGMP compliance.
 20 As Ms. Weil explained yesterday--and this is
 21 in the transcript at Page 242--"that a company
 22 receives a Warning Letter does not mean that it will

12:17:26 1 be put on the Import Alert." And we would add "or be
 2 subject to any other enforcement action."
 3 PRESIDENT VEEDER: Again, I'm sorry to raise
 4 this. That looks like a reference to the rough draft
 5 of the transcript.
 6 MR. BIGGE: That may be.
 7 PRESIDENT VEEDER: Give it to us later.
 8 MR. BIGGE: Okay.
 9 There are several significant points to a
 10 Warning Letter that I will review briefly. First, of
 11 course, the Warning Letter is public. So although it
 12 is nonfinal action, it may, by itself, have
 13 significant ramifications for the company receiving
 14 it.
 15 First, of course, there may be consumers who
 16 are dissuaded from purchasing the product based on the
 17 Warning Letter. So there may be a loss of market
 18 share. There could be other regulatory action, for
 19 example, in 2008 the company Bayer was subject to a
 20 number of State regulatory actions for false
 21 advertising, and this was based on a Warning Letter
 22 published by FDA in that year.

12:18:39 1 For publicly traded companies, it may also
 2 result, because it's public, in a loss in share value.
 3 And notably, all of Apotex's comparators in this case
 4 are publicly traded companies, whereas Apotex is
 5 privately held.

6 The point here is that although the Warning
 7 Letter is nonfinal action, Apotex's suggestion that
 8 FDA did nothing with respect to its comparators is
 9 simply untrue. Warning Letters list the most
 10 egregious cGMP violations and warn the offending
 11 companies of consequences that might result from
 12 failure to comply.

13 For example, as already discussed, Warning
 14 Letters typically advise companies that their ANDAs
 15 will not approved while cGMP violations exist.
 16 Warning Letters for foreign facilities also generally
 17 state that a facility's cGMP violations may result in
 18 its products being detained and refused admission at
 19 border. This was clearly stated in the Warning
 20 Letters to Apotex, like this one from June 2009: "In
 21 addition, failure to correct these violations may
 22 result in FDA denying entry of articles manufactured

12:20:00 1 at Apotex Inc., Etobicoke, Canada, into the U.S.
 2 These articles could be subject to refusal of
 3 admission pursuant to Section 801(a)(3) of the Act in
 4 that the methods and controls used in their
 5 manufacture do not appear to conform to Current Good
 6 Manufacturing Practice within the meaning of
 7 Section 501(A)(2)(b) of Act."

8 FDA officers reviewing imports read these
 9 Warning Letters and may detain products based solely
 10 on the cGMP violations listed in the Warning Letters.
 11 In fact, evidence in this case shows that a shipment
 12 of Teva's Jerusalem facility was detained at the
 13 border in 2011 on the basis of information in a
 14 Warning Letter, even though, as Apotex points out,
 15 drugs from Teva's Jerusalem facility were not put on
 16 the Import Alert. Critically, a foreign
 17 manufacturer's products can be subject to an
 18 enforcement action without the issuance of a Warning
 19 Letter apprising the manufacturer of the possibility
 20 of detention.

21 According to Regulatory Procedures Manual
 22 Chapter 4, there are--"there are instances when

12:21:16 1 issuing a Warning Letter is not appropriate and a
 2 Warning Letter is not a prerequisite to taking
 3 enforcement action."

4 Examples of such situations include a history
 5 of repeated or continual conduct of a similar or
 6 substantially similar nature during which time the
 7 individual and/or firm has been notified of a similar
 8 or substantially similar nature, and "when adequate
 9 notice has been given by other means and the
 10 violations have not been corrected." Both of these,
 11 we submit, apply here.

12 The RPM also states that "In certain
 13 situations, the Agency may also take other actions as
 14 an alternative to or concurrently with the issuance of
 15 a Warning Letter." As an example, the RPM cites cGMP
 16 violations.

17 Before turning to the available enforcement
 18 actions, it is important to emphasize that FDA's
 19 mandate is to protect public health. Warning Letters
 20 and enforcement actions both are intended to protect
 21 U.S. consumers from possibly harmful products and to
 22 bring offending companies into cGMP compliance so that

12:22:32 1 there is some assurance of drug safety. Often a
 2 Warning Letter is sufficient to accomplish this latter
 3 task and no further enforcement action is necessary.

4 If an enforcement action is warranted, FDA
 5 has several enforcement tools at its disposal. This
 6 slide lists just a few of the available options.
 7 First, as Mr. Bradshaw and Mr. Johnson note, FDA may
 8 seize product from non-cGMP compliant facilities or
 9 obtain court injunctions against the offending company
 10 and its personnel. If contested, both of these
 11 enforcement actions require FDA to establish
 12 adulteration; that is, in the case of cGMPs, establish
 13 the cGMP violations to the satisfaction of a judge.

14 These enforcement tools are almost never used
 15 for foreign facilities, however, for several reasons.
 16 First, both injunctions and seizures require U.S.
 17 court orders. But U.S. courts will not likely have
 18 the necessary jurisdiction. In particular, seizures
 19 are in rem actions against the manufactured drugs
 20 themselves and a U.S. court would likely not have
 21 jurisdiction over such drugs if they are warehoused in
 22 a foreign country. Seizures are also usually carried

12:23:58 1 out by U.S. marshals who generally do not have
 2 extraterritorial jurisdiction.
 3 In any event, seizures and injunctions would
 4 be highly detrimental to foreign facilities like
 5 Apotex's when compared to detention and refusal of
 6 admission, the enforcement action actually used
 7 against Apotex. Seizure generally results in the
 8 product's destruction. Injunctions typically prevent
 9 the enjoined Parties from manufacturing products for
 10 sale anywhere in the world. Detention and refusal of
 11 admission, on the other hand, allows the product to be
 12 sent back to the facility of origin for resale outside
 13 of the United States. And the company can continue to
 14 manufacture product and sell it in countries that
 15 permit it to do so, as Apotex did in this case. An
 16 injunction would generally not allow an offending U.S.
 17 facility to sell its products abroad.
 18 To be clear, detention and refusal are
 19 available only for products from foreign facilities
 20 that the manufacturer seeks to export into the United
 21 States. They are not even a possibility for domestic
 22 facilities. This is, therefore, another key legal

12:25:17 1 difference between domestic and foreign facilities.
 2 As I mentioned earlier, unlike for
 3 injunctions and seizures, to detain and remove
 4 products at the border, FDA relies on the appearance
 5 standard in Section 801 of the Act, a standard not
 6 applicable to domestically produced products. And as
 7 I explained earlier, this standard makes sense in
 8 light of the limitations that FDA faces for foreign
 9 facilities.
 10 Notably, the product--in a detention and
 11 refusal situation, the product can only be refused
 12 admission after there has been an opportunity for a
 13 hearing. Once a product is detained, FDA must provide
 14 notice to the owner or consignee of the product. That
 15 notice provides information about the reason for the
 16 detention of the product. The Detention Notices sent
 17 to Apotex, for example, state that "It appears that
 18 the methods used in or the facilities or controls used
 19 for manufacture, processing, packing, or holding, do
 20 not conform to or are not operated or administered in
 21 conformity with Current Good Manufacturing Practices."
 22 As you can see on the slide, the Detention

12:26:30 1 Notice also provides information about the Detention
 2 Hearing at which Apotex could have protested the
 3 detention and refusal of its products. I will say
 4 more about the Detention Hearing momentarily.
 5 So how do FDA import officers know which
 6 products to detain? That is, how do they know about a
 7 particular company's cGMP problems? Well, as we
 8 already discussed, one way that information is
 9 transmitted is by the publication of a Warning Letter.
 10 Another is by the OAI status in the FACTS system.
 11 In addition, however, FDA can place products on what
 12 is called an Import Alert to notify field offices of
 13 problems at particular facilities or with specific
 14 products.
 15 There are many Import Alerts used by FDA to
 16 notify field offices of a variety of issues that may
 17 arise. For example, that a company may try to ship a
 18 pharmaceutical product that has not been approved or
 19 that a certain product has labeling problems. The
 20 Import Alerts are regularly updated to add facilities
 21 or products as problems arise and remove facilities or
 22 products as problems are resolved.

12:27:48 1 Import Alert 66-40, the Alert at issue here,
 2 informs FDA field offices of facilities with cGMP
 3 issues. It is entitled "Detention Without Physical
 4 Examination of Drugs from Firms Which Have Not Met
 5 Drug cGMPs."
 6 Import Alert 66-40 states that the goods from
 7 the facilities listed are "subject to refusal of
 8 admission pursuant to Section 801(a) and that the
 9 methods and controls used in its manufacture and
 10 control of pharmaceutical products do not appear to
 11 conform to Current Good Manufacturing Practices. It
 12 instructs, importantly, that districts "may detain the
 13 specified pharmaceutical products from the firms
 14 listed in the attachment to this alert."
 15 Companies are added to the Import Alert
 16 through a standard process. According to the
 17 Regulatory Procedures Manual, recommendations that a
 18 facility should be added to the Import Alert are to be
 19 in writing and submitted with supporting data to FDA's
 20 Division of Import Operations and Policy or DIOP.
 21 In this case, the memorandum from CDER to
 22 DIOP was submitted as Exhibit C-64. DIOP then

12:29:02 1 prepares a clearance package that is reviewed by
 2 multiple offices at FDA, including the Office of Chief
 3 Counsel. Assuming it is cleared, DIOP will amend the
 4 Import Alert and send the Import Alert to field
 5 offices by e-mail.
 6 PRESIDENT VEEDER: Forgive me for
 7 interrupting. I thought we had some evidence about
 8 the review by the Office of Chief Counsel and the
 9 practice had changed?
 10 MR. BIGGE: No. The practice has changed
 11 with respect to Warning Letters.
 12 PRESIDENT VEEDER: I beg your pardon. You're
 13 quite right. Thank you.
 14 MR. BIGGE: Assuming it is cleared, DIOP will
 15 amend the Import Alert and send the Import Alert to
 16 field offices by e-mail. DIOP will also load
 17 information from the Import Alert into relevant
 18 tracking systems so that when goods from a particular
 19 facility appear at the border, the field agent will be
 20 alerted that the goods may be detained.
 21 To be absolutely clear, the Import Alert does
 22 nothing in and of itself. As Mr. Legum told the

12:30:01 1 Tribunal yesterday, the Import Alert is a nonfinal
 2 act. It is merely an internal FDA memorandum advising
 3 district offices that they may detain products
 4 pursuant to Section 801 of the Act. Final
 5 determinations as to actual detention are made after a
 6 company attempts to ship goods across the border.
 7 As Mr. Vodra explains in his Report, "An
 8 Import Alert does not itself determine the rights or
 9 interests of any person or Party; it merely sets the
 10 stage for a process to determine whether products can
 11 be imported into the United States. It is, by its
 12 terms, guidance from FDA headquarters to FDA field
 13 employees to consider initiating detention proceedings
 14 in the future, if certain conditions occur. The
 15 admissibility of any shipment of goods to the U.S. is
 16 made after there is an opportunity for a Detention
 17 Hearing. A Detention Hearing will result in either
 18 admission of the goods to the U.S. commerce or a
 19 notice of refusal of admission."
 20 Mr. Vodra concludes, "An Import Alert is
 21 neither a necessary nor a sufficient prerequisite for
 22 an import detention." And that is at Paragraphs 87

12:31:19 1 and then 89 of his Report.
 2 In fact, an adulterated product may be
 3 detained and removed under the Act regardless of
 4 whether the facility has been added to the Import
 5 Alert, as was shown by the Teva Jerusalem example I
 6 mentioned earlier. Rather, the cGMP violation itself
 7 gives rise to the detention.
 8 Mr. Vodra's view is confirmed by the version
 9 of the Import Alert Apotex produced. That version
 10 includes the following text in bold. "This Import
 11 Alert represents the Agency's current guidance to FDA
 12 field personnel regarding the manufacturers and/or
 13 products at issue. It does not create or confer any
 14 rights for or on any person and does not operate to
 15 bind FDA or the public."
 16 Now, Apotex correctly states that it was not
 17 entitled to a hearing prior to being added to the
 18 Import Alert. This is primarily because the Import
 19 Alert is merely an internal memorandum alerting field
 20 agents that they could detain Apotex's products.
 21 Apotex was fully entitled to a hearing once its
 22 products were, in fact, detained prior to a decision

12:32:30 1 on whether or not they would be admitted into the
 2 United States.
 3 But also, as Dr. Rosa points out in his First
 4 Witness Statement, "companies are not given a hearing
 5 prior to being added to the Import Alert because it
 6 would give them an opportunity to flood the market
 7 while the hearing was in process."
 8 This is not an idle concern. Such flooding
 9 of the market is easily accomplished. In the context
 10 of a patent dispute in 2006, for example, Apotex
 11 itself exported to the United States a six-month
 12 supply of a particular drug in just 23 days, between
 13 Apotex's launch of the product and its competitor's
 14 securing an injunction against it.
 15 Finally, although Apotex discussed seizures
 16 at some length yesterday, Apotex never pointed out
 17 that the United States does not notify a domestic
 18 company that it is the target of a seizure action
 19 prior to a decision to seize the product. Again, the
 20 reason that product can be seized without prior notice
 21 is that otherwise the company could flood the market
 22 and move the--or move the product to a different

12:33:41 1 location prior to the seizure.
 2 Like with a detention, both detention and
 3 seizure being in rem proceedings, the company that is
 4 subject to seizure is entitled to a hearing after the
 5 product is seized but before it is destroyed by FDA.
 6 There are, of course, other enforcement
 7 actions FDA can use, including criminal prosecution
 8 for the most egregious offenders. Whether to adopt an
 9 enforcement action and which enforcement action to use
 10 depends on a complex and discretionary balancing of a
 11 number of factors.
 12 Mr. Bradshaw and Mr. Johnson mentioned
 13 several of the factors that come into play in FDA's
 14 enforcement discretion. At Paragraph 47 of their
 15 Second Report, they note that the United States might
 16 weigh: 1, the seriousness of the cGMP violations; 2,
 17 risk to consumers; 3, the company's Response to the
 18 violation; and, 4, whether the enforcement action
 19 would create a drug shortage of medically necessary
 20 drugs.
 21 Each of these determinations can only be made
 22 by someone with regulatory and/or scientific

12:34:54 1 expertise, as well as knowledge of the pharmaceutical
 2 industry and market.
 3 Mr. Vodra adds two additional factors to
 4 Apotex's Experts' list. First, FDA must consider its
 5 own resources when determining whether to take
 6 enforcement action. An injunction, seizure, or
 7 criminal prosecution, for example, require a great
 8 deal of resources, including those of the Department
 9 of Justice. And, therefore, FDA may, in its
 10 discretion, choose not to adopt those enforcement
 11 actions if resources are limited. Second, whether to
 12 undertake an enforcement action may depend on the
 13 strength of the evidence collected. FDA has to be
 14 confident that its enforcement action would withstand
 15 challenge.
 16 As I have pointed out a few times today,
 17 Section 801 of the Act allows FDA to prevent products
 18 from being imported from foreign facilities based
 19 merely on the appearance of adulteration.
 20 Again, the standard is critical in the
 21 context of foreign inspections where, due to legal and
 22 resource limitations, FDA generally has less

12:35:59 1 opportunity to collect evidence. However, for an
 2 injunction or seizure, the enforcement actions
 3 available for domestic facilities, where more evidence
 4 can be collected, FDA must be able to prove the
 5 adulteration to the satisfaction of a judge. FDA must
 6 be confident that it has such evidence before pursuing
 7 the injunction or seizure.
 8 For all of these reasons, the U.S. Supreme
 9 Court has made clear the presumption that FDA's very
 10 nuanced decisions on enforcement will not be
 11 disturbed. In Heckler v. Chaney, a case specifically
 12 addressing FDA's enforcement discretion, the Supreme
 13 Court wrote "An Agency decision not to enforce often
 14 involves a complicated balancing of a number of
 15 factors which are peculiarly within its expertise.
 16 Thus, the Agency must not only assess whether a
 17 violation has occurred, but whether Agency resources
 18 are best spent on this violation or another, whether
 19 the Agency is likely to succeed if it acts, whether
 20 the particular enforcement action request best fits
 21 the Agency's overall policies, and, indeed, whether
 22 the Agency has enough resources to undertake the

12:37:18 1 action at all. An agency generally cannot act against
 2 each technical violation of the statute it is charged
 3 with enforcing. The Agency is far better equipped
 4 than the courts to deal with the many variables
 5 involved in the proper ordering of its priorities."
 6 Now, of course, this U.S. Supreme Court
 7 ruling is not binding on this Tribunal, but we submit
 8 that an International Tribunal is in no better
 9 position than a court to second-guess these various
 10 factors weighed by experienced, trained FDA
 11 professionals.
 12 Had FDA made some sort of mistake with
 13 respect to Apotex's Signet and Etobicoke facilities,
 14 Apotex had several means at its disposal for
 15 challenging FDA's cGMP findings and enforcement
 16 action. Mr. Blanck will address these in his
 17 discussion of Article 1105, but because the means for
 18 challenge have a basis in the regulations and guidance
 19 documents, I will briefly outline them now.
 20 As you recall, Mr. Bradshaw and Mr. Johnson
 21 pointed the Tribunal to numerous manuals and guidance
 22 documents FDA publishes for the industry. One of

12:38:37 1 these, published in 2006 and available on the
 2 Internet, was entitled "Guidance for Industry. Formal
 3 Dispute Resolution: Scientific and Technical Issues
 4 Related to Pharmaceutical cGMP." This document was
 5 submitted to the Tribunal as Exhibit R-140 and shows
 6 how a pharmaceutical company could, among other means,
 7 challenge cGMP findings through a dispute resolution
 8 panel convened by the FDA Commissioner.
 9 This guidance also highlights the
 10 availability of dispute resolution under 21 CFR
 11 Section 10.75. Section 10.75 allows anyone to request
 12 review of any decision made by FDA. Section 10.75
 13 challenges start with the supervisor of the employee
 14 who took the relevant action and could be appealed all
 15 the way to the FDA Commissioner.
 16 In addition, Apotex could have initiated a
 17 citizens petition through 21 CFR Section 10.25 and
 18 Section 10.30. This is a more formal mechanism to
 19 challenge FDA's actions. It is made public, which,
 20 according to Mr. Vodra, puts considerable pressure on
 21 FDA, particularly in cases where it has made a
 22 mistake.

12:39:56 1 Apotex also could have challenged the
 2 detention of its products through a formalized
 3 Detention Hearing. As was already mentioned, the
 4 Detention Notices themselves advised Apotex of this
 5 right. "You have the right to provide oral and
 6 written testimony to the Food and Drug Administration
 7 regarding the admissibility of the articles or the
 8 manner in which the articles can be brought into
 9 compliance." Had FDA wrongfully detained Apotex's
 10 products--that is, if Apotex was actually cGMP
 11 compliant--the Detention Hearing provided another
 12 opportunity to challenge FDA's enforcement action.
 13 Before actual agency action, the refusal of
 14 admission, Apotex had the opportunity for the hearing
 15 it now claims it was denied.
 16 Moreover--
 17 ARBITRATOR ROWLEY: Could I just ask, at such
 18 a hearing--let us say drug X is detained, a shipment
 19 of drug X. What is required to get the shipment
 20 released and allowed to proceed? Does the shipper
 21 have to show that the drug is not adulterated? Or
 22 does it have to show something such as the facility in

12:41:15 1 which it was made was cGMP compliant? You can answer
 2 this later if it's more convenient.
 3 MR. BIGGE: I actually think I know the
 4 answer to the question, but I will accept your
 5 invitation and consult also with our FDA counsel.
 6 We should note, by the way, that the
 7 Detention Hearing offered to Apotex would have been a
 8 full month after Apotex was added to the Import Alert,
 9 giving it ample opportunity to corral its arguments.
 10 Incidentally, we should add this requirement
 11 of U.S. law--and I'll leave the language on the
 12 screen--appears to be very similar to the provision of
 13 French law that Apotex submitted on the eve of the
 14 hearing. The U.S. Detention Hearing permits the owner
 15 or consignee to "provide oral or written testimony
 16 regarding the admissibility of the article."
 17 According to Apotex's translation, the French code
 18 similarly allows an affected person "to present its
 19 observations before the intervention of the Measures."
 20 Mr. President, Members of the Tribunal, as
 21 you know, Apotex utilized none of these challenge
 22 mechanisms. Mr. Bradshaw proposes a number of

12:42:41 1 post hoc rationalizations for this, but as the
 2 Tribunal observed, it does not appear that these
 3 rationalizations had anything to do with Apotex's
 4 decision not to challenge the cGMP violations, the
 5 Import Alert, or the detention.
 6 We should note here that Apotex was
 7 represented by skilled counsel at the time. At the
 8 September 11, 2009, meeting with FDA, Apotex brought
 9 Kate Beardsley of the law firm Buc & Beardsley.
 10 Ms. Beardsley is a Washington attorney who specializes
 11 in this particular area and represents a number of
 12 generic pharmaceutical companies, notably her partner,
 13 law firm partner, Nancy Buc is a former FDA Chief
 14 Counsel. Nor is Apotex shy about bringing lawsuits to
 15 assert its rights. Indeed, it touts litigation as one
 16 of its business models.
 17 The record, the Tribunal accurately
 18 ascertained, does not reflect any contemporaneous
 19 consideration of a challenge because Apotex knew that
 20 its facilities were not cGMP compliant. As Ms. Grosh
 21 showed you, Apotex repeatedly admitted its
 22 "significant deficiencies"--and that's just one of the

12:43:55 1 several quotes she showed you--in 2009. It also hired
 2 no fewer than six separate cGMP consultants to assist
 3 it back into compliance.
 4 Apotex claims, in Mr. Rosen's Report, to have
 5 paid ██████ in remediation costs, a figure that
 6 Apotex now claims at this hearing was actually lower
 7 than the amount it spent. Apotex fired its head of
 8 quality assurance, dramatically increased the number
 9 of quality personnel, restructured their quality
 10 assurance system, and took over a year to implement
 11 that restructuring sufficient to invite FDA back for a
 12 re-inspection. These are not goodwill gestures. They
 13 are admissions of systemic quality failures.
 14 Apotex's own consultant confirmed that Apotex
 15 failed compliance in all six of the cGMP systems that
 16 I mentioned earlier in my presentation. As Apotex's
 17 CEO admitted in November of 2009, "Our quality systems
 18 lack quality." Apotex's argument that it was entitled
 19 to a hearing on the Import Alert is specious because
 20 whatever arguments it could have presented at such a
 21 hearing could have been presented at the Detention
 22 Hearing or through the available administrative

12:45:11 1 remedies.
 2 It is fair for this Tribunal to assume that
 3 Apotex would not have invoked its theoretical right to
 4 an Import Alert hearing, if such a right existed, for
 5 the very reason it chose not to pursue these readily
 6 available remedies: Because it knew it was not in
 7 compliance with the U.S. law I laid out for the
 8 Tribunal this morning.
 9 If I could beg the Tribunal's indulgence, I
 10 have just a couple more minutes.
 11 For my last point, it is important to focus
 12 on the specific Measure at issue in this case.
 13 Apotex's theory of the relevant Measure is confusing,
 14 but there were, as I've described them, actually three
 15 distinct actions undertaken by FDA that affected
 16 Apotex.
 17 First, FDA found that Apotex's Signet and
 18 Etobicoke facilities were not cGMP compliant. As
 19 discussed, that finding by itself had the immediate
 20 effects of preventing Apotex's ANDAs from being
 21 approved, and subjected Apotex's products to possible
 22 detention and refusal at the border regardless of any

12:46:18 1 other actions.
 2 Second, FDA added the Etobicoke and Signet
 3 facilities to the Import Alert. That action
 4 communicated the cGMP findings to FDA field officers.
 5 Third, those field officers detained Apotex's
 6 products offered for import, advised Apotex of its
 7 right to a Detention Hearing, and when Apotex declined
 8 to invoke its right to a hearing, refused admission of
 9 those products into the United States. Critically,
 10 this third event could have happened simply based on
 11 Step 1, the cGMP findings, even if Step 2, the Import
 12 Alert never happened.
 13 Nonetheless, Apotex has repeatedly emphasized
 14 throughout these proceedings that it is only
 15 challenging Apotex's addition to the Import Alert,
 16 Number 2 on this list. Apotex stated plainly in its
 17 Reply that it is not challenging FDA's cGMP findings.
 18 This makes a certain amount of sense from Apotex's
 19 perspective. Apotex cannot argue that FDA's cGMP
 20 findings were the relevant measure for two reasons:
 21 One, Apotex repeatedly conceded that its facilities
 22 were not cGMP compliant in 2009; and, two, there were

12:47:30 1 well-established avenues for challenging the cGMP
 2 findings that Apotex ignored.
 3 Similarly, Apotex does not allege that the
 4 detention and refusal of its products was the Measure
 5 because there was a clear hearing procedure listed
 6 right on the notice of detention that Apotex again did
 7 not invoke.
 8 Thus, Apotex is challenging only the Import
 9 Alert in this arbitration. Again, the Import Alert
 10 was not a final agency action and it did not decide
 11 any of Apotex's rights. But also, as Mr. Sharpe will
 12 explain, the Import Alert did not relate to the two
 13 alleged investments, the ANDAs and Apotex Corp. The
 14 Import Alert had nothing do with the ANDAs, and it
 15 applies only to Apotex Inc. two Canadian facilities at
 16 Etobicoke and Signet, not to Apotex Corp., the U.S.
 17 company.
 18 To remedy this jurisdictional defect, Apotex
 19 seeks to blend the detention process and the Import
 20 Alert together, but these are clearly separate
 21 Measures. CDER could have added Apotex to the Import
 22 Alert, and yet had Apotex actually challenged the

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12:48:38 1 detention and presented a case that its facilities
2 were cGMP compliant, products might not have been
3 detained. Similarly, Apotex's products could have
4 been detained without having been added to the Import
5 Alert solely on the basis of Apotex's cGMP violations.

6 Apotex admits that it blends these two
7 Measures together because it's the Detention Notice
8 and not the Import Alert that was sent to Apotex Corp.
9 as consignee of those particular shipments. But
10 Apotex's attempt to rely on the Detention Notice to
11 create jurisdiction rather than the Import Alert
12 itself is unavailing.

13 You heard on Monday from Ms. Duf tre, when
14 she insisted that the Import Alert was only published
15 on September 30, 2009, she also wondered why this
16 issue was relevant. And again, I apologize to the
17 Tribunal. I'll get transcript cites. But it was
18 Apotex, not the United States, that made this fact
19 relevant. Apotex's sole justification for the melding
20 of its Detention Notice and the Import Alert to create
21 "relating to" jurisdiction is its claim that the
22 Detention Notice and not the Import Alert itself was

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12:51:05 1 September 30, 2009, in his First Witness Statement in
2 this very arbitration, he made clear that he had seen
3 the Import Alert on FDA's Web site almost a month
4 earlier and that the Import Alert was dated August 28,
5 2009.

6 MR. LEGUM: Excuse me for interrupting.

7 Mr. President, I want to object to this line
8 of questioning. The United States had an opportunity
9 to call Apotex's Witnesses and allow them to explain
10 any inconsistencies that they're alleging in their
11 Statement before this Tribunal. It did not avail
12 itself of that opportunity, and it is contrary, we
13 submit, to fair play to attack someone who is sitting
14 in the room and can answer these questions without
15 providing them an opportunity to do so.

16 MR. BIGGE: With respect, the contradiction
17 is plain in the document, and Apotex's own counsel
18 relied on the facts in the Second Witness Statement in
19 its own argument. It is only fair to point out the
20 contradiction in the First Witness Statement.

21 PRESIDENT VEEDER: Normally you would do that
22 in cross-examination.

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12:49:52 1 the "contemporaneous evidence of the Import Alert."

2 According to Apotex, "The Import Alert
3 concerning Apotex was not published on FDA's Web site
4 before September 30, 2009. And, thus, the Detention
5 Notice, which Apotex received on September 4, preceded
6 the Import Alert."

7 To support this assertion, Dr. Jeremy Desai,
8 Apotex Inc.'s CEO, wrote in his Second Witness
9 Statement that "Apotex never received a copy of the
10 Import Alert which, to my knowledge, was only posted
11 on FDA's Web site on September 30, 2009."

12 Ms. Duf tre also claimed on Monday that there
13 was no evidence showing that the Import Alert was
14 published a month earlier, on August 28, 2009,
15 predating the Detention Notice. But it is Apotex's
16 own evidence that demonstrates not only that the
17 Import Alert was published on August 28, 2009, but
18 that Dr. Desai and other Apotex employees saw it on
19 the Internet before they saw the Detention Notice.

20 Indeed, although Dr. Desai claims in his
21 Second Statement that to his knowledge the Import
22 Alert was only posted on FDA's Web site on

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12:52:17 1 MR. BIGGE: Again, the contradiction could
2 not be more plain. There doesn't seem to be any
3 confusion in the First Witness Statement as to the
4 facts, and the facts in the First Witness Statement
5 are also confirmed by contemporaneous evidence. So it
6 is not just Dr. Desai's Witness Statement that we are
7 relying on. If the Tribunal wishes, I can move to the
8 contemporaneous evidence instead.

9 PRESIDENT VEEDER: Let's start with that and
10 see where you go.

11 MR. BIGGE: Sure.

12 Abby, can we move to the next slide, C-76.

13 So, this is Exhibit C-76, which is dated
14 September 2. I was just handed a note by my
15 co-counsel that the relevant transcript cite for
16 Apotex's argument yesterday was Page 138 and 139--that
17 actually may have been on Monday.

18 So, again, this is Exhibit C-76. It is an
19 e-mail from Jeremy Desai dated September 2, 2009. And
20 in it Dr. Desai says--he relates a telephone
21 conversation they are having with Health Canada. I'll
22 just read it in full.

12:53:34 1 "We were just informed during a telecon with
 2 Health Canada (can you believe this) that there is an
 3 Import Alert posted on the FDA Web site dated
 4 August 28 for 'all finished dosage forms from both
 5 Signet and Etobicoke.'"
 6 We would also point you to, although these
 7 are not in the slides, Exhibits C-75 and
 8 Exhibit C-160, which are e-mails from two other Apotex
 9 employees, Bernice Tao, and Bruce Clark, who wrote
 10 e-mails the same day, on September 2, indicating that
 11 they saw the Import Alert with Apotex listed on FDA's
 12 Web site.
 13 MR. LEGUM: Mr. President, I must reiterate
 14 our objection to this.
 15 What counsel is doing is trying to impeach
 16 the credibility of a Witness who has no opportunity to
 17 respond. If the Witness were able to respond in
 18 cross-examination, he would make clear that there is
 19 no contradiction and that counsel is misinterpreting
 20 these documents.
 21 PRESIDENT VEEDER: Let's just take it very
 22 slowly.

12:54:33 1 If we look at the First Witness Statement of
 2 Mr. Desai, in Paragraph 56, he does refer to
 3 Exhibit C-76. So if we look at C-76--and I haven't
 4 looked at the full text--it looks as though it's a
 5 telephone conference with Health Canada placed not
 6 later than the 2nd of September.
 7 I think that's permissible, isn't it? He can
 8 make that point off the face of the Witness Statement
 9 and the document referred to?
 10 MR. LEGUM: Certainly.
 11 MR. BIGGE: Mr. President, if I may add, if I
 12 recall the argument by opposing counsel on Monday,
 13 they suggested that there was no evidence that the
 14 Import Alert was posted before September 30, 2009.
 15 These documents, these contemporaneous documents only
 16 refute that point.
 17 PRESIDENT VEEDER: You're arguing the point.
 18 We're just trying to see how far can you go. But I
 19 think, speaking for myself--my colleagues will say
 20 differently if they disagree--the Respondent can point
 21 to the First Witness Statement of Dr. Desai and point
 22 to the document therein referred to and make any

12:55:38 1 points that follow from that. I don't think it's an
 2 objection that can be sustained.
 3 But beyond that I think you'll have
 4 difficulties, because you should have cross-examined
 5 Dr. Desai.
 6 MR. BIGGE: Mr. President, with that
 7 instruction, I have mere sentences before lunch. So
 8 if you will allow me to conclude.
 9 PRESIDENT VEEDER: They may be very long
 10 sentences, but please conclude.
 11 (Laughter.)
 12 MR. BIGGE: Mr. Sharpe will take this
 13 argument up in full. The point is that there is no
 14 basis for Apotex to be relying on the Detention Notice
 15 to create "relating to" jurisdiction when the Measure
 16 that it is actually challenging is the Import Alert.
 17 With that, my presentation concludes unless
 18 you have any further questions.
 19 ARBITRATOR CROOK: We might add an admonition
 20 that it would be useful to the Tribunal, in your
 21 future slides, to provide transcript cites and cites
 22 to the exhibits. They aren't always here, and it is a

12:56:46 1 great help to the Tribunal if you could add those.
 2 PRESIDENT VEEDER: Can I explain why that's
 3 important?
 4 You have a Slide 39 on discretion, and orally
 5 you referred to the fact that the Claimants' Experts
 6 agreed with that in Paragraph 47 of their Second
 7 Expert Report. But if you look at that, they are, in
 8 fact, simply quoting the U.S. Counter-Memorial.
 9 So I think cites are important to allow
 10 everybody to know where they stand. I don't think it
 11 matters in the light of what you said, but it's
 12 important that we know where things come from.
 13 So let's break now, and we'll resume here at
 14 2:00.
 15 (Whereupon, at 12:57 p.m., the hearing was
 16 adjourned until 2:00 p.m., the same day.)
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12:57:27 1 AFTERNOON SESSION
 2 PRESIDENT VEEDER: Let's resume. The
 3 Respondent has the floor.
 4 MR. BIGGE: Mr. President, thank you. I have
 5 the lead chair just for a minute to answer two of
 6 Mr. Rowley's questions that he posed during my
 7 presentation.
 8 First, he asked if there was a definition of
 9 a "batch." And as it turns out, it is in the
 10 regulations at 21 CFR 210.3(b), and I will read that
 11 definition slowly for the benefit of the reporter.
 12 "Batch' means a specific quantity of a drug
 13 or other material that is intended to have uniform
 14 character and quality within specified limits and is
 15 produced according to a single manufacturing order
 16 during the same cycle of manufacture."
 17 The second question--and I will read it from
 18 the LiveNote. You asked, "Could I just ask, at such a
 19 hearing, let us say, drug X is detained, shipment of
 20 drug X. What is required to get the shipment released
 21 and allowed to proceed? Does the shipper have to show
 22 that the drug is not adulterated or does it have to

14:02:11 1 show something such as the facility in which it was
 2 made was cGMP compliant?"
 3 The answer to that question depends on the
 4 basis for the detention. So if there is a concern
 5 that a particular product or a particular shipment
 6 appears to be adulterated, the manufacturer can
 7 demonstrate that those drugs are, in fact, not
 8 adulterated.
 9 But, if the basis of the detention is a cGMP
 10 violation--and under the statute, that cGMP violation
 11 means that all drugs from that facility are deemed to
 12 be adulterated--there are several showings that a
 13 manufacturer could make to have that product released
 14 into the United States.
 15 First, and I should mention, of course, we
 16 have an Expert in this area, William Vodra, who will
 17 be testifying later today. So if you'd like to pose
 18 your question again to him, he could answer it.
 19 But my understanding is that the first thing
 20 you could do is show that there was no cGMP violation
 21 at the facility, that FDA simply made a mistake. And
 22 certainly, you could bring in lawyers like

14:03:22 1 Ms. Beardsley that Apotex hired or consultants like
 2 Mr. Yeun who Apotex hired, to say, "No, FDA made a
 3 mistake; this is not a cGMP violation."
 4 Also you could show that the particular drug
 5 that is subject to the shipment was not subject to the
 6 particular cGMP violation, because cGMPs violations
 7 are, you know, sometimes very specific. And so, for
 8 example, if a cGMP violation relates to sterile
 9 injectables and you are shipping oral solid dosages,
 10 you could say, "Look, you know, even if they were made
 11 at the same facility, the cGMP violation relates to a
 12 different set of drugs, not this set of drugs."
 13 And in fact, something similar happened in
 14 the case of Apotex. A shipment from the Richmond Hill
 15 facility was temporarily detained but then released
 16 because it was a different facility and also a
 17 different class of drugs.
 18 The third thing that you could do is, after
 19 remediation, you could make another shipment and argue
 20 that your--while there may have been cGMP violations,
 21 those cGMP violations have been fixed. And, of
 22 course, the Detention Hearing officer can consult with

14:04:33 1 CDER, and CDER is very often monitoring the
 2 remediation efforts, and CDER may weigh in on the
 3 adequacy of the remediation.
 4 So that is my understanding of arguments one
 5 could make. There may be others. But, again, you can
 6 ask our Expert if you want more information.
 7 With that, I cede the floor to Ms. Thornton,
 8 who is going to call our first Witness.
 9 MS. THORNTON: If you could just give us a
 10 moment, we'll collect our Witness.
 11 (Pause.)
 12 PRESIDENT VEEDER: Forgive me for an obvious
 13 question, but I'm not from these shores. How do I
 14 address you? Are you Commander or how do you like to
 15 be called? General?
 16 THE WITNESS: Can everybody hear me?
 17 PRESIDENT VEEDER: You might want to speak up
 18 a little bit.
 19 THE WITNESS: My apologies. So Commander
 20 Emerson, Ms. Emerson, Deb Emerson. I'll respond to
 21 any of the above.
 22 PRESIDENT VEEDER: Let's say Commander

14:06:26 1 Emerson. We'd like you to look on the table before
 2 you. And you should see the formal words headed
 3 "Witness Declaration." And if you're willing to do
 4 so, please state your full name and then read out the
 5 words on that sheet of paper.
 6 THE WITNESS: My name is Debra Emerson, Debra
 7 Marie Emerson.
 8 On the Witness declaration: I solemnly
 9 declare upon my honor and conscience that I shall
 10 speak the truth, the whole truth, and nothing but the
 11 truth.
 12 PRESIDENT VEEDER: Thank you very much.
 13 There shall first be questions from the Respondent.
 14 MS. THORNTON: Thank you, Mr. President.
 15 Just before we begin, I just want to alert
 16 the Tribunal that we had a brief conversation with
 17 opposing counsel. Because this examination may
 18 involve some drug names and applications, they would
 19 prefer that we cut the feed for this.
 20 PRESIDENT VEEDER: Is that confirmed?
 21 MR. HAY: Yes. There may be some questions
 22 related to that, so we would ask that the feed be cut.

14:07:30 1 PRESIDENT VEEDER: Are these questions
 2 arising in the direct examination of this Witness or
 3 the cross-examination only?
 4 MS. THORNTON: It may be both.
 5 PRESIDENT VEEDER: We better cut the feed,
 6 then. Could we cut the feed, please.
 7 SECRETARY TAYLOR: Confirming the feed has
 8 been cut.
 9 PRESIDENT VEEDER: Thank you.
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14:07:44 1 CONFIDENTIAL PORTION
 2 MS. THORNTON: Thank you very much.
 3 DIRECT EXAMINATION
 4 BY MS. THORNTON:
 5 Q. Ms. Emerson, good morning--I mean good
 6 afternoon. How are you?
 7 How long have you been employed at FDA?
 8 A. 11 years.
 9 Q. You're a licensed pharmacist?
 10 A. I am.
 11 Q. You mentioned you're a commander with the
 12 Public Health Service?
 13 A. I am.
 14 Q. Can you briefly explain your responsibilities
 15 with FDA as opposed to the Public Health Service?
 16 A. Sure. For Food and Drug specifically, I'm a
 17 drug specialist and pre-approval manager for my
 18 office, which means I perform--majority of my
 19 inspections are all drug inspections. And with
 20 regards to the pre-approvals, I deal with applications
 21 for firms that are within our district.
 22 For Public Health Service, for them I am a

14:09:04 1 pharmacist. And when there is a national disaster or
 2 a crisis, they call upon medical staff to come fill
 3 pods, medical pods, or we'll go to hospitals and
 4 backfill where they need additional staff.
 5 In addition, I am part of a rapid deployment
 6 team for the New England region, when there is local
 7 issues that are specific to the New England region.
 8 Q. And you're a member of the FDA Pharmaceutical
 9 Inspectorate and the Foreign Drug Cadre?
 10 A. I am.
 11 Q. Could you adjust briefly explain what those
 12 are?
 13 A. Sure. The Foreign Drug Cadre is a group of
 14 drug investigators throughout Food and Drug that
 15 conduct international inspections, any--that would
 16 include any company that's outside of the United
 17 States.
 18 For the Pharmaceutical Inspectorate, I am one
 19 of approximately 70 that has undergone additional
 20 training and credentialing, auditing, and a detail to
 21 be part of the national--FDA's National Pharmaceutical
 22 Inspectorate.

14:10:17 1 Q. And how long have you been inspecting
 2 pharmaceutical facilities with the FDA?
 3 A. Approximately 10 years.
 4 Q. How many inspections do you conduct a year?
 5 A. 12 to 15.
 6 Q. And about how many of those are foreign
 7 inspections?
 8 A. Four to six.
 9 Q. You've a statement in front of you. Is that
 10 your Witness Statement in this arbitration?
 11 A. I have two. They are.
 12 Q. Okay. Did you review it in preparation for
 13 this hearing?
 14 A. I did.
 15 Q. And does it represent your honest
 16 recollection of the events detailed therein?
 17 A. It does.
 18 Q. Your Witness Statement discusses your
 19 inspection of Apotex's Etobicoke facility in December
 20 of 2008. Can you just take a minute or two to briefly
 21 describe your findings during that inspection.
 22 A. Sure. There were multiple parts to the

14:11:07 1 inspection. The first part of the inspection had to
 2 do with nine pre-approvals. A pre-approval is a
 3 pending application for the site. So Apotex had
 4 submitted nine applications to FDA. Six were specific
 5 to add the Etobicoke facility as a laboratory.
 6 We recommended that all of them--all of the
 7 six applications be withheld because none of the work
 8 had been performed specifically by the Etobicoke site.
 9 The other three were for manufacturing at
 10 Etobicoke. They were three different drug products.
 11 One specifically was the hydrochlorothiazide capsules.
 12 In review of that, that was the only--of the three
 13 manufacturing that had firm had performed scaleup
 14 batches, which means they've gone into large-scale
 15 manufacturing, [REDACTED] batches that they had
 16 made had failed. This happened in first quarter of
 17 2008. I was there in December 2008. And all [REDACTED] of
 18 the [REDACTED] batches had failed for assay, which means
 19 potency.
 20 And when I was there in December, I
 21 specifically asked why the batches had failed. And at
 22 the time the firm did not know. They were still

14:12:23 1 trying to--they were in process of trying to figure
 2 that out and testing their hypothesis. But the
 3 documents that they had relative to the investigations
 4 had not been complete because the firm had not been
 5 able to determine why the batches had failed.
 6 In addition to that, the pre-approval--so
 7 then we did a for-cause type of inspection, which was
 8 for carbidopa-levodopa. And that was because we had
 9 received some complaints through FDA's MedWatch
 10 program, which is a voluntary program for consumers
 11 and health care providers to provide feedback for
 12 products to the FDA. And with that, there was some
 13 complaints of lack of effect.
 14 So I had gone to Apotex to review their
 15 records. And as part of that, I looked at the
 16 complaints that they had on-site. They had very
 17 limited complaints. I believe that there were [REDACTED]
 18 complaints. So I reviewed all of them.
 19 I couldn't find any trends. And by "trends"
 20 I mean that there were multiple complaints with the
 21 same lot number. They didn't have that. I also
 22 looked at--their out of specifications. There were

14:13:43 1 very few of those relative to that specific product.
 2 There were [REDACTED], and I--the data appeared okay. And
 3 then I looked at various deviations that they had, but
 4 I could not find any specific trends.
 5 In addition to that, I did a GMP. A cGMP is
 6 Current Good Manufacturing Practices. And so specific
 7 to that, we found deviations within our--within their
 8 systems. A couple examples for that have to do
 9 with--one of them was ketoconazole. It was a product
 10 that they had found, during stability studies, they
 11 had an unidentified peak. The unidentified peak
 12 turned out to be a [REDACTED]. And what had happened
 13 was the ketoconazole is an antifungal, and they had
 14 cross-contamination with [REDACTED]. [REDACTED] is used
 15 for [REDACTED]. And they found this at the three-month
 16 mark. So they do stability studies initially three
 17 months, six months, nine months, and so on. So they
 18 found this at three months.
 19 So what they did after this was they
 20 submitted a Field Alert to Food and Drug. And the
 21 Field Alert notifies us that there's a problem for a
 22 product that was already distributed within the U.S.

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14:15:09 1 However, they waited over 15 months to tell us.
2 This is truly significant and an issue for us
3 because some people have significant drug allergies,
4 and if a person who was taking the ketoconazole had an
5 allergy to [REDACTED], they would have no way to know
6 that there was a cross-contamination. The company
7 never recalled the product. They allowed it to stay
8 on the market.

9 There was also issues with--another product
10 was [REDACTED] where they had over-thick tablets. And
11 the way this particular product worked, the active was
12 in the over-thick part. So when the tablets were too
13 big, [REDACTED]. It was
14 approximately six months later, after they--because
15 Apotex had gotten a complaint about this. It was
16 approximately six months later that they notified FDA
17 of the problem.

18 And so I'm not sure if you're familiar with
19 the regulations that FDA has, but for products that
20 are covered under applications, if there's a problem
21 with a product that has already been distributed
22 within the U.S. market, you have three business days

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14:16:19 1 to notify us. And the reason for that is because we
2 need to be able to make a public health assessment and
3 determine whether or not we need to notify the public
4 for a potential problem. And so that's the reason for
5 the Field Alerts and the time frame.

6 MS. THORNTON: Thank you.

7 That concludes our direct examination.

8 PRESIDENT VEEDER: Thank you. There will now
9 be questions from the Claimant.

10 CROSS-EXAMINATION

11 BY MR. HAY:

12 Q. Thank you, Ms. Emerson. I am John Hay, and
13 I'm going to be asking you some questions this
14 afternoon. If for any reason you don't understand my
15 question or you would like me to repeat it or,
16 perhaps, say it loudly, whatever, just let me know and
17 I'm happy do that. I just want to make sure you
18 understand all my questions as I ask them.

19 A. Sure.

20 Q. Now, you have--you were one of the two
21 inspectors who inspected the Etobicoke facility
22 between December 10 and December 19, 2008; correct?

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14:17:15 1 A. Correct.

2 Q. And you have submitted a Witness Statement
3 that you referred to in this case; correct?

4 A. Correct.

5 Q. When you prepared your Witness Statement, did
6 you review any documents?

7 A. I reviewed my notes and the EIR. I believe
8 that's all.

9 Q. When you say your "notes," are you referring
10 to the EIR or is there separate notes from the
11 inspection?

12 A. So, no. We have--so the--my notes would be
13 the notes that I took while I was on-site in addition
14 to the EIR, because you can't put everything in an
15 EIR.

16 Q. Okay. Did you review the 483 that was
17 presented to Apotex after the completion of the
18 inspection?

19 A. The 483 is part of the EIR, so, yes.

20 Q. Okay. And in addition to those documents,
21 did you look, for example, at Apotex's Response to the
22 483?

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14:18:27 1 A. I did not.

2 Q. Did you--have you ever seen Apotex's Response
3 to the 483?

4 A. I have.

5 Q. Okay. And when did you see that?

6 A. I looked at that in preparing to come here.

7 Q. Okay. Is that the first time you saw it?

8 A. It is.

9 Q. Okay. So back in 2009 when these events were
10 occurring, you didn't have occasion to see Apotex's
11 Response to the 483?

12 A. So, domestically, that would be different,
13 but internationally the Responses are reviewed by
14 CDER, and so the Responses go directly to
15 headquarters. And if they have question, they'll
16 contact us, but they don't always come to us.

17 Q. Okay. And in this particular case, do you
18 recall receiving--getting any questions from CDER
19 about this inspection?

20 A. About the firm's response?

21 Q. About the--well, we'll start with the firm's
22 response, yes.

14:19:21 1 A. No, because I didn't review it.
 2 Q. Okay. So, now--I don't want to cut off your
 3 answer.
 4 Did you get any questions from CDER at all
 5 about the inspection at the time?
 6 A. Only one.
 7 Q. Which was?
 8 A. It was specific to the number of rejected
 9 lots.
 10 Q. Okay. And what was the question?
 11 A. It was a question about the rejected lots and
 12 the coverage of the rejected lots. So the rejected
 13 lot lists, the additional one, which provided on the
 14 last day of the inspection. The rejected lots were
 15 actually part of an exhibit that was collected on the
 16 first day of the inspection.
 17 But the document was 111 pages. The
 18 inspection was very intense and very difficult because
 19 the firm did not have data that they needed for the
 20 pre-approval, and that slowed the inspection and
 21 limited our time. So the night before the close of
 22 the inspection I had been reviewing some annual

14:20:33 1 product reviews, and there were a significant number
 2 of rejected batches.
 3 And so when I came in the next day, I asked
 4 Ms. Austin if she could pull a list for me of all the
 5 rejected batches, and she did. And it took a while.
 6 And so that was the last day that we were there. When
 7 I got the list, I asked her specifically about the
 8 list and why they had such a large number of rejected
 9 batches.
 10 Now, the list that was provided was for--
 11 Q. I don't mean to cut you off, but my question
 12 was: What was the question from CDER? You seem to be
 13 talking--
 14 A. Sorry.
 15 Q. --about a discussion with--during the
 16 inspection. So we can get to that in a few minutes,
 17 but can we start with my question, which was--you said
 18 there was one question raised by CDER. I'm just--I'm
 19 trying to understand what that was.
 20 PRESIDENT VEEDER: Would it help if you
 21 looked at Paragraph 29 and just explain more fully
 22 what you say in that paragraph of your Witness

14:21:31 1 Statement?
 2 THE WITNESS: Sure. The--she asked me about
 3 the rejected batches, and I told her that in my
 4 discussion with Ms. Austin, Ms. Austin had stated to
 5 me that Apotex is a generic company. They do not do
 6 R&D. If they make a batch and it passes, they release
 7 it. If it's rejected--if it does not pass, then it's
 8 rejected.
 9 BY MR. HAY:
 10 Q. And you made reference to receiving a
 11 150-page document or something. I didn't quite hear
 12 what that was at the beginning--
 13 A. The initial request to the company was a list
 14 of all batches that went to the U.S. that had been
 15 released, quarantined, or rejected, and it was 111
 16 pages, sir.
 17 Q. Okay. So is that the list you were talking
 18 about?
 19 A. The original list.
 20 Q. Okay. And I take it--have you seen the
 21 Warning Letter that was submitted with respect to the
 22 Etobicoke facility?

14:22:51 1 A. I did see the Warning Letter.
 2 Q. Did you see it at the time that it was
 3 issued?
 4 A. I saw it after it was issued.
 5 Q. Okay. And did you see the Response by Apotex
 6 to the Warning Letter?
 7 A. I saw the Response in preparation to come
 8 here.
 9 Q. Okay. But prior to that, you hadn't seen it?
 10 A. I had not.
 11 Q. Okay. And I apologize if I asked you this
 12 before. So in terms of Apotex's Response to the 483,
 13 you didn't review that in preparation of your
 14 testimony either?
 15 A. I reviewed the Response in preparation to
 16 come here.
 17 Q. Okay. But before that, you hadn't seen it?
 18 A. No.
 19 Q. Now, just kind of getting back to your
 20 background for a second, your Statement says that you
 21 started at FDA in 2002; correct?
 22 A. Correct.

14:23:51 1 Q. And you've been an inspector that entire
 2 time?
 3 A. I have.
 4 Q. But when did you do your first foreign
 5 inspection?
 6 A. 2008.
 7 Q. And I believe you said this was your second?
 8 A. I did a firm on the same trip in Canada just
 9 prior to this one.
 10 Q. If I direct your attention to Paragraph 3 of
 11 your Statement, the second sentence, you say that
 12 "Depending on the nature and scope of the
 13 investigation assigned, I may be joined by a chemist
 14 or a microbiologist."
 15 Do you see that?
 16 A. I do.
 17 Q. And that was the case for this inspection?
 18 A. I was accompanied by a chemist, yes.
 19 Q. Okay. And is that normal, the number of
 20 inspectors, two for most facilities?
 21 A. Especially on a pre-approval, to have a
 22 chemist do the methods it's very important because

14:25:05 1 we're there for a very short period of time and,
 2 truly, you need additional help.
 3 Q. Okay. So normally it's one if it's not a
 4 pre-approval? Is that how it works?
 5 A. It depends. I always travel with an analyst.
 6 If it's a sterile facility, I travel with a
 7 microbiologist. If it's a regular manufacturer, I
 8 travel with a chemist, because they help with the
 9 inspection, and you can't cover everything in the
 10 limited number of time they have--they have you there.
 11 So even on a GMP, I ask for an analyst.
 12 Q. So you usually have two on a GMP?
 13 A. Yep. We try.
 14 Q. I'm going to ask to put before you what has
 15 been--what is Exhibit C-034. I'm going ask you to
 16 identify that.
 17 A. Sure.
 18 Q. The Joint Core Bundle 07. Can you just
 19 identify what that document is.
 20 A. This is a form FDA 483. It's a list of
 21 observations that was issued at conclusion of the
 22 inspection for the Etobicoke site.

14:27:18 1 Q. And this was prepared by you?
 2 A. It was prepared by both myself and the
 3 analyst, Ms. Campbell.
 4 Q. And this is prepared by you and provided to
 5 the company before you leave from the inspection; is
 6 that correct?
 7 A. Correct.
 8 Q. And then the company has some amount of time
 9 to respond to this; is that correct?
 10 A. They do.
 11 Q. Do you know how long they have to respond?
 12 A. At the time of the inspection, I think--there
 13 was no--if I remember correctly, there was no specific
 14 time defined. Subsequent to the inspection, Margaret
 15 Hamburg implemented a 15 business day to respond if
 16 you want your observations--if you want your response
 17 to be considered prior to any regulatory action by the
 18 firm. I just can't tell you the date that she issued
 19 that because I can't remember. I'm sorry.
 20 Q. Okay. Did you review this before it was
 21 issued to the company?
 22 A. I spoke with them about it.

14:28:26 1 Q. Did you--but you reviewed your draft of it
 2 before it was issued to the company?
 3 A. No. We don't give them a draft. We give
 4 them the original, and we discussed each issue.
 5 Q. Okay. And this 483 that you issued raised
 6 all the issues that you thought significant at the
 7 time?
 8 A. Most of them.
 9 Q. Are you aware of a--strike that.
 10 Were there any documents or information that
 11 you asked for during the inspection that you didn't
 12 receive?
 13 A. Not that I remember.
 14 Q. And I may show you your EIR later, but there
 15 seems to be a number of occasions in it where there's
 16 a reference to whether or not--or it specifically
 17 says, "Refusals: There were no refusals in Canada
 18 during the inspection."
 19 What does that refer to?
 20 A. I'm sorry. Could you say that one more time?
 21 Q. In your EIR, there's a section that talks
 22 about refusals and it says, "There were no refusals in

14:29:45 1 Canada during the inspection."
 2 I mean, I can show you the document if you'd
 3 like to, but if you can tell me what that means.
 4 A. That means that the firm did not refuse to
 5 provide myself or Ms. Campbell any information.
 6 Q. So that means all the documents and
 7 information you requested during the inspection was
 8 provided by Apotex; correct?
 9 A. That is correct.
 10 Q. One of the things you told us you asked for
 11 was a list of batch rejections; correct?
 12 A. Correct.
 13 Q. But you didn't ask for the investigations
 14 related to those batch rejections; correct?
 15 A. I did not ask for the investigations specific
 16 for all of them because I needed to leave the firm and
 17 so I asked for a list only of the rejected batches.
 18 Q. And you told me that you had a conversation
 19 with CDER concerning the list that you brought back
 20 after the inspection; correct?
 21 A. Correct.
 22 Q. Did you make any attempt to contact the

14:31:01 1 company about the list of rejected batches after the
 2 inspection?
 3 A. It's not--the investigators can't do that, so
 4 we can't include anything that's received from a
 5 company after an inspection closes. So, no, I did
 6 not.
 7 Q. So is it fair to say that after the
 8 inspection you did not ask anyone at Apotex for copies
 9 of the batch rejection investigations; correct?
 10 A. The only ones that I collected were specific
 11 to the hydrochlorothiazide, which are included in the
 12 EIR. So I asked for those, I reviewed those, and
 13 those are part of the Inspection Report.
 14 I was not--due to the time constraint and the
 15 fact that I needed to leave the firm that day--I did
 16 not ask them to print all of the investigations that
 17 were associated with the batch failures that were on
 18 that list because it would take the firm too long to
 19 do that.
 20 Q. Well, did you ask--you didn't--strike that.
 21 You didn't ask Apotex for any other batch
 22 rejection investigations other than the ones you just

14:32:11 1 mentioned for that one product; correct?
 2 A. For hydrochlorothiazide only.
 3 Q. Right. And to your knowledge, did FDA ever
 4 ask Apotex for the batch rejection investigations?
 5 A. I can't answer that because I don't know.
 6 Q. Okay. So you have no knowledge that FDA ever
 7 asked that, asked for those records?
 8 A. That would be done by CDER, and I'm sorry,
 9 but they don't tell me what they do. So I can't
 10 answer that. I'm sorry.
 11 Q. Okay. Let's talk about--strike that.
 12 After your conversation with CDER, do you
 13 know how or if the issue of the batch rejections was
 14 resolved?
 15 A. I have no knowledge. I'm sorry.
 16 Q. So at that point in time you were not
 17 involved with the process of dealing with the issue of
 18 the batch rejections; correct?
 19 A. My job stopped when I finished the
 20 inspection. I came back, wrote the Report. I submit
 21 everything to my supervisor, and then it goes down to
 22 CDER for review.

14:34:05 1 Q. When you reviewed the Response to the 483
 2 that Apotex submitted in preparation of your
 3 testimony, did you see how--whether Apotex addressed
 4 the issue of the batch rejections investigations?
 5 A. There's not enough detail in there for me to
 6 be able to say yes to that. I would need to review
 7 the actual investigations. Sometimes firms code or
 8 use groupings for investigations, and unless you
 9 actually review what happened and what the firm did,
 10 that's very difficult to answer.
 11 Q. Well, let's try it this way: Looking back at
 12 your 483 that was submitted, there's no reference to a
 13 batch rejection investigation issue there, is there?
 14 A. There was not.
 15 Q. So there would be no reason why the company
 16 would address it in its response to your 483 if it's
 17 not raised in the 483; correct?
 18 A. That would be correct.
 19 Q. And when you looked at the Etobicoke Warning
 20 Letter, did you see that this issue of the batch
 21 rejection investigations was part of the Warning
 22 Letter?

14:35:26 1 A. I did.
 2 Q. Okay. And did you have occasion to look at
 3 Apotex's Response to the Warning Letter?
 4 A. At that time?
 5 Q. At any time.
 6 A. I did in preparation to come here. When the
 7 Warning Letter was issued in 2009, I didn't have
 8 access to their response back to that, so I didn't see
 9 that.
 10 Q. How is it that you received a copy of the
 11 Warning Letter when it was issued back in 2009?
 12 A. It was sent to me via e-mail by a colleague
 13 who had seen it posted. At the time I didn't know
 14 that it had already been issued, and--because they had
 15 known that I had done the inspection.
 16 Q. Did you talk to anyone at CDER regarding that
 17 Warning Letter at the time?
 18 A. No.
 19 Q. Did you talk to anyone at FDA about the
 20 Warning Letter at the time in terms of substance of
 21 what was in the Warning Letter other than your friend
 22 who sent it to you?

14:36:22 1 A. No.
 2 Q. So I take it before the Warning Letter was
 3 issued, you weren't contacted by CDER to get any input
 4 in terms of what you might think of the Warning Letter
 5 or what should be included?
 6 A. No.
 7 Q. With respect to carbidopa-levodopa that you
 8 went there to investigate an issue with, when you did
 9 the inspection, that drug, that was a drug that
 10 actually had prompted the Etobicoke inspection;
 11 correct?
 12 A. No. My understanding is that the inspection
 13 was prompted for the pre-approvals and to do a GMP.
 14 That was added on and provided to me later to follow
 15 up, in addition to the other two assignments that I
 16 already had.
 17 Q. Just so I understand, when were you advised
 18 of the inspection for the GMP and the pre-approvals?
 19 A. I can't give you an exact date, but it would
 20 have been September-October time frame.
 21 Q. Of 2008?
 22 A. Of 2008.

14:37:42 1 Q. Okay.
 2 A. Yes.
 3 Q. And then when were you told that you needed
 4 to add a directed or for-cause inspection?
 5 A. It came approximately mid-November. And it
 6 was--yep, mid-November.
 7 Q. And you've already described in your direct
 8 testimony some of the investigation you did with
 9 respect to that, that issue?
 10 A. Yes.
 11 Q. And did you remember--do you recall preparing
 12 a Report regarding that issue?
 13 A. I prepared a memo.
 14 Q. Memo?
 15 A. Uh-huh.
 16 Q. Okay. And do you know the date of the memo?
 17 A. Not exactly. I'm sorry.
 18 Q. Okay.
 19 A. January? December? January?
 20 Q. You don't have to guess. I'm happy to share
 21 it with you.
 22 A. Thank you.

14:39:03 1 Q. We'll hand you Exhibit C-339.
 2 Is that a copy of your memo?
 3 A. It is.
 4 Q. And I see it was prepared by you on
 5 February 9, 2009? Does that sound correct?
 6 A. Correct.
 7 Q. You have to answer verbally.
 8 A. Correct--oh, sorry, yes.
 9 Q. Who was Gary Hagan?
 10 A. He's my direct supervisor.
 11 Q. Okay. Directing your attention to this
 12 exhibit, it seems to talk about a 4/4/08. Was that a
 13 request? Does that refresh your recollection as to
 14 when the inspection of requested?
 15 A. That was the date of the assignment that was
 16 issued by CDER, but that's not the date that I got the
 17 assignment, sir.
 18 Q. Okay. So you believe you got the
 19 assignment--so CDER wanted to look into this issue on
 20 April 4, 2008, but then schedule spoke to you about
 21 the inspection in September?
 22 A. So you understand for the trips, they come

14:40:48 1 out about two months prior to when we leave, two to
 2 three months prior to when we leave. And we volunteer
 3 for the trips. And so I can't tell you exactly when I
 4 volunteered for that trip, but it was in and around
 5 the September time frame, September-October time
 6 frame. And that's when I was the traveler who was
 7 chosen for the trip. So I wouldn't have gotten this
 8 until after I was chosen.

9 I did not know at the time that I volunteered
 10 for the trip who the company was, and I did not know
 11 that there was a for-cause. I knew it was a
 12 pre-approval and a GMP.

13 Q. Okay. Thank you for that.

14 Now, getting back to your Report, so you
 15 investigated this issue that these complaints had come
 16 about; correct?

17 A. Correct.

18 Q. And as part of that--and this was taking
 19 place during the inspection; correct?

20 A. Correct.

21 Q. And did you bring back the investigations
 22 with respect--to your office with respect to that

14:41:53 1 product and issue, or did you complete your
 2 investigation on-site, I guess is my question.

3 A. I completed the investigation on-site.

4 Q. Okay. And during the inspection, you
 5 reviewed all of the complaints and investigations;
 6 correct?

7 A. No. I reviewed the [REDACTED] complaints. There
 8 were only [REDACTED], and I looked at all of them.

9 Q. Okay. So all [REDACTED] complaints you looked at?
 10 That's all the complaints there were for this product?

11 A. Correct.

12 Q. Okay. And you concluded in this memo that
 13 all the complaint files were well documented; is that
 14 correct?

15 A. The complaint files were complete per the
 16 firm's procedures and well documented, correct.

17 Q. And no product complaint trends were seen?

18 A. I could not find--there were no trends,
 19 correct.

20 Q. Okay. What does that mean?

21 A. So, complaints are trended, and so by
 22 "trending" they would trend them based off the type of

14:43:02 1 complaint, the lot number, the year, the month, and so
 2 on, a trend. If you have a problem with a lot, you
 3 would expect significant numbers or may have more than
 4 one complaint for the same lot number. That would be
 5 a trend. And so there were no trends specific to the
 6 carbidopa-levodopa.

7 Q. In fact, there were no significant issues
 8 found at all during the inspection; correct?

9 A. There were no significant issues found
 10 specifically for carbidopa-levodopa.

11 Q. Correct.

12 And in your mind, did that end the issue with
 13 respect to that particular product?

14 A. No. I didn't have time to go through all of
 15 their deviations, to go through the entire
 16 manufacturing process. So I was limited with the time
 17 that I could spend on everything, and there were only
 18 a limited number of days. So I did the best that I
 19 could in the time frame that I had.

20 Q. And you concluded at the end of that, there
 21 were no issues; correct?

22 A. There were no significant issues specific for

14:44:10 1 that product that I could find.

2 Q. Did an issue regarding that product
 3 instability arise during the inspection?

4 A. There was. Do you want me to explain?

5 Q. Okay. You can explain. What was the issue?

6 A. Specifically for the carbidopa-levodopa, the
 7 firm had a problem with their [REDACTED]

8 [REDACTED]
 9 [REDACTED]
 10 [REDACTED]
 11 [REDACTED]
 12 [REDACTED], and when
 13 they put the product on stability, they had completed
 14 three months of accelerated stability, which means
 15 they put it--under the regulations, you're required to
 16 have stability data to support your product within its
 17 shelf life at the storage conditions.

18 So when you change a critical component to
 19 your process, which an active ingredient is, you're
 20 expected to start your stability study over. When you
 21 do that, you don't have the--because the firm was
 22 using a two-year expiry, you don't have data for that.

14:46:18 1 So the guidelines that we use are you need to have
 2 done accelerated studies, which means you warm the
 3 chamber higher than your room temperature. That's how
 4 it is stored. You put it in a warmer chamber, and you
 5 would put it there for six months. You're expected to
 6 test it at 0, 1, 2, 3, and 6 months. If your product
 7 does not show negative change more than 5 percent, the
 8 Agency is in agreement that you can use a two-year
 9 expiry on your product.

10 [REDACTED]
 11 [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]
 16 [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 [REDACTED]
 20 [REDACTED]

14:47:26 1 [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 Does that help?
 5 Q. So you--I didn't mean to cut you off.
 6 A. That's okay.
 7 Q. So you indicated that on the 483, correct, as
 8 an issue?
 9 A. I believe so. Can I double-check?
 10 Q. Sure.
 11 A. I'm fairly certain. Yes, it is. Number 9.
 12 Q. Right. As a matter of fact, according to
 13 your Statement, you recommended a recall on an Import
 14 Alert based on that; correct?
 15 A. I believe I recommended an Import Alert. I
 16 don't have the power to be able to recommend a recall,
 17 although I believe that they should have recalled it
 18 because they did not have data to support the storage
 19 for--they didn't have data to support the expiry for
 20 the product that was on the U.S. market.
 21 Q. But to your knowledge, they didn't--at that
 22 time, they weren't put on Import Alert because of that

14:48:21 1 issue; correct?
 2 A. That I'm not sure, sir.
 3 Q. Okay. And there was no recall, to your
 4 knowledge?
 5 A. That I'm not sure about either.
 6 Q. And as a matter of fact, Apotex responded to
 7 your 483 by providing an explanation as to why they
 8 thought they were in compliance; correct?
 9 A. I read that response recently.
 10 Q. Okay. But you--that was just in preparation
 11 for your testimony?
 12 A. Correct.
 13 Q. Okay. You hadn't read it at the time you did
 14 your Statement?
 15 A. No.
 16 Q. Okay. And now, it was available at the time
 17 you did your statement, though; right? It was dated
 18 in 2009; correct? January of 2009?
 19 A. The firm's Response, I believe, was
 20 January--I don't have it. I'm sorry. But I believe
 21 it was in early 2009.
 22 Q. Okay. So, it was sometime in 2009 that they

14:49:18 1 did a response, correct, to your 483?
 2 A. I don't have it, so I can't tell you the
 3 date.
 4 Q. I can show it to you. I'm happy to share it,
 5 but I'll represent to you that it's dated January 30,
 6 2009.
 7 And the point I just want to establish is
 8 that you didn't see it at that point in time, and you
 9 didn't see it until you were coming here to testify;
 10 correct?
 11 A. That is correct.
 12 Q. Okay. And in terms of the Warning Letter,
 13 when you reviewed the Warning Letter back in 2009,
 14 around the time it came out, did you note that there
 15 was no reference in it to this issue?
 16 A. We don't put all of the issues that are found
 17 on an inspection in a Warning Letter. So that would
 18 not necessarily be uncommon, and it doesn't take away
 19 from the fact that the firm was missing the data. The
 20 Agency doesn't always put all issues on a Warning
 21 Letter.
 22 Q. They put the significant issues at the time

14:50:24 1 on a Warning Letter; correct?
 2 A. The decision by which they make that I'm not
 3 privy to. I just know that not all issues are on a
 4 Warning Letter.
 5 Q. Okay. And this issue wasn't on the Warning
 6 Letter; correct?
 7 A. Not to my knowledge.
 8 Q. So at that point in time, Apotex would have
 9 reason to believe that the--that it was no longer an
 10 issue, is that fair, because it wasn't on the Warning
 11 Letter?
 12 PRESIDENT VEEDER: Is that a fair question
 13 for this Witness?
 14 MR. HAY: Strike the question.
 15 BY MR. HAY:
 16 Q. The product that you mentioned earlier in
 17 your direct testimony about the, I think, [REDACTED] or [REDACTED]
 18 failures, you said. Which product was that?
 19 A. Hydrochlorothiazide. It was one of the
 20 applications that were pending for that facility.
 21 Q. Okay. So that was not a product for sale;
 22 correct?

14:51:33 1 A. Allowed for sale in the U.S., no.
 2 Q. It was in the process stage; right? It
 3 wasn't being sold in the U.S.; correct?
 4 A. Correct.
 5 MR. HAY: I have no further questions of this
 6 Witness.
 7 PRESIDENT VEEDER: Are there any questions by
 8 way of re-examination from the Respondent?
 9 MS. THORNTON: No, we have no further
 10 questions.
 11 PRESIDENT VEEDER: There may be questions
 12 from the Tribunal.
 13 THE WITNESS: Sure.
 14 QUESTIONS BY THE TRIBUNAL
 15 ARBITRATOR ROWLEY: Commander Emerson, I'm
 16 looking at a document which I can have put in front of
 17 you, if necessary, but I'm looking at--it's a chart of
 18 the Division of Manufacturing Product Quality, and it
 19 shows the manufacturing assessment and pre-approval
 20 compliance branch headed at the time of this chart by
 21 Edwin Rivera-Martinez, and then it has an
 22 International Compliance Team headed by Anthony

14:52:40 1 Charity. And it's got Hidee Molina and Carmelo Rosa
 2 in the team amongst a number of others.
 3 PRESIDENT VEEDER: Can we stop? Is there a
 4 spare copy of this for the Witness? This is the
 5 document we were given.
 6 ARBITRATOR ROWLEY: C-489 it is.
 7 PRESIDENT VEEDER: There is one coming up.
 8 ARBITRATOR ROWLEY: It's C-489.
 9 MR. DALEY: We have a copy that has some
 10 handwriting on it, so we're going to get a clean copy.
 11 ARBITRATOR ROWLEY: Do you see the branch
 12 that I was looking at?
 13 In any event, it wasn't a trick question, but
 14 I didn't see your name in this particular
 15 International Compliance Team, and I wondered whether
 16 it was because of the timing of the creation of this
 17 document or whether you were in an entirely different
 18 team.
 19 THE WITNESS: Sure. I work for the New
 20 England District Office, so I'm not part of the
 21 International Compliance Team.
 22 ARBITRATOR ROWLEY: I didn't hear you. Which

14:54:32 1 district?
 2 THE WITNESS: I work for Food and Drug out of
 3 the New England District Office, which is located in
 4 Stoneham, Massachusetts, and we perform the
 5 inspections that are reviewed by this team.
 6 ARBITRATOR ROWLEY: By "this team," you mean
 7 the International Compliance Team?
 8 THE WITNESS: That is correct.
 9 ARBITRATOR ROWLEY: Thank you.
 10 THE WITNESS: You're welcome.
 11 ARBITRATOR CROOK: Commander, I'm looking at
 12 JCB-12, which is the thick document you were handed
 13 about your carbidopa assessment. I'm just curious,
 14 that has a number of attachments. There would be seem
 15 to be the individual complaints regarding efficacy or
 16 whatever of this drug.
 17 And then there is, at the end of this, a
 18 succession of lists that looks like this. I'm holding
 19 it up. It's got a Bates Number of 317 down in the
 20 bottom corner. I'm just curious what this--what this
 21 thing is. Can you shed any light on that?
 22 THE WITNESS: The bottom number is 317 you

14:56:21 1 said; correct?
 2 ARBITRATOR CROOK: Yes, ma'am.
 3 THE WITNESS: So this was a list of
 4 investigations. The firm--the reason that these were
 5 attached is because it listed the specific number of
 6 investigations for carbidopa-levodopa, and they're
 7 alphabetical by product and, so the carbidopa-levodopa
 8 are about 20 percent down on the page.
 9 ARBITRATOR CROOK: Okay. I see. Okay.
 10 Thank you very much. That clarifies it.
 11 So this is the all the investigations they
 12 had undertaken with respect to a whole range of
 13 products over whatever the relevant time period is.
 14 THE WITNESS: Correct.
 15 ARBITRATOR CROOK: Okay. Thank you.
 16 THE WITNESS: You're welcome.
 17 PRESIDENT VEEDER: I had a similar question,
 18 but we need to start--don't put that away. Look at
 19 Paragraph 5 of your Witness Statement. And if you can
 20 skip to the third line. When you say there
 21 "later"--and you've explained that that may be October
 22 or November 2008--"Before the inspection, I was

14:57:26 1 informed that the CDER's Division of Manufacturing of
 2 Product Quality (now the Office...) had also requested
 3 a priority for-cause inspection of the facility
 4 prompted by consumer complaint that was sent to
 5 Congressman Moran concerning the lack of therapeutic
 6 effect of carbidopa-levodopa tablets, a drug for the
 7 treatment of Parkinson's disease."
 8 And if we look at the document appended to
 9 your memorandum, the document dated the 4th of April,
 10 2008, do you see that?
 11 THE WITNESS: I do.
 12 PRESIDENT VEEDER: If you look at the last
 13 paragraph of that, at the end of this memorandum "We
 14 strongly recommend that an investigator/analyst team
 15 with experience inspecting solid oral dosage form
 16 manufacturers be select to perform this inspection.
 17 The FDA team should consult with CDER ICT before
 18 conducting the inspection."
 19 THE WITNESS: Yes.
 20 PRESIDENT VEEDER: Now, in Paragraph 5, you
 21 say you were informed, but did it go beyond that? Did
 22 you consult or were you consulted by CDER's Division

14:58:34 1 of Manufacturing and Product Quality? Can you recall?
 2 THE WITNESS: I was aware of the initial part
 3 of the inspection being the GMP and the pre-approval
 4 much earlier, and I got an e-mail which attached this
 5 assignment to me which came sometime in mid-November,
 6 and I cannot--I don't remember. I'm sorry.
 7 PRESIDENT VEEDER: Let's leave it at that.
 8 Are there any questions from either side
 9 arising from the Tribunal's question. We ask the
 10 Respondent first?
 11 MS. THORNTON: Could you just give us one
 12 moment?
 13 PRESIDENT VEEDER: Of course.
 14 MS. THORNTON: Thank you.
 15 No questions. Thank you.
 16 PRESIDENT VEEDER: From the Claimant?
 17 MR. HAY: Just one second. No. No
 18 questions.
 19 PRESIDENT VEEDER: Thank you very much.
 20 We've come to the end of your testimony. Thank you.
 21 THE WITNESS: Thank you.
 22 (Witness steps down.)

14:59:49 1 PRESIDENT VEEDER: You can leave everything
 2 there. Don't worry.
 3 Can we proceed to the next Witness, or do you
 4 need time?
 5 MR. SHARPE: We can proceed to the next
 6 Witness if you can give us a minute to get the next
 7 Witness in. We'll be set up momentarily.
 8 (Brief recess.)
 9 PRESIDENT VEEDER: We'll come to you in a
 10 second. We had a query. We've forgotten what rules,
 11 if there were any, about Witness sequestration, but
 12 obviously they're finished once a Witness has
 13 completed their testimony?
 14 That's agreed, is it?
 15 MR. LEGUM: Yes, that's in the first
 16 Procedural Order.
 17 PRESIDENT VEEDER: I forgot what it says.
 18 MR. LEGUM: It says after a Fact Witness has
 19 testified, they may remain in the hearing room, if
 20 they so desire.
 21 PRESIDENT VEEDER: It's very important. Only
 22 if they so desire.

15:02:03 1 (Laughter.)
 2 LLOYD DUANE PAYNE, RESPONDENT'S WITNESS, CALLED
 3 PRESIDENT VEEDER: Thank you.
 4 So I'm going to ask you to state your full
 5 name and read the words on the declaration form you
 6 have in front of you on the table.
 7 Do you have that piece of paper?
 8 THE WITNESS: Yes, I do.
 9 PRESIDENT VEEDER: If you're willing to give
 10 that declaration, please state your full name and read
 11 the words.
 12 THE WITNESS: Lloyd Duane Payne.
 13 I solemnly declare upon my honor and
 14 conscience that I shall speak the truth, the whole
 15 truth, and nothing but the truth.
 16 PRESIDENT VEEDER: Thank you very much.
 17 There will first be questions from the Respondent.
 18 Just a question about the feed. Do we need
 19 the feed on or off?
 20 MS. CATE: It's my understanding that there
 21 are some specific drug names in the documents that
 22 could be talked about, but I will leave it up to the

15:03:03 1 opposing counsel to also have his word on this as
 2 well.
 3 PRESIDENT VEEDER: So your proposal is the
 4 feed should be off?
 5 MS. CATE: I'm willing to have that happen.
 6 PRESIDENT VEEDER: What's the Claimants'
 7 position?
 8 MR. HAY: We don't have an objection to
 9 having it off.
 10 PRESIDENT VEEDER: Let's have it off. Thank
 11 you. Please proceed.
 12 DIRECT EXAMINATION
 13 BY MS. CATE:
 14 Q. Mr. Payne, how long have you been employed
 15 with FDA?
 16 A. Almost 22 years.
 17 Q. Okay. And what is your current title?
 18 A. I am a consumer safety officer with the
 19 designation of resident in charge in the Oklahoma City
 20 resident post.
 21 Q. Okay. And how long have you been inspecting
 22 pharmaceutical facilities for FDA?

15:03:43 1 A. The first inspection I took part in with FDA
 2 was in 1992, and it was a human pharmaceutical
 3 manufacturer.
 4 Q. Okay. About how many inspections of
 5 pharmaceutical facilities have you conducted since you
 6 began working with FDA?
 7 A. I would say, on the conservative side,
 8 approximately 30.
 9 Q. Okay. And about how many foreign inspections
 10 have you done?
 11 A. Foreign in the human drug industry would be
 12 nine.
 13 Q. Okay. And is the statement before you your
 14 Witness Statement in this arbitration?
 15 A. I need to retract that. I would say seven.
 16 Q. Okay. And the Witness Statement before you,
 17 is that your Witness Statement in the arbitration?
 18 A. Yes, it is my Statement.
 19 Q. Okay. And does it represent your honest
 20 recollection of the events detailed in the Witness
 21 Statement?
 22 A. The Statement was developed based upon my

15:04:43 1 recollection of the events that took part during the
 2 2009 inspection of Apotex Signet campus.
 3 Q. Okay. And so you discuss the inspection
 4 of--the July 27 to August 14, 2009, inspection of
 5 Apotex Inc. Signet campus.
 6 What was your role during that inspection?
 7 A. I was the team leader.
 8 Q. Okay. As the team lead, did you maintain
 9 oversight over the other team members?
 10 A. Yes, I did.
 11 Q. And what were the systems you reviewed during
 12 the Signet 2009 inspection?
 13 A. I specifically reviewed the equipment and
 14 facilities, production, materials, and packaging and
 15 labeling.
 16 Q. And were there any observations found in
 17 relation to those systems?
 18 A. Yes, there were.
 19 Q. Okay. And what systems did other team
 20 members cover?
 21 A. Mr. Walden Lee was the chemist, and he
 22 reviewed the laboratory. And Ms. Zielny, along with,

15:05:44 1 at the last two-thirds of the inspection, Mr. Belz,
 2 reviewed the quality system. Ms. Zielny also had some
 3 part in the review of production and packaging and
 4 labeling and materials.
 5 Q. Okay. And did you review either the quality
 6 system or the laboratory system?
 7 A. I did not look at any of the--specifically
 8 myself, I reviewed anything that was presented to the
 9 team as far as any potential deviations. But
 10 specifically looking into the laboratory, I did not
 11 look into the laboratory section on my own. And as
 12 far as quality systems, I did some of--a bit of an
 13 overview in order to determine what areas in the area
 14 of the inspection that I was going proceed in as to
 15 give me an avenue of which direction I needed to go in
 16 those areas.
 17 Q. Okay. And were there any observations found
 18 in relation to the six systems?
 19 A. Yes, there were.
 20 Q. And were there any observations, repeat or
 21 recurring observations, from prior inspections?
 22 A. In full, I would say that the items that were

15:07:04 1 cited had very similar--was very similar with those
 2 sites at other locations, and some of which were
 3 specifically repeat violations.
 4 Q. And can you provide examples of any repeat or
 5 recurring violations from prior inspections?
 6 A. Of the prior inspections? Aside from we had
 7 environmental monitoring that was a duplication,
 8 repeat from the Signet--previous Signet inspection, we
 9 had a Field Alert, failure to file Field Alerts. We
 10 had a quality system failure to fulfill their
 11 responsibilities and had issues dealing with
 12 dissolutions, stability, just to name a few.
 13 Q. Okay. And how did the investigators classify
 14 a Signet campus facility?
 15 A. Classified--I'm sorry. Can you say that--
 16 Q. At the end of the inspection, how did you
 17 classify?
 18 A. How did the team proceed as far as
 19 classifying it or how did management?
 20 Q. The team.
 21 A. The team set forth--the inspection was an
 22 Official Action Indicated, issued a 483, and felt that

15:08:23 1 the deviations were significant enough to classify it
 2 as an OAI. And that's how it went out of the team.
 3 MS. CATE: Okay. Thank you. I have no
 4 further questions.
 5 PRESIDENT VEEDER: Thank you. There will now
 6 be questions from the Claimant.
 7 CROSS-EXAMINATION
 8 BY MR. HAY:
 9 Q. Yes, Mr. Payne. I'm John Hay and--the
 10 attorney for the Claimant. And I'm going to be asking
 11 you some questions. If you don't understand or would
 12 like me to repeat my question, just let me know. I'm
 13 happy to do so.
 14 A. I have a bit of a hearing issue.
 15 Q. Okay. So I will try and speak up.
 16 First, by way of clarification, you made
 17 reference to, in your direct testimony, numbers of
 18 inspections where you said 30 inspections.
 19 Is that per year? Is that what you're
 20 talking about?
 21 A. No. No. That would be over the full term of
 22 my career with FDA in the human pharmaceutical

15:09:17 1 industry. I'm a--typically a generalist because I'm
 2 in a rural area, so I have to know a little bit about
 3 almost everything. So, therefore, the 30 that I
 4 quoted on a conservative side is only in the human
 5 pharmaceutical.
 6 I also have veterinary, veterinary feeds,
 7 foods, cosmetics, human tissue, bioresearch
 8 monitoring. I have to have a little knowledge of all
 9 of those because those are the things that I'm called
 10 upon to do for inspection-wise.
 11 Q. Okay. Thank you for that clarification.
 12 And so the seven inspections are the seven
 13 foreign inspections you've done over your 22-year
 14 career?
 15 A. The seven foreign, yes.
 16 Q. Yes.
 17 A. They were as part of that 30, yes.
 18 Q. And as of 2009, when you did the Signet
 19 inspection, how many had you--how many foreign
 20 inspections had you done?
 21 A. In the human pharmaceutical arena?
 22 Q. Yeah.

15:10:11 1 A. I had two that encompassed six firms prior to
 2 going to Canada to inspect Apotex.
 3 Q. When you say you had "two that encompassed
 4 six firms," what do you mean by that?
 5 A. Two trips, six firms. It's a three-week trip
 6 generally. You conduct an inspection at one firm a
 7 week essentially. So I had a trip to Japan, for
 8 instance, three different firms. I had a trip to
 9 Mexico, three different firms.
 10 Q. Okay. So--that's helpful.
 11 So when you say that you've done seven
 12 inspections, is it safe to assume that that could
 13 include a larger number of actual facilities you
 14 visited?
 15 A. Foreign?
 16 Q. Yes.
 17 A. I'm sorry. Say that one more time.
 18 Q. Let me try it this way. In terms of the
 19 inspections at foreign facilities, actual individual
 20 facilities, how many inspections of a facility have
 21 you--
 22 A. In the human pharmaceutical arena--

15:11:08 1 Q. Yes.
 2 A. --it would have been six plus the one, which
 3 was seven, from Canada.
 4 Q. Okay. Thank you.
 5 And prior to--at the time you drafted or
 6 prepared your Witness Statement, did you review any
 7 documents to refresh your recollection about the
 8 inspection?
 9 A. Yes, I did review essentially the documents
 10 that I had maintained from the inspection that were
 11 provided during the inspection I may have had
 12 electronically that the firm provided, and then the
 13 previous or the actual inspection report and the 483.
 14 Q. Okay. Did you at the time review the
 15 Response to the 483?
 16 A. During the development of the--yes, it was
 17 part of what I had.
 18 Q. And just I have made--I may have confused
 19 things more than helped them.
 20 In terms of the documents you were reviewing
 21 at the time you actually prepared your Statement, you
 22 reviewed the Response to the 483, the Witness

15:12:38 1 Statement that you've submitted in this matter?
 2 A. Okay. For the Witness Statement?
 3 Q. Yes.
 4 A. Yes.
 5 Q. Okay. And had you seen the Response to the
 6 483 prior to that?
 7 A. I had seen a Response to a portion of the
 8 483.
 9 Q. Okay. And when did you see that? When was
 10 the first time you saw that?
 11 A. After the inspection was completed and the
 12 FDA had received a Response, there was a list of what
 13 observations that I needed to review. And I narrowed
 14 them down to the ones that I felt necessary to review.
 15 Q. Who gave you those items to review?
 16 A. They came out of CDER.
 17 Q. And was it all of the 483 items?
 18 A. No. I did not review all of them.
 19 Q. Were you asked to review certain particular
 20 ones?
 21 A. Two particular ones.
 22 Q. And why those two particular ones?

15:13:48 1 A. Because I was the sole person on those two
 2 particular observations.
 3 Q. And how many observations in total were there
 4 on the 483?
 5 A. 17.
 6 Q. So of the 17 observations, you were the sole
 7 person on two; correct?
 8 A. Sole person on two.
 9 Q. And is it normal that you would receive a
 10 request to review a Response to a 483?
 11 A. Yes, it is normal.
 12 Q. So that's something that, when you normally
 13 do an inspection after you do the 483 and the company
 14 responds, you would normally receive a copy of their
 15 Response; correct?
 16 A. Currently all responses in our district
 17 follow through to the investigator that was involved
 18 in the inspection for the review.
 19 In 2009, I would not necessarily say that all
 20 of them were officially sent through to the
 21 investigator. But in this particular case, the ones
 22 that were solely those of which I observed were passed

15:15:01 1 along for my review.
 2 Q. Do you remember how much after the company
 3 had responded did you receive these items to review?
 4 A. No, I don't recall. I have this thing about
 5 time, so, no. Days become weeks sometimes. And so,
 6 no, I don't really recollect as to the exact time
 7 period.
 8 Q. And do you recall what your response was to
 9 the person who sent you the items to review?
 10 A. The Response of the two was that I felt that
 11 the two Responses were adequate in their content.
 12 However, the issue with those two particular
 13 observations, the only way to verify correction is to
 14 actually do a real inspection to ensure that the
 15 company or the firm has made those corrections.
 16 There are certain observations that you can
 17 actually verify based upon supporting documents that
 18 they provide in their response. But in those two
 19 particular ones, they dealt with design or dealt with
 20 an actual visual observation.
 21 Q. Now, you were with the Office of Regulatory
 22 Affairs?

15:16:30 1 A. That is correct.
 2 Q. Okay. And just so I understand, I'm trying
 3 to understand the distinction between that and CDER.
 4 Can you explain to the Tribunal?
 5 A. I'm sorry. Say that one more time.
 6 Q. Between ORA and CDER.
 7 A. What would you like me to explain?
 8 Q. The difference between them in terms of
 9 responsibilities.
 10 A. ORA is the organization management portion
 11 that deals with the field investigators and the work
 12 of the field investigator. The CDER is actually made
 13 up of reviewers and administrative officials. They do
 14 include compliance officers that deal with the
 15 compliance relating to pharmaceuticals.
 16 Q. Right. And for these investigations, CDER
 17 is--excuse me--ORA is usually the lead office?
 18 A. When a field investigator is involved, then
 19 one--if there are more than one--at least one of them
 20 is designated as the lead. In this particular
 21 inspection, I was the investigator that was selected
 22 to be the lead.

15:17:55 1 Q. And how many people were on this inspection?
 2 A. Initially there were three, and then Mr. Belz
 3 joined during the second week to complete. It was
 4 essentially his second inspection, first foreign
 5 inspection. I looked at it more as a training.
 6 Q. A training for him?
 7 A. I mean, he was quite--throughout the
 8 inspection, it became quite clear that he had enough
 9 knowledge from his previous experiences that he was
 10 able to assist in the area that we designated as his
 11 area of assistance.
 12 Q. And who else besides him was on the
 13 inspection? Who were the other people?
 14 A. Kristi Zielny, compliance officer out of
 15 CDER, and then Walden Lee, who was a chemist out of
 16 LA.
 17 Q. With respect to Ms. Zielny, what was her
 18 experience?
 19 A. Ms. Zielny had been with the Agency seven or
 20 eight years, something along that line. And she was
 21 more of a specialized area of inspections in
 22 pharmaceuticals. She worked out of New Jersey, I

15:19:07 1 believe.
 2 Q. What was her specialty?
 3 A. Pharmaceuticals. I mean, from my
 4 understanding, from what I gathered in my
 5 determination of her experiences prior to the
 6 inspection, she primarily did pharmaceutical
 7 inspections.
 8 Q. So she had a--let me direct your attention to
 9 your Witness Statement at Paragraph 11 just for a
 10 point of clarification.
 11 When you say that "She had eight years of FDA
 12 inspection experience with large pharmaceutical
 13 firms," do you see that?
 14 A. Yes, I do.
 15 Q. Okay. And do you happen to know which firms
 16 or anything--
 17 A. No, I do not recall.
 18 Q. So she had been with FDA for eight years,
 19 though, doing that, as far as you know?
 20 A. From what I recollect, she had been with FDA
 21 for somewhere in the area of eight years and had vast
 22 experience in pharmaceuticals.

15:20:12 1 Q. And she had--at her initiative, had asked to
 2 inspect the quality area?
 3 A. During our pre-inspection meetings, when we
 4 were sitting around discussing different areas, and
 5 she said that she would be more than willing to do the
 6 quality system. And somebody volunteered for
 7 something and I feel they're capable of handling that
 8 task, then I'm more than happy to let them take on
 9 that portion. Mr. Lee was a default because he was
 10 the chemist, so pretty much, no matter what, he was
 11 handling that area.
 12 Q. And did you speak to anyone else at CDER
 13 concerning the inspection before it started?
 14 A. Prior to the inspection we had meetings
 15 with--there was a teleconference involving a large
 16 number of reviewers. This was primarily set forth
 17 initially as a pre-approval inspection. And so
 18 because there was such a large number of
 19 pre-approvals, they had reviewers that specialize in a
 20 specific type of drug. And so, therefore, the
 21 teleconference was more of a brainstorming. I
 22 observed. I listened, but didn't really take part in

15:21:40 1 it.
 2 They were determining which drugs they
 3 felt--because there were so many pre-approvals, it was
 4 impossible to really actually look at all of them in
 5 full. So they were trying to narrow it down to a
 6 grouping that, if those were fine, then we did a
 7 personal review of the others. And so it was kind of
 8 a brainstorming. And there was a large number of
 9 people which--some of which I couldn't even tell you
 10 who they were. I just knew they were reviewers.
 11 Aside from those, I'm not even sure if there
 12 were more than one. I don't recall but the one. And
 13 I do not recall having any other phone conversations
 14 with CDER prior to the start of the inspection.
 15 Now, there were phone conversations between
 16 the team members prior to the inspection, at least
 17 once. But it was not specific to any task.
 18 Q. Well, let me direct your attention to your
 19 Statement at Paragraph 9, and it goes over to the top
 20 of the page, from Page 4. Do you see where it says
 21 "CDER also informed us of concerns arising from prior
 22 Apotex's Inc.'s inspections, which suggested a

15:22:55 1 corporate-wide quality control issue."
 2 Do you see that?
 3 A. Yes. That actually would have been during
 4 that same--if I do recall this correctly, during that
 5 same phone session.
 6 Q. And who at CDER was saying that?
 7 A. Honestly, I could not really say. There was
 8 a large number of people, and they did not necessarily
 9 always state who was speaking. And so, like I said,
 10 it was more of a brainstorming. Honestly, I can't say
 11 positively. Possibly Edwin.
 12 Q. And who was Edward, for the record?
 13 A. Edwin. I don't know his title at the time.
 14 I knew that he was somebody that was supposed to be in
 15 charge of the compliance area for CDER, I believe.
 16 Q. Okay. Do you know his last name?
 17 A. Martinez, I believe.
 18 Q. Okay. So he participated in this call?
 19 A. Yes. And there was actually ORA, Ms. Laska,
 20 I believe, was on the call, if I'm recollecting
 21 properly. There was a large number of people on the
 22 call, which is really out of the ordinary, so many

15:24:18 1 were involved.
 2 ARBITRATOR ROWLEY: I'm sorry; I didn't hear
 3 you, who you say the other person was.
 4 THE WITNESS: Susan Laska. She was at that
 5 time a manager with the NFDA ORA, if I recall her
 6 position.
 7 BY MR. HAY:
 8 Q. Do you know approximately when the call was
 9 in relation to the inspection?
 10 A. It was within, I would say, a week, prior to
 11 the inspection.
 12 Q. And it's your recollection that it was
 13 Mr. Martinez who was the one who informed you about
 14 these concerns?
 15 A. It was a general discussion, yes. It wasn't
 16 directed specifically at me or anybody on the team.
 17 As I said, we were part of the phone conversation but
 18 didn't have any input into the conversation. It was
 19 more of an observatory-type role.
 20 Q. So what was the purpose of the comment, then?
 21 A. Purpose of the comment?
 22 Q. If it wasn't directed to you?

15:25:24 1 A. It was directed to all those that was on the
 2 phone call, but it was more of a discussion between
 3 individuals on the phone call, not necessarily team
 4 members. This phone call had--like I said, there was
 5 a large number of people on the call, and they were
 6 brainstorming about the inspection. And in the end,
 7 it didn't--in the end, it really wasn't relevant to me
 8 specifically in the sense that I conduct my
 9 inspections the way I've been trained. And I keep
 10 what's being said by managers or by reviewers in my
 11 mind in the event something occurs that I might need
 12 to bring it back to the forefront. But the process
 13 with which I conduct my inspection is not normally
 14 specifically directed.

15 And I remember them saying that there were
 16 concerns. I kept that there. Get into an inspection,
 17 it turns out that we need to go that direction, then
 18 we do that. But until then, no.

19 Q. But your testimony is that this was an
 20 unusual situation to have a meeting like this or a
 21 call like this with this many people discussing this
 22 issue, these issues?

15:26:42 1 A. I would have to say it was out of the
 2 ordinary because I've never, domestically or foreign,
 3 have been a part of that type of phone call. Usually
 4 there's not that many pre-approvals. One, two, three,
 5 sometimes maximum of ten. So you have one reviewer,
 6 maybe two reviewers. So you don't have a phone
 7 conversation with 30 people on the call or however
 8 many. But it was way too many. And so you have one
 9 or two people. It's more of a one-on-one. And
 10 they're discussing what they think is the relevant to
 11 that particular drug.

12 Q. Was there any discussion during this call
 13 about an Import Alert?

14 A. I don't recall during that phone conversation
 15 an Import Alert being mentioned.

16 Q. It was mentioned during the inspection,
 17 though?

18 A. During the inspection. During the phone
 19 call, during the inspection, yes.

20 Q. It was the phone call you were on?

21 A. Yes.

22 Q. Okay. And when was that?

15:27:49 1 A. It was toward the latter part of the second
 2 week, if I recall correctly. It might have been the
 3 beginning of the third week--well, specifically, I
 4 could not say. It might have actually been the night
 5 before we closed out, because we had a teleconference
 6 Thursday before we closed out on Friday. It might
 7 have actually been mentioned during that phone
 8 conversation.

9 Q. Or it could have been mentioned earlier?
 10 You're just not sure; correct?

11 A. I'm not sure. Import Alerts is not really
 12 part of my position and is not really relevant for an
 13 inspection. It's a follow-up situation outside of the
 14 inspection, just as a Warning Letter is outside the
 15 inspection.

16 What happens during the inspection is the
 17 firm provides you with documentation to support what
 18 they are currently doing, and you evaluate that,
 19 determine whether or not what they are doing is within
 20 GMPs, and, then, if not, you issue a 483, finish your
 21 inspection, write it up, send it in, let those who
 22 handle administrative issues handle administrative

15:29:07 1 issues.

2 Q. Ms. Zielny was on the call?

3 A. Who?

4 Q. The other inspectors were on the call as
 5 well?

6 A. Yes.

7 Q. Okay. And who from CDER was on the call?

8 A. That would have been Edwin Martinez. During
 9 the inspection he is the only person that you spoke
 10 with. And up until actually checking it out, I only
 11 knew him by "Edwin."

12 Q. I'm sorry. I didn't hear you.

13 A. I said, up until actually reviewing the
 14 documents for my Witness Statement, I only knew of him
 15 as "Edwin."

16 Q. So what was said about the Import Alert
 17 during this meeting, this call?

18 A. That there was a consideration of an Import
 19 Alert. That was pretty much the gist of it. And,
 20 again, it didn't pertain to my inspection.

21 Q. Do you recall that during the inspection
 22 time, the inspection period, a "Draft 483" was sent to

15:30:12 1 CDER without your observations in order to support an
2 Import Alert?

3 A. Yes. To support an Import Alert, no, I
4 didn't know anything about that. I knew that there
5 was a draft of the 483 that was submitted to CDER
6 during the inspection that did not include the two
7 observations that I had to have, yes.

8 Q. And that's unusual; correct?

9 A. No, not really. Well, an incomplete one?
10 No, because of the fact that things change clear up to
11 the point at which you issue the 483. And so the fact
12 that I did not have the observations that I wished to
13 have added as part of the 483 at the time that the
14 other issues were already prepared was not out of the
15 ordinary. I singularly will send a 483 that may
16 change. In fact, I did it last week.

17 Q. Wasn't it the role of the lead inspector to
18 send the 483?

19 A. The 483 was sent with my knowledge. It
20 wasn't done without my knowledge.

21 Q. Right. But wasn't that your role as the
22 leader, to be sending those things?

15:31:27 1 A. To put my name on it and send it with the
2 fax? I don't care who pushes the fax button.

3 Q. So it didn't bother you that it was sent?

4 A. No, I knew it was sent. We had the
5 discussion that we were going to send. I said yes.

6 Q. And what was the discussion as to why it
7 should be sent?

8 A. To give Compliance a heads-up. Anytime you
9 issue a 483 during an inspection, you determine that
10 you have a potential OAI or even a VAI and you're
11 issuing a 483, you need to give management and you
12 need to give Compliance a heads-up as to what may be
13 coming down the pike so that they will not be caught
14 off guard.

15 So at this particular instance, we had
16 actually been in discussions with CDER on issues
17 before the 483 was actually submitted the first time
18 to them as a draft for a few phone calls, clear up
19 maybe into the middle of the second week.

20 Q. So you participated in phone calls with CDER
21 during the inspection; correct?

22 A. During the inspection, yeah.

15:32:38 1 Q. There were also phone calls with CDER that
2 you didn't participate in; correct?

3 A. Early on there was a couple of--from my
4 understanding, a couple of phone calls. And once I
5 determined that that had happened during conversations
6 with Ms. Zielny, we discussed the fact that that
7 doesn't need to happen again.

8 And so--in a reality of it, as an
9 investigator, you sometimes bounce--as a term--things
10 you are thinking. Generally, when you're working with
11 a team, you bounce those ideas off the team before you
12 go outside the team, which is the issue that I
13 addressed with Ms. Zielny at that point.

14 But it's not out of the ordinary for me to
15 bounce issues off of someone who I respect their view
16 and see what they say, if I'm seeing what I'm seeing
17 is correct. But generally when you're working on a
18 team inspection, you try do that within the team, and
19 then the team decides, well, maybe we should go
20 elsewhere to see if what we are seeing is actually
21 what we have at hand.

22 Q. And at the time, the issue was she was

15:33:45 1 bouncing them off CDER rather than the team; correct?

2 A. Early on, first week. I mean, no, I would
3 not say she was bouncing them only off CDER. From
4 Day 1 the team knew what each person had observed, and
5 we discussed it at the end of the day each day, maybe
6 not every single day. But each day for the most part,
7 we discussed after the inspection at the end of the
8 day observations that we saw and provided
9 documentation to support of which we had collected on
10 that day, if we had it. If we didn't have it, we
11 said, Well, this is what we have. We haven't got our
12 documentation to support that yet, but this is what
13 it's looking like.

14 And then, you know, amongst the team, I mean,
15 it's pretty fluid. We all have different expertise.
16 We all have different strengths. And so, with that in
17 mind, we work off of each other's strengths.

18 Q. Okay. And when you raised the issue about
19 the calls to CDER without your participation, did they
20 stop at that point in time?

21 A. No. She--we basically--at that point, it was
22 a decision that, when we need to talk with CDER, then

15:34:59 1 we were going to do it as a group.
 2 Q. And then there were further calls with CDER
 3 as a group?
 4 A. As a group.
 5 Q. Do you know if she had further calls with
 6 CDER by herself?
 7 A. If that occurred, I was not aware of it.
 8 Q. The inspection closed on August 14; correct?
 9 A. That is correct.
 10 Q. And that was a Friday?
 11 A. That's what I recollect. It was a Friday.
 12 Q. And at the end of the inspection, a 483 was
 13 provided to Apotex?
 14 A. That is correct.
 15 Q. And you--as the leader, you provided that to
 16 them?
 17 A. We completed the 483 and it was presented, I
 18 don't know whether I directly handed it to Mr. McKay
 19 [sic] or whether it was passed around or given to
 20 another individual on the team to pass around. It was
 21 a large number of people, and he wasn't sitting next
 22 to me.

15:35:55 1 Q. Okay. Aside from handing it to him, was
 2 there any discussion about the findings on the 483?
 3 A. Yes, we discussed each item on the 483.
 4 Q. Okay. And who led those discussions?
 5 A. Depending upon the observation, if
 6 the--whoever the individual that determined that
 7 observation or wrote that part of the 483, that's who
 8 had the latitude to discuss it.
 9 Q. And you told us that you had two items on the
 10 483?
 11 A. I had two that I wrote specifically because I
 12 was the only one that observed it.
 13 Q. Right. And the CDER inspectors, how many did
 14 they have?
 15 A. Well, if I only had two and there were 17,
 16 then Ms. Zielny or Brian. Ms. Zielny is actually the
 17 one who wrote them. We had different approaches. I
 18 generally tend to write my observations in my diary.
 19 At the end of the week, if I feel that I have
 20 supporting documents and I'm done with that
 21 observation, I'll compile the observation for that
 22 day.

15:36:53 1 But Ms. Zielny had a different approach. At
 2 the end of each day, she wrote her 483, if she had
 3 one, even if she didn't have supporting documentation
 4 for it. So by the time we got to a point at
 5 which--that's why she had hers ready to roll out,
 6 because she had hers ready each day. That was the way
 7 she operated. Not everybody does it the same way.
 8 In my case, I tend to let things go until I
 9 know I've got everything together, and then I prepare
 10 my 483 items.
 11 And so with that in mind, she had already
 12 written some of those observations that we both or all
 13 three of us observed during the inspection. So as
 14 long as I had the documentation and what she had
 15 written was supported by the documentation, it was
 16 observed by me and her and then we agreed, then it
 17 didn't matter to me who wrote it. If I had had a
 18 secretary, I would have had them write it as long as
 19 they had what I wanted on there.
 20 Q. Okay. But in terms of the discussion, since
 21 she had written apparently 15 of the 17, she did most
 22 of the discussing?

15:37:59 1 A. The ones that I had input on that I observed
 2 also along with her at the same time, if there was
 3 something I needed to interject, I would interject
 4 into it.
 5 Q. But she led the discussion; correct?
 6 A. Well, she started off because she had the
 7 first one. I basically introduced it and said we're
 8 going to discuss it based upon who was the--whoever
 9 observed it or wrote it.
 10 Q. And she observed the lion's share; correct?
 11 A. She observed--yeah, she observed 15 of them,
 12 yes. I observed--of the 15, I observed--I'll throw an
 13 estimate of about 7, somewhere along that line. I'd
 14 have to go back and look exactly and say which ones I
 15 took a part in.
 16 Q. Was there a direction given at the close of
 17 that meeting to contact CDER on Monday?
 18 A. Yes, at the closeout, I instructed
 19 Mr. McKay--I believe was his name. I have to go back
 20 there. But the CEO, I instructed him that we--that
 21 the firm needed to contact CDER the following Monday
 22 to discuss what they plan to do with product that was

15:39:22 1 in the marketplace.
 2 Q. And who directed you to do that?
 3 A. Mr. Martinez.
 4 Q. Okay. And did Mr. Martinez also tell you
 5 that they needed to respond to the 483 within 10 days?
 6 A. Actually, no.
 7 Q. Who--
 8 A. It was actually a 15-day, and I believe in
 9 the Report it is mentioned two ways. And that was
 10 actually a mistake and went through several layers of
 11 review, and nobody seemed to have caught the fact that
 12 it was a 15-day, and there was a 10-day written in the
 13 very end of the Report, but it was actually a 15-day.
 14 We were at a transition, as some were in
 15 that--prior to, we were going from a
 16 10-day--10-working day, 15-working day. And so
 17 previous habit, I believe I must have put in the 10.
 18 Q. Were you present on that call on Monday?
 19 A. No.
 20 Q. You were not asked to participate in the call
 21 on Monday; correct?
 22 A. No.

15:40:32 1 MR. HAY: Can I ask the Tribunal if we can
 2 take a break for a couple minutes so I can review my
 3 notes to see if--
 4 PRESIDENT VEEDER: Yes. Of course.
 5 (Discussion off microphone.)
 6 PRESIDENT VEEDER: Do you want longer than a
 7 couple minutes or we'll stay here?
 8 MR. HAY: Bathroom break would be
 9 appreciated.
 10 PRESIDENT VEEDER: Bathroom break is always
 11 appreciated. Let's have an afternoon break. Let's
 12 have until 4:00. We'll all take a break. But we'd
 13 ask you as a Witness not to discuss the case with
 14 anybody until you come back before the Tribunal at
 15 4:00.
 16 THE WITNESS: I don't necessarily have to
 17 leave, do I?
 18 PRESIDENT VEEDER: Well, if you want to
 19 leave, you can. We're not tying you to the chair.
 20 THE WITNESS: I'll sit right here. I have
 21 nothing. I just need that Mountain Dew over there and
 22 I'll be happy.

15:41:17 1 PRESIDENT VEEDER: Okay.
 2 (Brief recess.)
 3 PRESIDENT VEEDER: Let's resume.
 4 BY MR. HAY:
 5 Q. When we took a break, we were talking about
 6 that closeout meeting on the 14th.
 7 A. Yes.
 8 Q. At the beginning of the closeout meeting, was
 9 the Vice President of Quality for Apotex given an
 10 affidavit and told he had to sign that?
 11 A. He was presented with an affidavit, but there
 12 was no--without a doubt--ever, any type of coercion
 13 that he had to sign that, ever.
 14 Q. He wasn't told if that he didn't sign it,
 15 there wouldn't be a closeout meeting?
 16 A. No, without a doubt.
 17 Q. Who suggested that he sign it? Where did
 18 that come from?
 19 A. I'll explain to you the process of an
 20 affidavit.
 21 An affidavit is generated for many purposes.
 22 In this particular purpose, it was generated to have a

16:00:48 1 written narrative description of a process of which an
 2 active pharmaceutical ingredient was taken and used to
 3 manufacture a finished product, and that finished
 4 product was distributed, in this particular case,
 5 documenting its distribution into the U.S.
 6 An affidavit of that type, or essentially any
 7 type, I generally present the affidavit to whomever it
 8 was written for, ask them to read it, make any
 9 corrections in order to make sure that it is accurate
 10 to their knowledge, and then explain to them that--and
 11 where they got the idea, if that was their case, that
 12 they had to sign it--because I always state the same
 13 thing every single time: "This is an affidavit that I
 14 ask you to sign. You do not have to sign this
 15 affidavit. It is merely something that I am required
 16 to provide when I collect a documentary sample of a
 17 product. If you choose not to sign it, it does not
 18 imply that you are not in agreeance with it. It is
 19 just some companies have a policy, don't sign
 20 anything."
 21 Now, what I--I thought about this, because it
 22 bothered me to think that someone actually thought

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16:02:08 1 that I was saying "you had to sign this." What was
2 said during the inspection--we were on a point where
3 we were ready to get done and we had to be done.
4 Well, the affidavit can't be presented prior to
5 closeout. Once you issue the 483, then you're pretty
6 much done unless you collected a physical sample; then
7 you have issue a receipt for the sample.

8 So in this particular case, I had to get it
9 prepared. And I was at a point where I had to make
10 some changes. So I had to get it prepared before we
11 could actually proceed with the closeout. There was
12 never any mention that I have to have this signed in
13 order to do closeout. I had to have it finished,
14 presented, before the closeout could proceed.

15 Q. So he could have signed it--you could have
16 finished the inspection, left, and he could have
17 signed it at some other point? Is that your
18 testimony?

19 A. No. If he would have chose not to sign it
20 before we closed out, that was fine. I would have
21 just went on and submitted it just like it was. He
22 didn't have to sign it. I never asked him--or

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16:03:04 1 indicated to him that he had to sign it. I had to
2 have it presented before we could close out.

3 Q. Okay. And was a suggestion made to you that
4 an affidavit be presented to him?

5 A. You know, I've thought about this. I don't
6 really truly recall a conversation of requiring me to
7 develop an affidavit. I do recall discussing it among
8 the team that we've got documentation; we're going to
9 do a documentary sample. We discussed, do we really
10 need to have an affidavit? And, you know, it's one of
11 those things, if you're not certain and it's normally
12 the protocol of which you proceed, then an affidavit
13 is not going to hurt.

14 So I recall the conversation within the team.
15 I don't recall anybody saying, "You collect an
16 affidavit."

17 Q. Was there any items listed on the 483 from
18 the chemist?

19 A. No.

20 Q. As a matter of fact, didn't the chemist
21 comment that this was one of the best labs he's ever
22 seen?

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16:04:36 1 A. I don't know if those were the exact words,
2 but he was somewhat impressed with the laboratory.

3 Q. And the lab side of it is one of the six
4 areas of inspection; correct?

5 A. That is correct, one of the systems, yes.

6 Q. Let me ask that you be given Exhibit C-115.
7 Have you seen this document before?

8 A. Yes, actually.

9 Q. Okay. And for the record, it says--first of
10 all, this is from you to Sean Cheney? Is that--

11 A. That is correct.

12 Q. And what is Mr. Cheney's position?

13 A. I think he--at that time he was my
14 supervisor, first line supervisor.

15 Q. And this was on the 19th of August, correct--

16 A. That is correct.

17 Q. --that you sent this?

18 And it says, "I saw there is going to be a
19 massive recall of Apotex for the Apotex inspection and
20 an Import Alert is also coming. However, I can't say
21 I deserve much of credit for this happening."

22 A. That's exactly what I said.

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16:06:25 1 Q. How did you know that there was going to be a
2 recall and Import Alert?

3 A. Well, if I remember this correctly, there
4 actually was some news that was placed. I had a call
5 from another investigator in another office that--I
6 mean, it was shortly after the inspection, I see. But
7 I recall someone from another office calling and
8 saying, "Hey, I saw where there was a recall that was
9 initiated." And I knew that they had already
10 considered the Import Alert by that time.

11 Q. You mean--when you say "they," you're talking
12 about CDER?

13 A. Yes. I'm sorry. Management, yes.

14 Q. Right. By the 19th, you knew that an Import
15 Alert was already in the works; correct?

16 A. I knew that there was an Import that
17 was--Import Alert being considered. What exact stage
18 of approval or stage of enactment, I'm not sure at
19 this moment whether I could say what that was.

20 Q. When you say you don't deserve much credit
21 for this, you mean that it wasn't something that you
22 had recommended or anything of that nature?

16:07:35 1 A. No. I'm kind of a humble kind of back guy,
2 you know. I don't take credit for somebody else's
3 work. Import Alert, somebody else's work; recall,
4 somebody else's; Warning Letter, somebody else's work.
5 My job is the inspection, 483, EIR, and I'm done
6 unless somebody calls asking questions.

7 PRESIDENT VEEDER: I'm sorry to query this,
8 but what was the exhibit number you gave?

9 MR. HAY: I'm sorry. I was just told that I
10 misstated it on the record.

11 PRESIDENT VEEDER: I think it's the wrong
12 exhibit.

13 MR. HAY: Yes. It's C-151--155. I'm sorry.
14 515. I'll get it right. Thank you.

15 BY MR. HAY:

16 Q. I'm going to now show you Exhibit C-505.

17 Exhibit C-505 appears to be a thread of
18 e-mails. You can look at any of them you want, but
19 I'm going to direct your attention to the last one,
20 the last in the thread. So it's the first one on the
21 page, first page.

22 A. Okay.

16:09:24 1 Q. And it looks to be an e-mail that you were
2 cc'd on that was sent to a Mr. Lee?

3 A. Sent to Mr. Lee from Heriberto, yes.

4 Q. Who are those gentlemen, just so we have
5 context?

6 A. Heriberto Negron-Rivera was the trip planner
7 for the trip, and Mr. Walden Lee was the chemist.

8 Q. Okay. And this was in July 15 of 2009?

9 A. That is the date.

10 Q. And there was an indication on this where
11 he's referring to the fact that this inspection may
12 result in legal sanctions. Do you see that?

13 A. He is making mention that he had been--he
14 participated in inspections that resulted in legal
15 sanctions; and that if we needed anything from him as
16 far as--I assume, he was offering his experience.

17 Q. Right. Because this particular inspection
18 was thought that there may be legal sanctions arising
19 from it as well; correct?

20 A. Mr. Heriberto is a trip planner. Granted, he
21 had the experience with FDA, but as a trip planner,
22 his job is to plan the trip. Even if I felt he was a

16:11:05 1 qualified reference, I would not rely on his
2 experience. So, I mean, the fact that he's saying
3 that means nothing to me.

4 Q. Well, did you ask him what he was referring
5 to at the time?

6 A. No, I didn't.

7 Q. But at the time, he seems to be indicating
8 that there was an understanding that there very well
9 may be legal sanctions from this inspection; correct?

10 A. That's not what I gathered from this.

11 Q. So sitting here today, you don't know why he
12 referenced legal sanctions?

13 A. No, I do not. Complex EIs. I was assuming,
14 based upon what he had written there, that he was
15 trying to demonstrate that he has a vast amount of
16 knowledge and if we wanted to reference him in any
17 assistance, that he was available. That's what I
18 basically gathered from this e-mail.

19 Q. What about the reference to "this great
20 challenging moment"? What was he talking about this?

21 A. Well, you have understand about Heriberto.

22 He--trying to think of how to describe him. He speaks

16:12:36 1 in a manner of which--more of an elegance. So
2 everything that he states--when you look at all of his
3 e-mails, he has a tendency to bring his thoughts in an
4 elevated fashion. So everything is extravagant. So I
5 mean, I think it's his character.

6 So for him to say in it "great challenging
7 moment," I think if you read his other e-mails, you're
8 probably going to find him saying that about obtaining
9 a limo to take us to the firm. I mean, he--everything
10 he expresses. So it's just his way of speech. I
11 don't know. I didn't--this particular memo meant
12 nothing to me.

13 Q. So this doesn't reflect that at the time
14 there was an understanding that this inspection may
15 very well end up with legal sanctions?

16 A. No.

17 Q. Let me show you Exhibit C-508.

18 Have you seen this e-mail before?

19 A. Yes, I have.

20 Q. Okay. And do you remember sending the first
21 e-mail that's dated July 22, 2009, at the bottom
22 there?

16:14:23 1 A. Yes, I do.
 2 Q. Okay. And you were sending this to Kristi
 3 Ziely regarding the upcoming--the upcoming Signet
 4 inspection; correct?
 5 A. It was in reference to the pre-inspection
 6 meeting where everyone was brainstorming, yes. That
 7 was purpose for this e-mail. It was following that--a
 8 good date. July 22--or when did I write it? July 22
 9 had to have been the date, because I sent this just
 10 shortly after the meeting where we had so many people
 11 putting their two cents' worth in.
 12 And my impression of gathering from that, I
 13 wrote, "These people seem to think differently among
 14 themselves. It would have been better if they would
 15 have compiled their thoughts, come up with a rational
 16 decision, and then purveyed that to the team. But as
 17 it was, I honestly gathered very little out of it."
 18 So I was making that statement that it
 19 appeared that nobody knew what the heck was going on,
 20 because everybody was wanting to put their two cents'
 21 worth and had different directions of which they
 22 thought this drug was more important than that drug or

16:15:41 1 this particular one we should look at because it had
 2 health implications. And there was no rhyme or
 3 reason.
 4 Q. That's the way you felt at the time, correct,
 5 that was there mass confusion?
 6 A. I felt it was a very--for myself, an
 7 unproductive brainstorming session.
 8 Q. Because the inputs you were getting were
 9 scattered; correct?
 10 A. As to which drugs to look at of those that
 11 were for pre-approval, yes, it was quite scattered.
 12 Q. And what about as to the concern about a
 13 corporate-wide issue?
 14 A. That really wasn't--it was mentioned during
 15 the meeting, but it wasn't the issue that I was
 16 referring to here.
 17 Q. I'm going to now show you Exhibit C-516.
 18 A. Okay.
 19 Q. Okay. Have you seen this exhibit before?
 20 A. Yes, I have.
 21 Q. Okay. Looking at the e-mail on the bottom of
 22 the first substantive page of it, which at the bottom

16:17:55 1 is numbered Bates Number 004077, do you see that?
 2 A. Yes.
 3 Q. And that's an e-mail from you to Susan--
 4 A. Susan Laska.
 5 Q. Laska, right.
 6 A. August 21.
 7 Q. And the status of Apotex. Do you see that?
 8 That's the "Re."
 9 A. I'm sorry. Where?
 10 Q. I was just--the subject, "What is the status
 11 of Apotex?" Do you see?
 12 A. Yeah, that was initially sent by Susan.
 13 That's how I received it. She was asking me what is
 14 the status? And then we were--I replied. She replied
 15 back. I replied.
 16 Q. Okay. So it was Edwin who insisted on
 17 setting up the meeting?
 18 A. With Apotex the--
 19 Q. Yes.
 20 A. --following Monday?
 21 Q. Right.
 22 A. Yes.

16:18:59 1 Q. So he was the one who gave that direction,
 2 and then Susan responds back. Do you see her
 3 response, the--just going above that?
 4 A. What page are we referring to? I'm sorry.
 5 Q. The same page.
 6 A. 277. Okay.
 7 Q. Yes. So on Friday, August 21--
 8 A. She replies, yes.
 9 Q. Yeah. And what did she mean when she said,
 10 "Remember that you are the lead on this inspection"?
 11 Did she think that you didn't remember that?
 12 A. I have no idea, to be honest with you.
 13 Because the inspection was over, and at that point
 14 it's a matter of compiling a Report. And
 15 unless--under all other normal circumstances, when I
 16 issue a 483, I submit the Report, it goes through the
 17 channels, goes through multiple layers of review, ends
 18 up at Compliance, if it's so deemed to be an OAI
 19 inspection. And then if Compliance or anyone along
 20 the way decides they need additional information, then
 21 they would contact me. But there are many times that
 22 a Warning Letter is issued based upon an inspection

16:20:24 1 that I've done and I've got no follow-up on it. So I
 2 never really did understand why she was saying
 3 "Remember you're the lead."
 4 Now, if she would have presented that early
 5 on, I can understand. But in this particular text,
 6 "Remember you're the lead," the lead was to finish the
 7 Report, make sure everybody had their part done, and
 8 submit it up the channel.
 9 Q. Yeah. She's telling you to remember that
 10 you're the lead and it needs to go through ORA;
 11 correct?
 12 A. That is correct there.
 13 Q. And prior to being sent to CDER; correct?
 14 A. The e-mail--it does state that ORA needs to
 15 receive it prior to being sent to CDER, Office of
 16 Compliance.
 17 Q. So she's telling you she's concerned, that
 18 she doesn't want this to go to CDER before ORA gets
 19 it?
 20 A. Before she gets an opportunity to review it.
 21 ORA. ORA.
 22 Q. She didn't want to CDER to control it, in

16:21:29 1 other words; correct?
 2 A. I don't know what--her intent there. And
 3 it's normally sent through ORA.
 4 Q. And she was concerned in this case that it
 5 might not be sent. It might go right to CDER;
 6 correct?
 7 A. She wanted to confirm that--made sure it was
 8 sent through ORA. And, you know, I submit it based
 9 upon what is placed upon our distribution listing.
 10 And so once I provided it to management, management
 11 works it up the chain. So--district management.
 12 So I would assume it did go to ORA because it
 13 was supposed to. And if I saw the cover sheet, I
 14 could state exactly where it went. Her reasoning--I
 15 mean, it's normally sent through ORA anyway.
 16 Q. So then why in this case did she have a
 17 concern?
 18 A. I would just have to assume.
 19 Q. Okay. Well, I don't want you to assume, but
 20 you do agree with me that she seemed to have a
 21 concern; correct?
 22 A. She did seem to want to make sure things were

16:22:48 1 done the way they were supposed to be done.
 2 Q. And sitting here today, you have no idea why
 3 she would have that concern? That's your testimony?
 4 A. Again, I would have to assume. ORA is the
 5 lead when an ORA investigator is present during a
 6 foreign inspection. And, typically, always it works
 7 the same way. Inspection reports go through ORA. ORA
 8 has the opportunity to be familiar with the situation
 9 prior to it going to the Center.
 10 Q. She's also telling you that after this
 11 Toronto inspection, CDER is considering an Import
 12 Alert for both sites; correct? She says that in that
 13 e-mail as well?
 14 A. I'm sorry. Would you state your question one
 15 more time.
 16 Q. Let me direct your attention to that same
 17 e-mail that we were just discussing--
 18 A. Right.
 19 Q. --and the last sentence in it.
 20 A. "Did I have it correct from the attached
 21 report? Following the June 25 Warning Letter to
 22 Etobicoke, no Import Alert. After this Toronto

16:24:18 1 inspection, CDER is considering Import Alert for both
 2 sites."
 3 That's your question?
 4 Q. Yeah. So she was--she told you that;
 5 correct?
 6 A. No. She was actually asking me if I was
 7 aware that was the case.
 8 Q. Okay. And you responded that the Import
 9 Alert was mentioned to the inspection team during the
 10 inspection by Edwin; correct?
 11 A. That is correct.
 12 Q. Okay. And that it would be company-wide?
 13 A. And that it appears that it is being
 14 considered as company-wide, not just for the two sites
 15 that have been inspected due to the quality unit being
 16 the same for all three production sites, meaning,
 17 Etobicoke, Signet, and Richmond Hill.
 18 Q. Okay. And this was on August 21, 2009, that
 19 you're saying that to her?
 20 A. That is correct.
 21 Q. Okay. And then you reassure her that the
 22 Report will go through ORA; correct?

16:25:14 1 A. That's correct.
 2 Q. Then I ask you to look at the next paragraph,
 3 and I'll read it for the record.
 4 "If there are any more telecons with CDER, I
 5 will insist on ORA being involved. There were just
 6 too many going on during the inspection that
 7 apparently ORA wasn't privy to. There is more to the
 8 story, but I'll need more time to overcome the sizzle
 9 that remains in me since the inspection. So I'll
 10 probably talk with you after I get what is needed to
 11 complete the Report before addressing some concerns."
 12 A. That is what it says.
 13 Q. Okay. So in this paragraph, you're saying
 14 that there seem to be continuing telephone
 15 conversations with CDER that ORA wasn't involved in?
 16 A. Yeah. And that was my mistake in reality,
 17 because during those telecons with CDER, I should have
 18 insisted that someone with ORA be participating. But
 19 that's more of a technicality, in my mind. I don't
 20 necessarily always do that. In fact, it happens
 21 probably less than 50 percent of the time.
 22 Q. Well, that's part of what gave you the

16:26:48 1 sizzle; right?
 2 A. What gave me the sizzle was that--and I'm
 3 going to have to give a little input before--is when
 4 you do a team inspection, you have individuals that
 5 may not have ever worked together with different
 6 personalities. And some are dominant; some are
 7 passive aggressive; some are very--operating on
 8 adrenaline, very high; some are flatlined. Different
 9 personalities sometimes don't necessarily mesh. As
 10 the lead, it was my responsibility to make sure that
 11 the personality on teams and the personalities within
 12 the firm did not clash.
 13 And so my sizzle was that it was extremely
 14 stressful in some areas of which, in my mind, really
 15 had nothing to do with the actual inspection itself
 16 and the information being gathered, but on
 17 personalities, because there were instances where the
 18 firm wasn't very happy with Ms. Zielny, times when I
 19 wasn't necessarily happy with Ms. Zielny.
 20 Personalities don't necessarily always work well
 21 together.
 22 My sizzle was on that. My sizzle had--phone

16:28:12 1 calls--you know, I'm there to do an inspection. And
 2 it happens not just here; it happens with all
 3 inspections that are violative. It's just that
 4 sometimes Compliance seems to think that they need to
 5 know everything, and you have to take an hour out of
 6 your time in the morning and an hour out of your time
 7 in the afternoon to keep them abreast of what's going
 8 on. Well, I like--once a day is pretty nice. Two
 9 times a day or every single day and you have nothing
 10 to add at that time is kind of a waste of my effort.
 11 So too many telephone calls going on during the
 12 inspection. You could have probably eliminated a few
 13 of those and still got the same thing across. But,
 14 you know, I've seen it every way.
 15 In this particular case, stress. It was a
 16 tedious inspection. Lots of information. It would
 17 have been nice if we wouldn't have had--if we could
 18 have actually been able to approach the pre-approvals.
 19 It would have been a lot easier inspection if it had,
 20 but GMPs didn't allow it. So the tension was there.
 21 Q. So there were calls every day?
 22 A. I wouldn't say there was calls for sure every

16:29:31 1 day. Towards the middle, through the end, there were
 2 a number of calls. And in my mind, really, if I don't
 3 have anything new, I don't need to call you, but...
 4 Q. And this e-mail you sent on the 21st of
 5 August; right?
 6 A. August 21.
 7 Q. And the inspection ended on the 14th;
 8 correct?
 9 A. That's correct.
 10 Q. So a week had passed, and you still haven't
 11 overcome the sizzle?
 12 A. I probably still got a little sizzle, if you
 13 really want to know the truth of it. Yes. I had not
 14 overcome the sizzle. It was stressful. It took--to
 15 be honest, that inspection took probably to the point
 16 of which the Report was submitted before you actually
 17 could come down from the stress level, which was a
 18 month.
 19 Q. We're now going to show you Exhibit C-081.
 20 A. Okay.
 21 Q. And you're welcome to look at as much of the
 22 document as you want. It's fairly voluminous. I'm

16:31:07 1 just trying to put this in time perspective. That's
 2 why I've given you this document.
 3 This is dated September 3, 2009; correct?
 4 A. I'm sorry. Let me look at this document.
 5 September 3, 2009--
 6 Q. Right.
 7 A. --from Apotex.
 8 Q. Right.
 9 A. Okay.
 10 Q. And this is the Response by Apotex to the
 11 483; correct?
 12 A. That is what the first paragraph says.
 13 Q. Okay. And so at the closeout meeting, you
 14 had told Apotex that they had 10, 15 days, whatever it
 15 was, to respond--
 16 A. That's correct.
 17 Q. --to the 483; correct?
 18 A. Yes.
 19 Q. And they timely responded; correct? Business
 20 days or whatever. Isn't that the way it works?
 21 A. 15 business days.
 22 Q. Right.

16:32:09 1 A. Without a calendar, I'd have to say that's
 2 pretty close to the 15 days.
 3 Q. Okay. So despite that, in the interim, they
 4 were put on Import Alert; correct?
 5 A. I actually don't really know for sure when
 6 the Import Alert was placed. Again, that's not my
 7 area. The only time I really got that would have been
 8 if somebody would have actually pinpointed it, that
 9 "Import Alert went into effect today." And I'm not
 10 sure if I got that. And if I did, I don't recall it.
 11 Q. I'll show you now C-525. Again, you're
 12 welcome to look at the exhibit, but I'm presenting it
 13 to you to try to put things into time context. This a
 14 couple of e-mails, correct, from--between you and
 15 Ms. Molina; correct?
 16 A. Yes, Molina.
 17 Q. And she had sent you the Apotex Response to
 18 the 483?
 19 A. Yes.
 20 Q. So on the 28th of October, she's asking you
 21 for your comments on your observations; correct?
 22 A. That is correct.

16:33:54 1 Q. Okay. And you sent them back on the 28th of
 2 October as well; correct?
 3 A. That is the date.
 4 Q. Okay.
 5 A. I find it real surprising that the date was
 6 at 8:33 p.m., because I promise you, I did not review
 7 it that late.
 8 Q. Okay.
 9 A. I've seen this in a number of things I've
 10 looked at in the e-mails, that the times do not really
 11 flow properly.
 12 So assuming these actually occurred in the
 13 order in which they're on this page, I think there
 14 must be some time-stamping on mine. But I will state
 15 that I was quite diligent in responding to the review.
 16 So I would assume that that happened on the same date.
 17 Q. Okay. Well, I'm sure Apotex appreciates your
 18 diligence. It took two months for it to be sent to
 19 you, though; correct?
 20 A. Based upon what I have here, it was--and the
 21 date that is on this letter, it was a good--over a
 22 month; short of two, but more than a month.

16:35:25 1 MR. HAY: Claimant has no further questions
 2 of this Witness.
 3 PRESIDENT VEEDER: Thank you very much.
 4 Are there any questions by way of
 5 re-examination for the Respondent?
 6 MS. CATE: No, there are no further
 7 questions.
 8 QUESTIONS FROM THE TRIBUNAL
 9 ARBITRATOR ROWLEY: Mr. Payne, am I right
 10 that this was the only time that you worked with
 11 Ms. Zielny?
 12 THE WITNESS: Yes, it is.
 13 ARBITRATOR ROWLEY: Do you know whether
 14 Ms. Zielny works on the International Compliance Team?
 15 THE WITNESS: Currently?
 16 ARBITRATOR ROWLEY: Yeah.
 17 THE WITNESS: She no longer works with FDA.
 18 ARBITRATOR ROWLEY: Do you know when she left
 19 the FDA?
 20 THE WITNESS: No, I do not. I understood she
 21 went to industry.
 22 ARBITRATOR ROWLEY: Thank you.

16:36:22 1 THE WITNESS: You bet.
 2 ARBITRATOR CROOK: Mr. Payne, this may not be
 3 so much directed you to as the Parties. Do we know
 4 whether this controversial affidavit, whatever it
 5 said, is in the record someplace?
 6 PRESIDENT VEEDER: It is.
 7 ARBITRATOR CROOK: Can someone, in due
 8 course, give me the cite to that? Not now, but in due
 9 course.
 10 MR. HAY: Certainly.
 11 MS. DUFÊTRE: It is C-062 and C-063. There
 12 were two affidavits.
 13 PRESIDENT VEEDER: I'd like to go back to the
 14 questions that my colleague to my right asked and ask
 15 you a cultural question, which is: Where does
 16 "sizzle" fit in? If 1 is suicide and 100 is homicide,
 17 where does "sizzle" fit in between the two?
 18 (Laughter.)
 19 THE WITNESS: Wow.
 20 PRESIDENT VEEDER: It's not a phrase that I'm
 21 familiar with.
 22 THE WITNESS: Homicide or suicide. Probably

16:37:45 1 suicide.
 2 (Laughter.)
 3 THE WITNESS: If we're going to go one
 4 direction or the other, but it's a very fine line. In
 5 fact, I thought there was going to be a homicide.
 6 (Laughter.)
 7 THE WITNESS: But not by me. But on my part,
 8 it was more of a suicide.
 9 PRESIDENT VEEDER: Well, I'm going to take
 10 you to some passages. I'm going to ask you to read
 11 them to yourself; don't read them aloud. And then I'm
 12 going to ask you to respond to these passage.
 13 Now, I'd like the Witness to be given the
 14 Witness Statements of the 30th of July put in by the
 15 Claimant. I don't know if there's a bundle like this
 16 from the Claimants' side that we can just hand to the
 17 Witness.
 18 We're going to start with the Witness
 19 Statement of Mr. Bruce Clark, the First Witness
 20 Statement. It's Tab B. This is the Statement of
 21 Mr. Bruce Clark. You needn't read anything other than
 22 Paragraph 30, but read it to yourself. Paragraph 30

16:39:02 1 is at Page 6.
 2 THE WITNESS: 13 or 30?
 3 PRESIDENT VEEDER: 3-0.
 4 THE WITNESS: Okay.
 5 PRESIDENT VEEDER: Stop there. The next
 6 statement should be against Tab C. It's the First
 7 Witness Statement of Mr. Jeremy B. Desai. I'd like
 8 you to read Pages 8 and 9, Paragraphs 44 and 45.
 9 THE WITNESS: Okay.
 10 PRESIDENT VEEDER: The last reference is
 11 against Tab G. It's the First Witness Statement of
 12 Bernice Tao. And if you could turn to Page 11 and
 13 read Paragraph 44, which continues over the page to
 14 Page 12. So Page 11, Paragraph 44.
 15 THE WITNESS: All right.
 16 PRESIDENT VEEDER: Now, does this have to do
 17 with the sizzle, what you just read?
 18 THE WITNESS: The "sizzle"? Which portion?
 19 PRESIDENT VEEDER: All of it.
 20 THE WITNESS: All of it? No.
 21 PRESIDENT VEEDER: Well, comment generally,
 22 if you will, on whether you can agree or accept what

16:42:09 1 is being said by these three Witnesses in writing.
 2 THE WITNESS: Well, it appears that the three
 3 Witnesses seem to feel that I was, in one's terms,
 4 "sidelined" as the lead. And I believe I may have
 5 mentioned it--maybe I did not--but that in I
 6 allow--when someone observes something, their
 7 observation, feel free to address it. They are the
 8 one who saw it. The fact that Ms.--and stating that I
 9 made no comment was incorrect because I did discuss
 10 the two that I did have, that I specifically--and then
 11 the ones that we saw as a team was addressed.
 12 The fact that the--it was handed out by
 13 Ms. Zielny, first, it has to be signed by all four
 14 individuals. And you know, Ms. Zielny kind of was a
 15 determinator of that fact she wrote and prepared--even
 16 my observations I provided to her and said, "You just
 17 add to these what you've already got put together, and
 18 then we will forward it on," which we had a discussion
 19 what order they needed to be and so forth.
 20 And so, with that, she was--thinking back,
 21 she probably actually printed it. But either way,
 22 whoever printed it, it was signed by all four

16:43:29 1 investigators, and the fact that she actually was the
 2 one that handed it out doesn't really mean anything
 3 either. She was the one who was going to cover the
 4 first observations. That was fine with me also.
 5 Sidelining, you know, what--interpretation of
 6 what someone considers as a sideline, I'm assuming
 7 that she took over as the lead, which was not the
 8 case. I'll say that today, and it wasn't the case
 9 then.
 10 What was the other point? There was another
 11 point that was made.
 12 PRESIDENT VEEDER: Well, perhaps the other
 13 point was that she was much more aggressive than you.
 14 Was there a difference between the two of
 15 you?
 16 THE WITNESS: Well, there is a difference.
 17 She's a pretty dominant person. Whether that
 18 be--well, during an inspection, Ms. Zielny expresses
 19 herself in a manner that I feel, because she was
 20 young--and young compared to me--she was young and she
 21 was female and I feel that she tried to emphasize more
 22 of a dominant feature because she may have felt that

16:44:34 1 people didn't respect her otherwise, or it could have
 2 been just her normal demeanor. But after, outside of
 3 the inspection, she was quite cordial and joked about
 4 things all the time.
 5 So it was a totally different person in the
 6 firm. But her--she was dominant in her nature. I
 7 tend to go in with a smile; I'll leave with a smile.
 8 And sometimes it's what happens afterwards you have to
 9 worry about, but I try to be as cordial and work with
 10 people as well as I can, and generally do.
 11 Her being dominant in her expression--and she
 12 did run on an adrenaline high. She was nonstop,
 13 worked late--which we all worked late, but she
 14 didn't--she was always on the go.
 15 But as far as her basically taking over, you
 16 know, the dynamics of a team, instances where--I'm
 17 trying to say this in a way that--when one person is
 18 dominant, you have to have someone to equal that out.
 19 And Ms. Zielny only knew one way, and that was
 20 dominant. And so someone had to keep the firm
 21 cooperative, because with her dominant passion, the
 22 firm would have closed themselves off to

16:46:15 1 cooperativeness. And--got close to that, I felt. So
 2 I had to take the other side. I had to be more
 3 cooperative. I had to be--and that took away from
 4 some of the things I was trying to accomplish. But
 5 during an inspection, the dynamics of individual team
 6 members, you kind of have to have a balance. In this
 7 particular case, I had to go the other route.
 8 PRESIDENT VEEDER: Well, thank you for that.
 9 I have one last question, which is quite
 10 different. If you could turn to the--it's in the
 11 joint--what's it called?--the JCB, the Joint Core
 12 Bundle.
 13 Could the Witness being given that?
 14 I'm going to look at C-61. Maybe you had
 15 that loose earlier, but maybe could you be helped. So
 16 this is the Signet Form 483.
 17 THE WITNESS: Okay. C-061?
 18 PRESIDENT VEEDER: C-061. You recognized the
 19 document and you showed us your signature.
 20 Now, 17 items, you said two of those were
 21 yours.
 22 THE WITNESS: Yes.

16:48:21 1 PRESIDENT VEEDER: Which two, please?
 2 THE WITNESS: The two specific that I saw on
 3 my own would be Number 5.
 4 PRESIDENT VEEDER: Is that the one--
 5 THE WITNESS: That deals with the
 6 environmental monitoring.
 7 PRESIDENT VEEDER: So the control systems.
 8 THE WITNESS: I will go through here and tell
 9 you the ones that I actually observed and we discussed
 10 as a joint--
 11 PRESIDENT VEEDER: Just deal with the two--
 12 THE WITNESS: --as far as both of us
 13 observing at the same time. Obviously, all of them
 14 was discussed and verified.
 15 And then Number--actually, the equipment for
 16 the purified water system, Number 17. Yes. Put these
 17 back in order. If you want to know those--
 18 PRESIDENT VEEDER: You're going to give us
 19 the--
 20 THE WITNESS: Number 6 was one that we
 21 observed during the walk-through and where we had a
 22 failure of line clearance.

16:50:26 1 Then the Number 7, where we had logbooks that
 2 were signed and checked by the same individuals. That
 3 was the same--both the same drug product that was
 4 observed. Let's see. And--well, actually, with
 5 Number 7, there were two observations there. One
 6 dealt with the submerging of the blister
 7 packs--actually, let me back this up, read this.
 8 Actually, B doesn't tell--found it.
 9 Bulk hold time was brought up during the time
 10 we were in the material warehouse.
 11 PRESIDENT VEEDER: What number is this?
 12 THE WITNESS: That would be Number 11. I'm
 13 sorry.
 14 And Number 12 was the blister pack not being
 15 submerged properly.
 16 I leave it with that.
 17 PRESIDENT VEEDER: Thank you very much. I
 18 have no further questions.
 19 Are there any questions arising from the
 20 Tribunal's questions? We ask the Respondent first.
 21 MS. CATE: No, there are no further
 22 questions.

16:52:35 1 PRESIDENT VEEDER: And the Claimant?
 2 MR. HAY: No, Mr. President.
 3 PRESIDENT VEEDER: Well, thank you very much.
 4 So we've come to the end of your testimony.
 5 THE WITNESS: Thank you.
 6 PRESIDENT VEEDER: Please leave everything
 7 there.
 8 (Witness steps down.)
 9 MICHAEL ROBERT GOGA, RESPONDENT'S WITNESS, CALLED
 10 PRESIDENT VEEDER: Okay. Let's resume. Good
 11 evening. I'm going to ask you to find the piece of
 12 paper before you that's headed "Witness Declaration."
 13 THE WITNESS: Very well.
 14 PRESIDENT VEEDER: And then I'm going to ask
 15 you in the name of the Tribunal, if you could state
 16 your full name and if you're willing to read out the
 17 Declaration.
 18 THE WITNESS: I am willing to read the
 19 declaration. My full name is Michael Robert Goga,
 20 spelled G-o-g-a.
 21 And I solemnly declare upon my honor and
 22 conscience that I will speak the truth, the whole

17:00:27 1 truth, and nothing but the truth.
 2 PRESIDENT VEEDER: Thank you.
 3 DIRECT EXAMINATION
 4 BY MR. BIGGE:
 5 Q. Mr. Goga, how long have you been employed at
 6 FDA?
 7 A. I have been employed with FDA since March of
 8 1989, which translates into 24 years and 8 months.
 9 Q. What do you do at FDA?
 10 A. My position with FDA is Consumer Safety
 11 Officer or the more generic term "investigator."
 12 Q. Have you had the position of investigator
 13 since you began your employment at FDA?
 14 A. That is correct. I was hired in 1989 as an
 15 investigator.
 16 Q. Now, you currently focus solely on
 17 pharmaceuticals; is that correct?
 18 A. That is correct.
 19 Q. And how long have you focused solely on
 20 pharmaceuticals?
 21 A. Since 2005.
 22 Q. Before 2005, had you done any pharmaceutical

17:01:27 1 inspections?
 2 A. I had. They were smaller companies, not the
 3 most complex companies in our geographical area, but
 4 since 2005, I've been conducting 100 percent
 5 inspections of pharmaceutical manufacturers,
 6 increasingly more complex.
 7 Q. And you're also a member of the Foreign Drug
 8 Cadre; is that correct?
 9 A. That's correct.
 10 Q. And how long have you been a member of the
 11 Foreign Drug Cadre?
 12 A. In January, it will make it five years.
 13 Q. Have you performed--so that's 2009?
 14 A. Correct. January of 2009 is when I began
 15 working full-time on the Dedicated Foreign Drug Cadre.
 16 Q. Had you done foreign pharmaceutical
 17 inspections before 2009?
 18 A. I had, back to 2005.
 19 Q. How many inspections do you do,
 20 approximately, each year?
 21 A. Approximately between 16 and 18 per year.
 22 Q. Now, you have a document in front of you. Is

17:02:34 1 that your Witness Statement for this hearing?
 2 A. Yes, it is.
 3 Q. Did you review it in preparation for the
 4 hearing today?
 5 A. Yes, I did.
 6 Q. And does that Witness Statement represent
 7 your honest recollection of the events detailed in the
 8 Witness Statement?
 9 A. Yes, it does.
 10 Q. Now, you state in the Witness Statement that
 11 you inspected Apotex's Etobicoke and Signet facilities
 12 in 2011.
 13 Can you briefly describe your findings during
 14 those inspections?
 15 A. During the inspection at both of these
 16 facilities, basically we found deviations from Good
 17 Manufacturing Practices. We found deficiencies
 18 related to not conducting failure investigations
 19 appropriately when the company was identifying
 20 problems with their products. They weren't
 21 documenting these problems or investigating these
 22 problems through appropriate channels. That was one

17:03:41 1 observation at the Signet facility.
 2 At the Etobicoke facility, we identified a
 3 situation where the company was aware of a problem
 4 with one of their batches and they didn't recall the
 5 product in a timely manner. They were delayed in
 6 recalling a product that was a known defect.
 7 Then Etobicoke, there was six 483 items. At
 8 Signet, there were 22 observations. I spent the
 9 majority of my time at the Signet site and was
 10 involved with the majority of those observations. We
 11 had a team of four inspectors, two investigators, and
 12 two analysts, and each one of us contributed, made
 13 findings, and the 483 was basically a collaboration of
 14 all our findings. Some were related to production.
 15 Some were related to documentation. Some were clear
 16 GMP violations that our regulations, Part 211 in the
 17 CFR, the Good Manufacturing Practices regulation, has
 18 some clear responsibilities that drug manufacturers
 19 have to follow, and we identified cases where the
 20 company was not fulfilling their obligations to the
 21 cGMPs.
 22 MR. BIGGE: We don't have any further

17:05:18 1 questions at that time.
 2 PRESIDENT VEEDER: Thank you. There will now
 3 be questions from the Claimant.
 4 CROSS-EXAMINATION
 5 BY MR. HAY:
 6 Q. Yes, good evening. I'm going to ask you some
 7 questions now. If you don't understand my question,
 8 I'd appreciate you advising me of that and I'll try to
 9 rephrase it.
 10 A. Very well.
 11 Q. For the actual inspection of Signet and
 12 Etobicoke, did you visit both sites?
 13 A. I did.
 14 Q. Did you spend equal time on each, or how did
 15 that work?
 16 A. No, I did not. I spent the majority of my
 17 time at the Signet facility. At the Etobicoke site, I
 18 was actually only there one day--the first day.
 19 Q. And what was the purpose of your visit the
 20 first day at the Etobicoke site?
 21 A. Basically to initiate the inspection. It was
 22 treated as a separate inspection. It was two unique

17:06:14 1 inspections. So I had to show my credentials--the FDA
 2 Protocol is we have to identify our credentials to the
 3 top responsible person at each location, and it was
 4 our responsibility to inspect both facilities. But
 5 they were done simultaneously. So each of us couldn't
 6 be at both locations at the same time, so we kind
 7 of--the team that we put together-- four of us, we
 8 broke the team up into two and-- myself and Sarah
 9 McMullen, we spent the majority of our time at Apotex
 10 at Signet site, and Francis Guidry and Steven Weinman,
 11 they--I gave them the kind of responsibility of
 12 inspecting the Etobicoke site.
 13 So I just basically went on the first day
 14 just to meet the staff and show our credentials. And
 15 I did take a walk-through the facility on the first
 16 day. It wasn't practical to go back and forth between
 17 the two sites in one day. So then, after the second
 18 day, I returned to the Signet facility, and then I
 19 stayed there to the remainder of the closeout meeting.
 20 Q. So in terms of actual inspection, you did not
 21 inspect the Etobicoke site?
 22 A. Not completely, no. But I did make a couple

17:07:32 1 observations that ended up on the 483 from the one day
 2 that I was there. Two of the observations on the 483
 3 were mine and were identified on that first day.
 4 Q. On the Etobicoke 483?
 5 A. That's correct.
 6 Q. And how many observations totally were on the
 7 Etobicoke?
 8 A. I think six.
 9 Q. Are you familiar with the Investigations
 10 Operations Manual?
 11 A. Yes.
 12 Q. The Investigations Operations Manual provides
 13 detailed instructions for domestic investigations;
 14 correct?
 15 A. That's correct.
 16 Q. The manual states that the Form 483 is to
 17 notify the firm's top management in writing of
 18 significant objectionable conditions; correct?
 19 A. That's correct.
 20 Q. This manual states that written observations
 21 should be significant; correct?
 22 A. Well, "significant" is kind of open to

17:08:42 1 interpretation. Yeah.
 2 Q. But the manual says they have to be
 3 significant?
 4 A. They do.
 5 Q. This manual also instructs that observations
 6 of questionable significance should not be written,
 7 but instead should be discussed verbally; correct?
 8 A. That's correct.
 9 Q. This manual also instructs the investigator
 10 not to characterize any condition as "violative";
 11 correct?
 12 A. No. That's not our responsibility to use
 13 that term, "violative."
 14 Q. Well, it instructs you not to use that term;
 15 correct?
 16 A. Yes.
 17 Q. The Investigation Operations Manual states
 18 that determining--the determination of whether any
 19 condition is violative is the Agency decision made
 20 after consideration of all circumstances; correct?
 21 A. That's correct.
 22 Q. The Investigation Operations Manual also

17:09:37 1 states that the specific guidance or compliance
 2 programs may supplement its general instructions;
 3 correct?
 4 A. That's correct.
 5 Q. FDA drafted the Guide to International
 6 Inspections and Travel to provide detailed guidance on
 7 foreign inspections; correct?
 8 A. That's correct.
 9 Q. This guidance directs the investigator to
 10 report on the Form 483 any situation that needs
 11 attention or corrections; correct?
 12 A. That's correct.
 13 Q. The guidance explains that foreign firms
 14 respond better to observations left in writing than
 15 those discussed verbally; correct?
 16 A. That's correct.
 17 Q. This is a different approach from domestic
 18 firms; correct?
 19 A. Well, I've been doing strictly foreign
 20 inspections now for five years, so, you know, I
 21 have--I've been following the approach that I was
 22 trained for foreign inspections which--so it's been

17:11:00 1 five years since I've stepped foot in a domestic firm,
 2 so I'm not really up to date on what the requirements
 3 are for domestic inspections. I'm knowledgeable in
 4 the requirements for foreign inspections because I've
 5 been doing that for five years now.
 6 Q. Okay. My point simply is that for foreign
 7 inspection, foreign facilities, according to the
 8 manual, react better to written observations rather
 9 than discussions; correct?
 10 A. I guess I'm not privy to that--of that
 11 statement. I don't know what the justification for
 12 that is. But, to me, a domestic company would respond
 13 to a written observation just like a foreign company
 14 would.
 15 MR. HAY: Why don't you give him
 16 Exhibit CLA-299.
 17 BY MR. HAY:
 18 Q. Are you familiar with Exhibit CLA-299? I'll
 19 give you a couple seconds to look at it.
 20 A. Yes, I am.
 21 Q. And can you tell us what it is, for the
 22 record?

17:13:18 1 A. Well, it's Chapter 3 of the Inspector's
 2 Operations Manual covering establishment inspections.
 3 Q. And with respect to foreign inspections,
 4 there are a number of differences between the foreign
 5 and domestic?
 6 A. There are, yes.
 7 Q. And one of them, for example, relates to
 8 annotations of--for example, at 3.2.1.
 9 A. 3.2--
 10 Q. Excuse me, 3.12.2.
 11 A. Okay. Yeah, that program area there is
 12 specific for medical devices where we annotate 483s
 13 for the medical device industry, but not for the
 14 pharmaceutical industry. So FDA treats--there's a
 15 different system when it comes to issuing a 483 when
 16 it comes to involving medical device manufacturers
 17 versus pharmaceutical manufacturers. If a medical
 18 device manufacturer, from my understanding, initiates
 19 a corrective action during the inspection, then the
 20 483 is annotated with the corrective action, but for
 21 pharmaceutical companies, that's not the case.
 22 Q. Okay. If you look above that at 3.12,

17:15:04 1 reportable operations, do you see that?
 2 A. Yes.
 3 Q. In the second sentence, it talks about
 4 "listed observations should be significant, but
 5 experience has shown that foreign firms respond better
 6 to observations left in writing on the 483 rather than
 7 those discussed verbally."
 8 Were you familiar with that?
 9 A. No, I wasn't.
 10 Q. And with respect to the inspections of Signet
 11 and Etobicoke, I believe your Statement says that
 12 there were a number of written observations, but also
 13 some discussed; correct?
 14 A. There was.
 15 Q. Do the same cGMPs apply to both foreign and
 16 domestic companies, facilities?
 17 A. Yes. If they're exporting to U.S. I mean,
 18 if they're exporting to U.S., then the expectations
 19 are that they comply to U.S. GMP requirements.
 20 Different countries have their own GMP requirements
 21 and different countries might have different
 22 expectations for the company, but if they're shipping

17:16:15 1 to the United States, then the expectation is the
 2 company has to be in compliance with 211 of the CFR,
 3 part 21 of the CFR, Section 211, Good Manufacturing
 4 Practices.
 5 Q. Are there different cGMPs related to tablets
 6 versus injectables, sterilized injectables?
 7 A. There is different compliance programs for
 8 it. FDA has issued some guidance documents relating
 9 to different dosage forms, but overall, it doesn't
 10 matter if you're producing a tablet, capsule,
 11 injectable, suppository, topical product, all
 12 companies have to comply with the minimum GMP
 13 requirements.
 14 Q. Right. And but would you agree that--strike
 15 that.
 16 Injectables, injectable products are more of
 17 a health risk than tablets?
 18 A. Yes.
 19 Q. So with respect to a facility that is mostly
 20 an injectable manufacturer, the cGMPs are even more
 21 important to be complied with because of the potential
 22 health risk?

17:17:41 1 A. That's correct. You've got microbial
 2 controls. Injectable drugs need to be sterile, and
 3 the company has to have controls to ensure sterility,
 4 which you're not going to see in a solid oral dosage
 5 product or a topical product.
 6 Q. Let me direct your attention to your Witness
 7 Statement at Paragraph 29.
 8 A. Okay.
 9 Q. I see that you state there, "For both Apotex
 10 sites, we recommended OAI and that the two sites
 11 remained on Import Alert based on the observations the
 12 team made during the January/February 2011
 13 inspection." That was your conclusion?
 14 A. It was.
 15 Q. And that was based on, as I understand your
 16 earlier testimony, that there were similar violations
 17 as to what were found at the earlier inspections?
 18 A. That's correct.
 19 Q. And I think you said there were even new and
 20 different violations?
 21 A. There were.
 22 Q. Was your recommendation followed?

17:19:03 1 A. No, it wasn't.
 2 Q. Okay.
 3 A. Well, let me retract that. It was followed
 4 by my supervisor. My supervisor at the time, he
 5 concurred and endorsed it with the same recommendation
 6 that I had made, but then from there, it went to CDER
 7 Office of Compliance, and then they made the ultimate
 8 decision.
 9 Q. And CDER decided to end the Import Alert;
 10 correct?
 11 A. That's correct.
 12 Q. In so doing, to your knowledge, they didn't
 13 put any conditions on ending the Import Alert;
 14 correct?
 15 A. I wasn't privy to the company's response or
 16 the correspondence that was going back and forth
 17 between Apotex management and CDER. I was--I just
 18 completed my work and I submitted my work, and then
 19 that--at that point, my role ended.
 20 Q. You submitted your 483; correct?
 21 A. That's correct.
 22 Q. For the two facilities, and then Apotex

17:20:12 1 responded to your 483s; correct?
 2 A. That's correct. But again, I wasn't privy to
 3 those responses. I wasn't provided copies of those
 4 responses.
 5 Q. Okay. But as a result of those responses,
 6 the Import Alert was lifted; correct?
 7 A. It was. Yes.
 8 MR. HAY: I have no further questions.
 9 PRESIDENT VEEDER: Very well. Thank you.
 10 Are there any questions from the Respondent?
 11 MR. BIGGE: No, Mr. President. Thank you.
 12 PRESIDENT VEEDER: Well, thank you very much.
 13 We've come to the end of your testimony. Okay.
 14 THE WITNESS: My pleasure.
 15 PRESIDENT VEEDER: You can leave everything
 16 there.
 17 THE WITNESS: All right.
 18 (Witness steps down.)
 19 PRESIDENT VEEDER: We move straight on to the
 20 next Witness, Dr. Rosa.
 21 CARMELO ROSA, RESPONDENT'S WITNESS, CALLED
 22 PRESIDENT VEEDER: Good evening, sir. As

17:23:19 1 you've seen and you've heard, we ask each Factual
 2 Witness to make the declaration, which you will find
 3 on a piece of paper on the table in front of you. And
 4 if you're willing to do so, we'd ask you to state your
 5 full name and then read out the words of the
 6 declaration.
 7 THE WITNESS: Yes.
 8 My name is Dr. Carmelo Rosa. I solemnly
 9 declare upon my honor and conscience that I shall
 10 speak the truth, the whole truth, and nothing but the
 11 truth.
 12 PRESIDENT VEEDER: Thank you very much. So
 13 first there be questions from the Respondent.
 14 THE WITNESS: Yes.
 15 DIRECT EXAMINATION
 16 BY MR. DALEY:
 17 Q. Dr. Rosa, could you please summarize your
 18 educational background for the Tribunal?
 19 A. Certainly. I have a bachelor's degree in
 20 science and biology, minor in chemistry micro. I have
 21 a master's and a doctor's degree in clinical
 22 psychology with specialization in trauma and, you

17:24:24 1 know, physiology and other specialized--and courses
 2 related to the area of clinical psychology as well.
 3 Q. And where are you currently employed?
 4 A. At the United States Food and Drug
 5 Administration based in Silver Spring, Maryland.
 6 Q. What's your current position at the FDA?
 7 A. I'm the current director for the Division of
 8 International Drug Quality and Center for Drugs,
 9 Office of Compliance.
 10 Q. And that's called CDER; is that correct?
 11 A. Yes, CDER.
 12 Q. How long have you been working at the FDA?
 13 A. For a little over 23 years.
 14 Q. Could you please just briefly summarize for
 15 the Tribunal the positions you've held at the FDA,
 16 including the various positions you've held at CDER up
 17 until now?
 18 A. Yes, sir. I started with the FDA in 1990 as
 19 an investigator. And I worked as such for about
 20 11 years or so in the San Juan District Office. I was
 21 promoted as compliance officer shortly after. As a
 22 compliance officer, I continued doing inspections. So

17:25:27 1 I was doing dual role of compliance officer and
 2 investigator for the United States Food and Drug
 3 Administration.
 4 In 2008, I transferred to Maryland, a lateral
 5 transfer, as a compliance officer for the Center for
 6 Drugs. In 2009, I was promoted as team leader for the
 7 Center for Drugs at the Office of Compliance. In
 8 2010, branch chief, 2011 and '12 I was acting as
 9 branch chief and promoted subsequently to director for
 10 the current position.
 11 Q. And you've submitted two statements in this
 12 case; is that correct?
 13 A. Yes, sir.
 14 Q. And can you just look at the statements and
 15 confirm that the ones before you are the ones that you
 16 submitted?
 17 A. Yes, these are the two statements.
 18 Q. Have you reviewed those statements in
 19 preparation for your testimony today?
 20 A. I looked at them, yes.
 21 Q. And did those statements reflect your honest
 22 recollection of the events discussed in those

17:26:29 1 statements?
 2 A. Yes.
 3 Q. During your various positions in CDER, did
 4 you have any involvement in issues relating to Apotex?
 5 A. Yes. 2009, I was a team leader for the
 6 Division of International Drug Quality, at that time
 7 called International Team of Compliance.
 8 Q. Could you please briefly summarize for the
 9 Tribunal the factors that led the FDA to place
 10 Apotex's Etobicoke and Signet facilities on Import
 11 Alert in 2009?
 12 A. Yes, certainly. Significant GMP violations
 13 were found when several inspections at these
 14 facilities. If you look at the history of the
 15 facilities, the history of the facilities, especially
 16 if you look at the Etobicoke facility, goes back to
 17 2006, and we had in that inspection significant GMP
 18 violations that were reported. And then we had an
 19 inspection in 2008, and then we had, again, another
 20 inspection in 2009 at the Signet facility. The 2008
 21 inspection at the Etobicoke facility, we sought the
 22 intervention of one in June of 2009. There was an

17:27:41 1 inspection that occurred in 2009, again, finding
 2 significant violations through Current Good
 3 Manufacturing Practices that led the Agency to make
 4 that decision of placing the firm on the Import Alert
 5 to current violations, significant violations, that
 6 were found during the course of these inspections.
 7 MR. DALEY: Thank you. No further questions.
 8 PRESIDENT VEEDER: Thank you.
 9 There will be questions now from the
 10 Claimant.
 11 CROSS-EXAMINATION
 12 BY MR. LEGUM:
 13 Q. Good afternoon, Dr. Rosa. My name is Bart
 14 Legum. I'm a partner with the firm of Dentons based
 15 in Paris, and I represent the Claimants, Apotex
 16 Holdings and Apotex Inc., in this arbitration against
 17 the U.S. Government. I'll be asking you some
 18 questions today and, I'm afraid, also tomorrow
 19 morning.
 20 I first want to say that Apotex is very
 21 grateful to you for taking time away from your
 22 functions to be here with us. We appreciate that. I

17:28:44 1 can't promise you that this examination will be short,
 2 but I can promise you that it will be courteous. So,
 3 if at any point in time you don't understand a
 4 question that I ask, just stop me and tell me that you
 5 don't understand. If you don't hear a question that I
 6 ask, just, again, let me know and I'll say it again.
 7 A. Certainly. I appreciate that.
 8 Q. Okay. So you are currently the Division
 9 Director of the Division of International Drug
 10 Quality; is that correct?
 11 A. Yes, that's correct.
 12 Q. And the Division of International Drug
 13 Quality is in the Office of Manufacturing and Product
 14 Quality?
 15 A. Yes, that's correct.
 16 Q. And then that office, in turn, is in the
 17 Office of Compliance?
 18 A. Correct.
 19 Q. And the Office of Compliance is a part of the
 20 CDER?
 21 A. Right.
 22 Q. Okay. Now, I'm referring right now to

17:29:39 1 Paragraph 2 of your First Witness Statement. So you
 2 should feel free to have that in front of you, if
 3 you'd like.
 4 So your role is to review inspectional
 5 observations for foreign cGMP inspections; correct?
 6 A. One of my responsibilities is for the
 7 overseeing the entire operation within the FDA in that
 8 capacity. And one of the things that I do is I review
 9 when I have to inspection of findings.
 10 Q. And you evaluate recommendations made by
 11 inspectors?
 12 A. I evaluate recommendations that come to me
 13 from the compliance officers. Those recommendations
 14 usually come with a recommendation from the field
 15 offices, from the inspectors who do the audits. So
 16 they do the audits, they submit the recommendation,
 17 that recommendation comes into the office. It is
 18 channeled through the appropriate process within the
 19 office, and I subsequently eventually get those
 20 recommendations if there's a case that I need to look
 21 at.
 22 Q. And you review and evaluate Advisory Actions

17:30:55 1 as well; correct?
 2 A. Yes.
 3 Q. And Advisory Actions include Warning Letters
 4 and Untitled Letters?
 5 A. Yes, that's correct.
 6 Q. So what's an Untitled Letter?
 7 A. An Untitled Letter is, as you well stated, an
 8 Advisory Action that we issue to companies. When we
 9 issue an Untitled Letter, usually the Untitled Letter
 10 is issued when the threshold of a Warning Letter has
 11 not been met. That's one of the criterias for issuing
 12 an Untitled Letter.
 13 In the Center for Drugs, the International
 14 Division, we also issue an Untitled Letter to
 15 companies that have significant violations, if these
 16 are not shipped--if these companies are not shipping
 17 products to the U.S. So we would normally not issue
 18 necessarily a Warning Letter to a company who has no
 19 shipment--has made no shipment to the U.S. So we
 20 would select the Advisory Action of an Untitled Letter
 21 because that's a way of communicating to that company
 22 that we have some concerns as well.

17:32:05 1 Q. Now, you provide the director of the Office
 2 of Manufacturing and Product Quality with information
 3 about a firm's inspection and compliance. So can I
 4 say OMPQ because that's shorter?
 5 A. Yeah, OMPQ. That's fine.
 6 Q. So you provide the director of OMPQ with
 7 information about a firm's inspection and compliance
 8 so that OMPQ can decide to take--whether any action,
 9 Advisory Action, should be taken; is that correct?
 10 A. Yes, yes. I provide the director of the
 11 Office of Manufacturing Product Quality information
 12 about a firm that is found with significant GMP
 13 violations. If a Report comes in and there is no
 14 significant violation, there is no issues related to
 15 that firm that would generate any action, there is no
 16 need to share any inspection of findings unless asked
 17 for, unless they ask for it for a particular reason.
 18 Q. So it's the director of OMPQ that decides
 19 whether to take an Advisory Action; is that correct?
 20 A. The director of Office of Manufacturing and
 21 Product Quality is one of the deciding officials that
 22 uses the recommendation that has come forward

17:33:27 1 regarding an action. His signature is the signature
 2 that appears on an Advisory Action.
 3 Q. You don't make the decision to take an
 4 Advisory Action yourself, do you?
 5 A. No.
 6 Q. Now, you also state that you provide the
 7 director of OMPQ with information to evaluate whether
 8 to place a firm on Import Alert; is that correct?
 9 A. Right. That's correct.
 10 Q. Your superiors in--is it OMPQ that makes that
 11 decision, or is it the CDER Office of Compliance that
 12 makes that decision?
 13 A. Well, the Center for Drugs, within the
 14 division, it goes--you know, I don't know how the
 15 testimony that has been given before. But once the
 16 recommendation is prepared, it's discussed with the
 17 team leaders, discussed with the branch chief, then it
 18 comes to me. And then I initial it and I would submit
 19 it to the director of the office. And he would make a
 20 final decision as to if it should go forward.
 21 Now, having said that, there is instances
 22 where he might need more information regarding the

17:34:38 1 placing a firm on Import Alert. The information could
 2 be more information about any drug shortages, more
 3 information about the history of the firm, more
 4 information--he could even ask to see the EIR, the
 5 483, and any history of the firm. And he would use
 6 that information to make a final determination as to
 7 if we should go forward with that proposed action.
 8 Q. So before you were division director, you
 9 were branch chief of the International Compliance
 10 Branch; correct?
 11 A. Yes.
 12 Q. And this role, you state in your Witness
 13 Statement that you reviewed Warning Letters and Import
 14 Alert recommendations.
 15 A. Yes.
 16 Q. So your duties in your current role and that
 17 role were similar?
 18 A. Were pretty much similar. There was a
 19 reorganization in 2011 of the Center for Drugs and
 20 Office of Compliance, and the branches were elevated
 21 to a level of division. So as part of the
 22 reorganization, I was promoted to the division

17:35:35 1 director, but some of the functions are similar. The
 2 functions that I had as a branch chief with additional
 3 responsibilities as a division director.
 4 Q. Now, as a leader in the Division of
 5 International Drug Quality, you don't normally review
 6 domestic facilities; correct?
 7 A. That's correct. We--I normally do not review
 8 the domestic facilities, although we're just a door
 9 away. So there's communication between the
 10 offices--divisions, I should say.
 11 Q. Now, before the reorganization in 2011, you
 12 were part the international compliance team; is that
 13 right?
 14 A. Yes. International compliance team, which
 15 was changed to become the Division of International
 16 Drug Quality. So it was called international
 17 compliance team. Then they referred to it as a branch
 18 and now as a division.
 19 Q. Now, currently OMPQ--
 20 A. Yes.
 21 Q. --is one of four offices that's part of the
 22 Office of Compliance?

17:36:46 1 A. Yes.
 2 Q. And the Office of Drug Security, Integrity,
 3 and Recalls is another office within the CDER Office
 4 of Compliance?
 5 A. Yes. Referred to as ODSIR under the umbrella
 6 of Office of Compliance as well.
 7 Q. ODSIR did you say?
 8 A. ODSIR.
 9 Q. Oh, ODSIR.
 10 A. You have an OMPQ and ODSIR.
 11 Q. ODSIR. I can't say ODSIR. So I'm going to
 12 say the Office of Drug Security, Integrity, and
 13 Recalls. That's not part of the OMPQ.
 14 A. No. That's part of the Office of Compliance.
 15 Q. And within the Office of Drug, Security,
 16 Integrity, and Recalls, is the recalls and shortages
 17 branch; correct?
 18 A. There's a recall and shortages branch there
 19 that basically manages daily operations, daily issues
 20 regarding recalls. But the drug shortages group for
 21 the Center for Drugs does not reside in Office of
 22 Compliance. That resides in the Office of New Drugs

17:37:52 1 that's under OND. So when we refer to as drug
 2 shortage being consulted, it's not drug shortages and
 3 recalls under Office of Compliance necessarily. It's
 4 drug shortages, the people who do the assessment and
 5 evaluation of any potential drug shortages or
 6 medically necessary drugs.
 7 Q. So the people who do the evaluation of drug
 8 shortages are under the Office of New Drugs?
 9 A. Yeah.
 10 Q. And is that part of CDER?
 11 A. Yes, part of CDER as well.
 12 Q. All right. So it's--well--
 13 A. It's complicated.
 14 Q. It is. So what is a medically necessary
 15 drug?
 16 A. A medically necessary drug is one of the
 17 terms that is used to define a product that--for which
 18 there is no alternate treatment, or if there's an
 19 alternate treatment, it's very limited in terms of
 20 scope of that drug. So a medically necessary drug is
 21 a drug that is a lifesaving drug and for which there's
 22 very limited or no alternate type of medication.

17:39:13 1 Q. And for drug shortages purposes, is it enough
 2 that it's a medically necessary drug, or does the
 3 availability of the drug on the market also enter into
 4 it?
 5 A. That's a very good question. Medically
 6 necessary drugs and drug shortages are usually used
 7 interchangeable, although by definition they shouldn't
 8 be used in that way. But normally when we're talking
 9 about drug shortages, it is availability of drugs.
 10 Medically necessary drugs, strict to the
 11 definition, should involve the definition of no
 12 alternate treatment but it's usually commonly used in
 13 both ways. Medically necessary drug, drug shortage.
 14 The easiest way to look at a medically necessary drug
 15 from a definition perspective would be the, if you're
 16 a sole supplier, which that is also used in that
 17 terminology.
 18 But when we look at--when we consult drug
 19 shortages, we often would get responses in terms of
 20 availability of drugs. If the drug is a sole
 21 supplier--if the manufacturer is a sole supplier of
 22 that drug, then they would use medically necessary,

17:40:33 1 but they would also refer to it, this will create a
 2 shortage. So both terms are used when you're looking
 3 at that assessment.
 4 Q. Now, you referred to consulting with drug
 5 shortages.
 6 A. Uh-huh.
 7 Q. Which, I take it, is the office that's under
 8 the office of new drugs?
 9 A. Right.
 10 Q. It's not part of your responsibilities to
 11 conduct drug shortage analysis; correct?
 12 A. Right. We--our office makes the request and
 13 consults with the office of drug shortages, and they
 14 respond to us via e-mail or via phone call or in a
 15 meeting about that drug shortage situation.
 16 Q. So I'm going to ask a very general question
 17 about your Witness Statement.
 18 A. Yeah.
 19 Q. So under the rules in this arbitration,
 20 usually a Witness Statement is supposed to say what
 21 the source of the information is that the Witness
 22 relies on for the statements that he makes in the

17:41:37 1 Witness Statement. And there isn't a statement like
 2 that in yours. So can you tell us how do you know the
 3 things that you talk about in your Witness Statement?
 4 A. Because I do them every single day.
 5 Q. Okay. Now, in your Witness Statement, you
 6 talk about the Etobicoke 2006 inspection; correct?
 7 A. Can you refer me to the paragraph in the
 8 Witness Statement, please?
 9 Q. Yes. Give me just one moment. It begins
 10 around Paragraph 26-27.
 11 A. Of the First Witness Statement?
 12 Q. Of your First Witness Statement. Essentially
 13 26-30. So that's where you talk about that
 14 inspection.
 15 A. Oh, yes.
 16 Q. So in 2006, you were an inspector in FDA
 17 San Juan office; correct?
 18 A. That's correct. I was a compliance officer.
 19 Q. So you did not inspect Apotex in 2006?
 20 A. I have never inspected Apotex.
 21 Q. And you weren't at CDER when the EIR and the
 22 483 for that inspection were prepared; correct?

17:43:08 1 A. No. That's correct. But just for your--all
 2 these reports are in my office. So...
 3 Q. So all of the reports--
 4 A. Of international drug inspections are
 5 received at my office, GMPs, pre-approval inspections.
 6 Q. Now, when you say "in your office," do you
 7 mean like in your office, behind your desk in a file
 8 cabinet?
 9 A. No.
 10 Q. Or someone else is dealing with them in your
 11 office?
 12 A. No. I think that we should have started with
 13 that. The International Drug--Division of
 14 International Drug Quality that I manage receives, is
 15 responsible for receiving all the inspection reports
 16 of international inspections, foreign inspections that
 17 the Agency conducts, GMP pre-approval inspections. So
 18 when I say we received them, that is received in our
 19 office following a process, and they are
 20 electronically maintained. They are assigned to the
 21 compliance officers for review. So when I say "we
 22 have them all," that's what I meant.

17:44:18 1 Q. Okay. And were you assigned as the
 2 compliance officer to review the 2006 Etobicoke
 3 Establishment Inspection Report or 483?
 4 A. No. No. I was not at the office in 2006. I
 5 reviewed the 2006 inspection, of course, in
 6 preparation for this hearing just to get some
 7 background on it. But, yeah.
 8 Q. Now, in your Witness Statement when you talk
 9 about what happened during the 2006 inspection, how do
 10 you know that?
 11 A. Because I read the Report.
 12 Q. Okay. And when did you read the Report? Was
 13 it back in 2009, or did you read it in preparation for
 14 this arbitration?
 15 A. Okay. I read it in both occasions. I read
 16 the Report in preparation of, of course, for the
 17 hearing to refresh my memory. In 2009 when I was a
 18 team leader, as part of every review that we do of
 19 cases that we receive or any proposed action, we look
 20 at the history of that company. And the compliance
 21 officer's responsibility is to look at that Report. I
 22 will ask questions about the history of that company.

17:45:32 1 I will ask questions about that previous inspection.
 2 I will look at previous Inspection Report and see what
 3 the findings were. And that's my involvement with the
 4 2006.
 5 Q. Would it be the job of the compliance officer
 6 principally to familiarize himself or herself with the
 7 prior history, or was that your job as the team
 8 leader?
 9 A. The compliance officer is the person who must
 10 be familiar with every single detail of the case. As
 11 a team leader and as you heard me say, in 2008, I come
 12 to the Center for Drugs as a compliance officer. I
 13 was within the Center for Drugs one of the most senior
 14 compliance officers that they had there coming from
 15 the field. So I would definitely look at--just as a
 16 routine review, I would look at this Report.
 17 So it's not like you have to or you don't
 18 have to. It's the right thing to do if you're going
 19 to look at the history of a firm. So I would look at
 20 that Report and have discussions about those findings
 21 and the 2008 findings and any other inspection that
 22 may have been conducted to that facility.

17:46:37 1 Q. I guess I should have asked this before, but
 2 when did you become the acting team leader and then
 3 the team leader for the International Inspections
 4 Team? I'm sorry. I'm not saying it correctly.
 5 A. I became acting team leader effective date
 6 December of--exact date, I don't remember--of 2008,
 7 acting team leader. The permanent team leader was
 8 several months after when the announcement came out
 9 and I was promoted. 2009.
 10 Q. Okay. So December 2008 you were acting team
 11 leader?
 12 A. I was acting, yeah. So...
 13 Q. Now, in your Witness Statement you also talk
 14 about things like drug shortage analyses. You
 15 personally didn't perform those drug shortage
 16 analyses?
 17 A. No. That's not our role.
 18 Q. So that's based on your reading documents?
 19 A. Can you refer me to where I'm saying that I
 20 did an analysis? I don't recall.
 21 Q. No. Well, no. What I'm saying is, for
 22 example, in Paragraph 72 of your First Statement--

17:47:43 1 A. Okay.
 2 Q. --you talk about drug shortage analyses.
 3 A. Right. In addition FDA's drug shortage team
 4 evaluated the products. At no point--that's not my
 5 responsibility.
 6 Q. Okay.
 7 A. Yeah.
 8 Q. And so, you know that based on reading
 9 documents or based on what somebody else told you, or
 10 how do you know that?
 11 A. How do I know what? That a review was done?
 12 Q. Yes.
 13 A. Because we have information. We discuss--the
 14 Agency doesn't operate in a vacuum, with all due
 15 respect. We have meetings on a weekly basis. We have
 16 discussions about upcoming concerns about firms that
 17 are found with significant GMP violations. It is
 18 normal process for us that, before we pursue any
 19 Advisory Action or any action of an Import Alert to go
 20 to drug shortage. How that's done, I will not get a
 21 Warning Letter. I will not get an Import Alert
 22 recommendation without that being done by the

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17:48:55 1 compliance officer because the first thing I will ask
2 is, "Did you check with shortage?" But that's not the
3 only thing we do. "Did you check with the reviewers
4 if there's any issues that the reviewers need to know
5 about this facility?" So there's discussion between
6 different units, you know, within the office.

7 We have discussions with--on a weekly basis
8 with the domestic side. So I'm a division director.
9 Teddi Lopez, Division Director for Drug Quality
10 Domestic; David Jaworski for pre-approvals. We have
11 weekly meetings, we discuss issues. We discuss--if
12 there's going to be an Import Alert, there's a
13 discussion there. But requesting a drug shortage
14 assessment is common practice. It's a common process
15 before we pursue any action.

16 Q. Okay. I'd like to change topics a little bit
17 and talk about Current Good Manufacturing Practices.

18 A. Okay.

19 Q. So you started your career in 1990 at FDA?

20 A. Yes.

21 Q. And you were an investigator for something
22 like 13 years?

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17:50:08 1 A. Yes. Actually, I still do inspections. I
2 still do GMP inspections. So the title is a little
3 bit irrelevant. I still do inspections, GMP
4 inspections.

5 Q. Now, cGMP standards have evolved since 1990;
6 correct?

7 A. Yes.

8 Q. What was acceptable back in 1990 isn't
9 acceptable today necessarily?

10 A. I would not say that.

11 Q. So some things back in 1990 are acceptable
12 today, and some things that were done back in 1990 are
13 not acceptable today; is that right?

14 A. No. I would not say that. I would say that
15 GMPs have evolved in a positive way. There is more
16 understanding. There is more knowledge about
17 expectations. There is more guidances. There is more
18 information regarding regulatory expectations. There
19 is more discussions about common expectations among
20 regulators. There is--yes, it has evolved in that
21 sense. I wouldn't say that what was good in 1990 is
22 bad today and vice versa. I wouldn't agree with that

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17:51:18 1 statement.

2 Q. So would you agree that cGMP standards are
3 constantly evolving?

4 A. I will say that cGMP are standards that are
5 established for firms to follow. It's not that cGMPs
6 are evolving as--you have better understanding when we
7 have issues that, perhaps, need some further
8 clarification. And there would be a need to revise a
9 specific part of the regulation, and we'll do that.
10 But it's not something that is evolving every single
11 day. There is a process for any changes on cGMPs. So
12 I wouldn't say that it is evolving every single day.

13 Q. Now, does FDA communicate changes in cGMP
14 mainly through changing the regulation or through
15 guidance documents?

16 A. Guidance documents is one of the mechanisms
17 that the agency has to provide further clarification
18 of the interpretation of regulations. There is also
19 ICH guidances. There is international guidances that
20 also clearly states the Agency's expectation. One
21 example is the ICHQ7 for APIs, that is an
22 international guidance that we use for inspecting

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17:52:50 1 APIs. So we use the guidances. We use different
2 source of communication. We are in conferences--I
3 cannot tell you how many conferences a
4 year--communicating our expectations to industry. So
5 there's also Level II guidances that are published
6 where FDA, if there's a need to apply provide further
7 clarification, we'll provide to some guidances.

8 Q. Now, cGMP requirements are the same for all
9 firms supplying finished drugs to the United States'
10 market; correct?

11 A. For the United States' market?

12 Q. So, in other words, whether a facility is
13 located in the United States or outside of the United
14 States, the cGMP standards are the same.

15 A. Yes.

16 Q. And you referred to international cGMP
17 standards. Did I understand you correctly about that?

18 A. Yes. That's the ICH document, ICH guidance
19 document, that we use. There's no specific cGMPs by
20 reg for the APIs. So the international community has
21 adopted, has--and FDA has agreed that those are the
22 standards that would be accepted when inspecting API

17:54:15 1 manufacturing. And that's a guidance document. It's
 2 not a reg.
 3 Q. Are cGMP standards in different countries
 4 pretty much the same for finished drug products, or
 5 are they different?
 6 A. I wouldn't--I wouldn't want to--I haven't
 7 looked at cGMPs in every other country. I know but,
 8 there are some common expectations among regulatory
 9 authorities.
 10 Q. Okay. I'm going to change topics a little
 11 bit and ask you whether beginning in 2009 there was a
 12 significant increase in Warning Letters and
 13 enforcement actions by FDA as compared to the
 14 previous years?
 15 A. In 2009--I believe there was increase in
 16 Warning Letters issued in 2009. At least--yes, I can
 17 say that there was an increase, at least we saw that
 18 increase in our division.
 19 Now, I think it's important to mention that
 20 there were more inspections being conducted. So
 21 there's no specific reason as to what the increase
 22 could be attributed to. There might be different

17:55:37 1 factors to it that would be related to that increase.
 2 Q. Now, also in 2009, there was a new
 3 commissioner of the FDA that came into office; right?
 4 A. Yes, I believe so. Dr. Hamburg.
 5 Q. Yes, that's right.
 6 And did she have a different strategy for
 7 enforcement by FDA than the previous administration
 8 had had?
 9 A. See, I am not sure. And I'm being very
 10 honest. I come from Puerto Rico, and I have no
 11 involvement in policies or political interests of
 12 commissioners or--I was brought to the Center for
 13 Drugs to do a job, and I've done it no differently
 14 there than what I was doing it for my entire career.
 15 So I wouldn't say that there was a different policy or
 16 there was something different occurring because I
 17 would not know.
 18 Q. And, in fact, you came to CDER right around
 19 that time, correct, back in 2008, late 2008, early
 20 2009?
 21 A. Yes, 2008 I came to CDER in--effective date
 22 August 30 or 31, and started formally on September 18

17:56:54 1 at the Center for Drugs.
 2 Q. Was there an emphasis when you joined CDER on
 3 taking Advisory Actions and enforcement actions more
 4 rapidly than it had been done in the past?
 5 A. Not that I'm aware of.
 6 MR. LEGUM: Before starting on a new line of
 7 questions, this may take a little while.
 8 PRESIDENT VEEDER: This would be a good time
 9 to break.
 10 MR. LEGUM: It might be.
 11 PRESIDENT VEEDER: Let's do that. We're
 12 going to break now because we've come to the end of
 13 the working day. We're going again at 9:00 tomorrow
 14 morning. We'll continue with your testimony.
 15 THE WITNESS: Great.
 16 PRESIDENT VEEDER: We would say this to all
 17 Witnesses, please don't discuss the case or your
 18 testimony with anyone away from the Tribunal.
 19 THE WITNESS: Okay.
 20 PRESIDENT VEEDER: So talk about anything
 21 else but not this case until 9:00 tomorrow morning.
 22 THE WITNESS: Great. You have my commitment.

17:57:47 1 Thank you.
 2 PRESIDENT VEEDER: Thank you. So we'll
 3 adjourn until 9:00 tomorrow.
 4 THE WITNESS: Shall I leave these Statements
 5 here?
 6 PRESIDENT VEEDER: Leave everything there.
 7 THE WITNESS: Okay.
 8 PRESIDENT VEEDER: Just before we go, this
 9 doesn't involve you, so please go. This doesn't
 10 involve you. It is just for Counsel.
 11 Just to the timetabling, how are things
 12 going? Are we still ahead of our schedule? I guess
 13 this is more a question to the Claimant. But we've
 14 got to finish this Witness's testimony tomorrow.
 15 MR. LEGUM: That's correct.
 16 PRESIDENT VEEDER: And then we have the
 17 Expert Witness from the Respondent.
 18 MR. LEGUM: So we have an allotment of
 19 7 hours.
 20 PRESIDENT VEEDER: Yes.
 21 MR. LEGUM: And it seems likely that we will
 22 use that allotment.

17:58:24 1 PRESIDENT VEEDER: So all tomorrow?
 2 MR. LEGUM: All tomorrow? No, no, no. We've
 3 probably used--
 4 PRESIDENT VEEDER: I'm sorry. I thought you
 5 were talking of a further 7 hours.
 6 MR. LEGUM: No, no, no, not a further
 7 seven hours.
 8 PRESIDENT VEEDER: I was just beginning to go
 9 white. Okay. That's fine.
 10 MR. LEGUM: So we have about--well, if we're
 11 at 2 hours, 15, we might use the full 7. It will be
 12 close to the full 7.
 13 PRESIDENT VEEDER: Okay. So you've got to
 14 make some submissions, have you, after this testimony?
 15 MR. DALEY: Yes, that's correct.
 16 PRESIDENT VEEDER: We're not trying to tie
 17 anybody down. We're trying to get some feel for where
 18 we're going. Do you know how long those submissions
 19 will be after the end of the Expert testimony?
 20 MR. SHARPE: We anticipate that, if the
 21 testimony wraps up tomorrow morning, that we would
 22 conclude our jurisdictional--

17:59:16 1 PRESIDENT VEEDER: I didn't understand the
 2 testimony would finish tomorrow morning. It might,
 3 but it might not.
 4 MR. LEGUM: That may be a little bit
 5 optimistic given the time for direct examination and
 6 Tribunal questions. But I would expect that we'll be
 7 concluded certainly in the first--before the coffee
 8 break in the afternoon.
 9 MR. SHARPE: Then I think it might be
 10 difficult for us to predict at this time when we would
 11 wrap up. But we could, perhaps, address the issue
 12 again tomorrow at the close of business and might have
 13 a better sense then.
 14 PRESIDENT VEEDER: Yes, of course. There is
 15 no hurry. It looks as though we'll certainly go into
 16 Friday. But you'll finish your oral case by Friday
 17 evening, won't you? That's what I'm trying to get a
 18 feel for.
 19 MR. SHARPE: Right. It might be easier to
 20 provide greater guidance to the Tribunal tomorrow
 21 evening.
 22 PRESIDENT VEEDER: Let's do it tomorrow.

18:00:15 1 Thank you very much. We'll see you all tomorrow.
 2 (Whereupon, at 6:00 p.m., the hearing was
 3 adjourned until 9:00 a.m. the following day.)
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CERTIFICATE OF REPORTER

I, Dawn K. Larson, MBA-RDR, 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.

DAWN K. LARSON