

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 7

HEARING ON JURISDICTION AND THE MERITS

Tuesday, November 26, 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
Realtime Reporter
B&B Reporters
529 14th Street, S.E.
Washington, D.C. 20003
(202) 544-1903

APPEARANCES: (Continued)

Attending on behalf of the Respondent:

MS. MARY McLEOD
Acting Legal Adviser

MS. LISA J. GROSH
Assistant Legal Adviser

MR. JOHN D. DALEY
Deputy Assistant Legal Adviser

MR. JEREMY K. SHARPE
Chief, Investment Arbitration,
Office of International Claims
and Investment Disputes

MR. NEALE H. BERGMAN

MR. DAVID M. BIGGE

MR. JOHN I. BLANCK

MS. ALICIA L. CATE

MS. NICOLE C. THORNTON

MS. ABBY L. LOUNSBERRY (Paralegal)
Attorney-Advisers,
Office of International Claims and
Investment Disputes
Office of the Legal Adviser
U.S. Department of State
Suite 203, South Building
2430 E Street, N.W.
Washington, D.C. 20037-2800
(202) 776-8443

APPEARANCES:

Attending on behalf of the Claimants:

MR. BARTON LEGUM

MS. ANNE-SOPHIE DUFÊTRE

MS. LARA ELBORNO

MS. BRITTANY GORDON
Salans FMC SNR Denton Europe LLP
5 boulevard Malesherbes
75008 Paris
France

MR. JOHN J. HAY

MS. KRISTEN WEIL

MS. ULYANA BARDYN
Dentons
1221 Avenue of the Americas
New York, NY 10020-1089
USA

Claimant's Representative:

MR. JEREMY DESAI
President and Chief Operating Officer
Apotex Inc.

MS. ROBERTA LOOMAR
General Counsel, U.S., Apotex Corp.

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1 P R O C E E D I N G S
 2 PRESIDENT VEEDER: Let's start the final day
 3 of this hearing. Unless there is some housekeeping,
 4 we give the floor to the Claimant for the Closing
 5 Reply Submissions.
 6 CLOSING REPLY SUBMISSIONS
 7 MR. LEGUM: No housekeeping here,
 8 Mr. President. I would simply note that we've handed
 9 out a handout, which you should now have, as well as
 10 opposing counsel. So this is a handout that--we're
 11 going low tech today and there won't be slides.
 12 Mr. President, Members of the Tribunal, I
 13 will now provide Apotex's Reply to the United States's
 14 Closing Argument. I will not, in the next 30 minutes,
 15 be able to cover every point made during the 90-minute
 16 presentation that we heard yesterday. So I will again
 17 ask the Tribunal to recall that the fact that I do not
 18 mention a point does not mean it is conceded. Apotex
 19 continues to rely on its written and oral submissions
 20 already made in this case.
 21 My first main topic concerns the evidentiary
 22 record. The Closing Argument of the United States was

09:04:17 1 product that Sandoz Canada was not authorized to sell
 2 in the United States. Apotex introduced this evidence
 3 with its Reply at Paragraph 329. Regulatory action
 4 against Boucherville could not cause a shortage of
 5 this product in the U.S. because there was no market
 6 for it. Sandoz could not legally sell it in the
 7 United States, and no one in the United States relied
 8 on Sandoz to supply it.
 9 What the Reply showed was that despite the
 10 cGMP violations at Boucherville and despite the fact
 11 that Sandoz was not authorized to sell this product in
 12 the United States, six months after the Sandoz Warning
 13 Letter, FDA invited Sandoz to begin selling the
 14 product in the U.S.
 15 What the record shows is not that Sandoz
 16 voluntarily limited its production for the U.S.
 17 market; rather, it shows that FDA voluntarily allowed
 18 Sandoz to expand its production for the U.S. market by
 19 selling a product that it was not otherwise authorized
 20 to sell there.
 21 The U.S. also stated that "Apotex's response
 22 to FDA also contrasts starkly with the voluntary

09:02:50 1 heavy on representations concerning the record and
 2 short on references. There are no record references
 3 for much of what we heard yesterday because much of it
 4 has no record support. I will provide a few examples.
 5 The U.S. stated that "Sandoz Canada
 6 voluntarily limited its production for the U.S. market
 7 to sterile injectables, in particular, life-saving
 8 single-source drugs with the concurrence of FDA's drug
 9 shortage office." That's in the transcript at
 10 Page 1670.
 11 Nothing in the record suggests either that
 12 Sandoz Canada limited its production for the U.S.
 13 market to sterile injectables or that FDA's drug
 14 shortage office concurred in such a thing. The record
 15 contains no evidence concerning communications between
 16 FDA's drug shortage office and Sandoz Canada. It
 17 refers to a suspension of some production of
 18 injectables at Sandoz Boucherville, but it says no
 19 more. And what I'm referring to there is
 20 Exhibit C-452, which was what was referred to
 21 yesterday.
 22 What the record does contain is evidence of a

09:05:58 1 responses of Sandoz/Novartis and Teva." This is the
 2 record at 1664--the transcript, I mean. The record
 3 does not support this assertion. Before the Import
 4 Alert was adopted, Apotex voluntarily proposed
 5 precisely the same kind of extensive systemwide
 6 Corrective Action Plan that Teva put forward in the
 7 October 28, 2010, meeting with FDA.
 8 I refer the Tribunal to Exhibit 66, the
 9 August 28, 2009, letter that Apotex transmitted to FDA
 10 on the day that the Import Alert was adopted. I also
 11 refer the Tribunal to Exhibit C-81, Apotex's 45-page
 12 response to the Signet 483, which also reflects a deep
 13 and comprehensive commitment to ensuring the quality
 14 of Apotex's processes. This document, the response to
 15 the 483, was transmitted to FDA on September 3, 2009,
 16 and was prepared before Apotex was made aware of the
 17 existence of the Import Alert. Each of these two
 18 documents reflects a purely voluntary response on
 19 Apotex's part, as it had no idea at the time that the
 20 Import Alert had already been put into place.
 21 The U.S., of course, does not mention these
 22 very concrete manifestations of Apotex's commitment to

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09:07:41 1 addressing the issues raised by FDA. It does not do
 2 so for a simple reason: FDA did not care about
 3 Apotex's Corrective Action Plan. It had made up its
 4 mind before it received these documents.
 5 Apotex invites the Tribunal to compare these
 6 documents to the description of Teva's proposed
 7 Corrective Action Plan described in the minutes of the
 8 October 28, 2010, meeting, and the accompanying slide
 9 deck, Exhibits C-424 and 424A. The Tribunal will find
 10 these Corrective Action Plans to be fully comparable.
 11 There is, of course, no evidence of any Corrective
 12 Action Plan on the part of Sandoz, and no evidence of
 13 any communication by Sandoz with FDA. There is
 14 nothing to compare with regard to Sandoz.
 15 The record, therefore, in no way supports the
 16 assertion that Apotex's voluntary response to FDA
 17 contrasts starkly with the voluntary responses of
 18 Sandoz/Novartis and Teva. What is stark on this
 19 record is that both Sandoz and Teva had months to
 20 propose voluntary Corrective Action Plans to FDA.
 21 Teva availed itself of that opportunity. Sandoz we
 22 just don't know. But we do know that Apotex had no

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09:09:11 1 opportunity to propose a Corrective Action Plan that
 2 FDA would actually take into consideration in making a
 3 regulatory action decision.
 4 Yesterday, the U.S. endorsed Mr. Vodra's
 5 colorful statement that: "Companies frequently do not
 6 hear FDA clearly until FDA basically hits them
 7 alongside the head with a 2 by 4." The reference is
 8 to the transcript at Page 1641.
 9 The Tribunal will see, if it reviews
 10 Exhibit C-66 and C-81, that Apotex heard FDA very,
 11 very clearly. FDA would have seen that as well if it
 12 had looked before picking up that large wooden beam.
 13 Before leaving the topic of Apotex's
 14 response, I note that in our earlier submissions we
 15 detailed the extensive nature of Apotex's commitments
 16 in terms of changing leadership, reinforcing its
 17 quality staff, and restructuring its systems. The
 18 U.S. recalled again the description of Sandoz's
 19 efforts yesterday in a newspaper article and in an SEC
 20 filing. No evidence of record supports the U.S.'s
 21 suggestion that Sandoz's response, or Teva's, for that
 22 matter, was somehow better than Apotex's.

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09:10:45 1 One final point on this topic. The U.S.
 2 suggested that Ed Carey of Apotex had endorsed the
 3 view that the Import Alert was needed to spur Apotex
 4 to action. This is not at all what Mr. Carey said.
 5 He explained that Apotex decided to substantially
 6 revamp all of its processes to meet or even exceed
 7 regulatory requirements. I refer here to his First
 8 Witness Statement at Paragraph 49. He also reaffirmed
 9 that Apotex was committed to take all necessary steps
 10 to ensure its cGMP compliance regardless of the Import
 11 Alert. However, without the Import Alert, Apotex
 12 would have had the flexibility to implement the
 13 additional enhancements while its manufacturing
 14 processes were ongoing, as was the case for Teva and
 15 Sandoz.
 16 As another example of the need to closely
 17 consider the record, the U.S. yesterday addressed Teva
 18 Jerusalem and drug shortages by quoting the internal
 19 FDA e-mail that is Exhibit C-569. The U.S. stated
 20 that "when cGMP deficiencies were identified at Teva
 21 Pharmaceutical's Jerusalem, Israel, facility and Teva
 22 offered to shut it down, FDA saw the need for a

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09:12:12 1 teleconference with Teva as soon as possible to let
 2 them know the medical need for these." And I'm
 3 referring to the transcript at Page 1671.
 4 The record does not support this statement in
 5 several respects. First, the e-mail exchange the U.S.
 6 quotes is from February 23, 2011. The Teva Warning
 7 Letter, which is at Exhibit C-191, was issued on
 8 January 31 of that year. What prompted the e-mail
 9 exchange on drug shortages was neither the
 10 deficiencies identified in the Warning Letter nor any
 11 Teva offer to shut down the facility. Indeed,
 12 Dr. Rosa in Exhibit C-569 states that CDER Compliance
 13 "has no information indicating that the Teva Israel
 14 Jerusalem site has stopped or intends to stop
 15 production or distribution."
 16 Instead, the occasion for the e-mail exchange
 17 was Teva's announcement of a recall of 30 lots of
 18 product. This e-mail exchange does not address a
 19 decision by FDA on regulatory action concerning Teva
 20 Jerusalem. It does not address a drug shortage
 21 analysis for purposes of a regulatory action decision.
 22 Instead, it concerns drug shortage concerns as to a

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09:13:47 1 relatively small number of products implicated by a
 2 product recall.
 3 Now, I note that yesterday we also heard the
 4 U.S. assert in its Closing Submissions on Day 6 of a
 5 7-day Merits hearing that it had been unable to
 6 present relevant evidence in its defense because of
 7 internal legal constraints. And I refer here to the
 8 transcript at Pages 1661-1662, 1677, and 1679. This
 9 assertion is remarkable in several respects.
 10 First, if a Party to an arbitration truly had
 11 been prevented by some obstacle in presenting evidence
 12 in support of its case, one would expect to have heard
 13 something about this difficulty before the final
 14 closing argument on jurisdiction and liability. Had
 15 such a critical issue been raised earlier in the
 16 proceedings, the Parties and the Tribunal would have
 17 been in a position to do something to address it, such
 18 as, if necessary, applying for a court order in aid of
 19 arbitration ensuring protection of relevant
 20 information in accordance with applicable law. It is,
 21 to say the least, surprising to hear such an a
 22 assertion so late in a proceeding.

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09:15:16 1 Second, the assertion is remarkable because
 2 there is already in place in this arbitration a
 3 Confidentiality Order with provisions for Attorneys'
 4 and Tribunals' Eyes Only access to particularly
 5 sensitive documents. This has worked well for certain
 6 information that the U.S. found highly sensitive in
 7 and relevant to its defense.
 8 Third, the assertion is remarkable because
 9 the Statutory and Regulatory Authority cited by the
 10 U.S. on its face has no application to the evidence at
 11 issue now. We have, for the Tribunal's convenience,
 12 distributed a handout with the text cited by the U.S.
 13 yesterday.
 14 As the Tribunal can see, the main protection
 15 applies to trade secrets. Trade secrets are defined
 16 in 21 CFR Section 2061(a) to mean "any commercially
 17 valuable plan, formula, process, or device that is
 18 used for the making, preparing, compounding, or
 19 processing of trade commodities and that can be said
 20 to be the end product of either innovation or
 21 substantial effort." It is not at all apparent why a
 22 drug shortage analysis would fall under this

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09:16:48 1 provision. These analyses appear to be performed by
 2 FDA based on a list of the products made at a given
 3 facility and on market share data from IMS, which is
 4 an industry marketing information company.
 5 As the Tribunal will perhaps recall from the
 6 document disclosure phase, there is no statutory or
 7 regulatory protection for the names of drugs produced
 8 by a given facility, but FDA adopted a policy not to
 9 disclose such names publicly in 2012. A recently
 10 adopted policy hardly qualifies as a legal impediment,
 11 particularly given the protection of the
 12 Confidentiality Order in this case. And it is hard to
 13 understand why any of this could be a legal impediment
 14 given the e-mails on this subject that the U.S. has
 15 already offered into evidence, which deal with limited
 16 drug shortage analyses and which the U.S. has
 17 presented in open session.
 18 Nor is it apparent why the other
 19 circumstances identified by the U.S. as relevant to
 20 its treatment of Sandoz and Teva--the firm's responses
 21 to FDA on what it would do to address FDA's cGMP
 22 concerns--it is not apparent why this would prevent

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09:18:14 1 the U.S. from producing evidence in support of its
 2 case. None of this information would appear to
 3 involve any trade secret, and, again, the U.S. has
 4 produced for Teva information on this very topic in
 5 the form of Exhibits C-424 and 424A, albeit in partly
 6 redacted form.
 7 For these reasons, the U.S.'s invocation of a
 8 legal impediment to putting on its case at this very
 9 late date cannot be taken seriously.
 10 In its submission yesterday, the U.S. again
 11 placed heavy reliance on the newfound distinction
 12 between injectable drugs and solid-dose drugs. I will
 13 not repeat our earlier submissions on this. I will,
 14 however, note that Apotex's Signet facility also
 15 produced an injectable drug, as Exhibit C-127
 16 demonstrates. The record shows that Apotex's
 17 facility, like Sandoz Boucherville, produced drugs in
 18 both solid dose and injectable form.
 19 A few final notes on facts before turning
 20 briefly to the law. First, yesterday the U.S.
 21 attempted to draw significance from Ms. Woodcock's
 22 statement in Exhibit C-359 that "Apotex is a great

09:19:41 1 illustration of why generics need QBD." That's
 2 quality by design, and the reference is at transcript
 3 Page 1633. FDA was also concerned with Teva's lack of
 4 quality by design. I refer the Tribunal to Dr. Rosa's
 5 Statement in Exhibit C-424 at Page US867.
 6 Second, the U.S. continues to disagree with
 7 testimony by Apotex's Witnesses that Apotex-U.S. was
 8 set up as a distribution arm of Apotex-Canada. It
 9 relies on Apotex's submissions in a U.S. court case.
 10 The appeals court in that case, however, observed as
 11 follows: "The District Court found that Apotex-U.S.
 12 acts as the marketing and distribution arm of
 13 Apotex-Canada in the United States, a relationship
 14 that was not disputed." The U.S. courts did not see
 15 the inconsistency that the U.S. asserts here. The
 16 reference is CLA-536 at Page 527.
 17 Third, yesterday the U.S. relied on Commander
 18 Emerson's report of a supposed statement that Apotex
 19 did not perform research and development. The
 20 transcript reference is 1635. As Ms. Emerson noted in
 21 her testimony, Apotex did have a development function
 22 at Etobicoke. Ms. Emerson referred to the development

09:21:37 1 department and its office at Page 726 of the
 2 transcript.
 3 Other evidence of record confirms the
 4 substantial effort that Apotex devotes to the
 5 development of new products. And I refer the Tribunal
 6 here to the Memorial at Paragraph 292 and the evidence
 7 cited therein and the Reply at Paragraph 194 and the
 8 evidence cited there.
 9 Fourth, yesterday the U.S. again made
 10 reference to the change in FDA enforcement policy in
 11 2009 which the U.S. characterizes as a return to the
 12 levels of the Clinton years. It suggested that Apotex
 13 was treated the same as others subject to the new
 14 policy. The transcript reference is Pages 1629-1631.
 15 Not so. The relevant period for the
 16 comparison effected by Mr. Johnson and Mr. Bradshaw
 17 was 2008-2011. The comparators that they looked at
 18 were all during the same time period of increased
 19 enforcement as Apotex was subject to. For each of
 20 Sandoz and Teva, the FDA findings of cGMP violations
 21 took place after the new enforcement approach was in
 22 full swing. Even looking at this period of increased

09:23:16 1 enforcement activity, Mr. Bradshaw and Mr. Johnson
 2 found that comparable firms received more favorable
 3 treatment in like circumstances.
 4 I turn now to the law. I begin with the
 5 Bellarno versus FDA case which found Import Alerts to
 6 be binding. The U.S. yesterday attempted to
 7 distinguish Bellarno based on a change in some of the
 8 language of the relevant Import Alert here. The
 9 transcript reference is Page 1690. But the language
 10 used in the document was only one of several factors
 11 that the Court considered. Moreover, review of the
 12 Import Alert shows that the new language added by FDA
 13 was mere window dressing.
 14 Now, if the Tribunal looks at the handout
 15 which includes, in the back two pages, the first two
 16 pages of Exhibit C-110, it will see that the Reasons
 17 for Alert section of the Import Alert made clear that
 18 the products remain subject to automatic detention.
 19 Automatic detention could be removed only when and if
 20 FDA confirmed that corrections had been made. And
 21 this is fully concordant with the evidence and the
 22 submissions in this case.

09:24:46 1 The products at Etobicoke and Signet were
 2 detained at the border. As Dr. Rosa testified, FDA
 3 would confirm that the requisite corrections had been
 4 made only after a re-inspection. As the Bellarno
 5 Court held, the mere fact that the FDA labeled the
 6 Import Alert as guidance did not prove anything.
 7 The U.S. also referred, at Page 1645 of the
 8 transcript, to the Parties' agreement that Apotex
 9 Holdings is a privy of Apotex-Canada. There is
 10 agreement on this point, but the Tribunal should
 11 understand the limits of that agreement. Apotex
 12 agrees that Apotex Holdings is a privy, but only to
 13 the extent that the rights in question are based
 14 exclusively on Apotex-Canada's standing. As we have
 15 shown in our submissions, Apotex Holdings has standing
 16 in its own right to assert claims as an investor. Its
 17 position is significantly different from that of
 18 Apotex-Canada because it is the ultimate owner of
 19 Apotex-U.S. and numerous other investments in the
 20 United States. Apotex Holdings cannot be seen to be a
 21 mere exporter of goods.
 22 In this regard, it is notable that the U.S.

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09:26:17 1 acknowledged at Page 1683 that Apotex Holdings was an
 2 investor in the U.S. and did not dispute that it had
 3 contributed resources within the meaning of
 4 Article 1139 (h). Apotex Holdings's status as a privy
 5 in no way detracts from its claims in its own right
 6 which were not and could not have been addressed in
 7 the Apotex I and II Award.
 8 Turning to the U.S. arguments on "relating
 9 to," the U.S. attempts in vain to distinguish Cargill.
 10 And the transcript reference here is 1691-1693. The
 11 U.S. argues that the purpose of the import permit
 12 requirement in Cargill was a significant factor in
 13 that Tribunal's decision on "relating to" under
 14 Article 1101(1). It was not. This was relevant to
 15 the Tribunal's Merits decision.
 16 The U.S. speculates that that Tribunal would
 17 have reached a different result if Mexico had deemed
 18 the corn syrup adulterated by law while acknowledging
 19 that there was no evidence that the corn syrup was in
 20 any way unsafe or ineffective. That was not the issue
 21 presented in Cargill, and it is not the issue
 22 presented here. The U.S. then suggests that a finding

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09:27:51 1 on this record that this Measure related to
 2 Apotex-U.S. would imply an endless expansion of
 3 Article 1101(1) to include all customers of
 4 Apotex-U.S.
 5 Cargill, again, does not support the U.S.
 6 position here. Just like Apotex-U.S., Cargill de
 7 Mexico sold products sourced from its affiliate across
 8 the border to customers in the host State. The
 9 Cargill Award addressed precisely the situation
 10 presented here. Whether the Import Alert related to
 11 customers of Apotex is, as we noted in our written
 12 submissions, an interesting question. It is not one
 13 presented to this Tribunal. The record in this case
 14 clearly shows that this Measure relates to Apotex-U.S.
 15 That is enough.
 16 One word on Article 1105. At Page 1696 of
 17 the transcript, the U.S. attempted to draw a
 18 distinction between the due process issues that are
 19 presented in this case and denial of justice under
 20 customary international law. The Restatement, in a
 21 series of sections, extensively addresses substantive
 22 and procedural denial of justice. Section 181 of the

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09:29:29 1 Restatement is part of the very long succession of
 2 Articles on this very topic. The U.S. has, in other
 3 arbitrations, relied on the Restatement as evidence of
 4 customary international law on denial of justice. The
 5 question of why the Restatement Section 181 is not
 6 relevant here is one that remains unanswered.
 7 Mr. President, Members of the Tribunal, for
 8 all of these reasons, Apotex respectfully submits that
 9 the Tribunal should dismiss the jurisdictional
 10 objections of the United States, find that the United
 11 States has breached Articles 1102, 1103, and 1105, and
 12 proceed to a hearing on damages.
 13 This concludes the rebuttal of Apotex, if
 14 there are no questions from the Tribunal.
 15 QUESTIONS FROM THE TRIBUNAL
 16 ARBITRATOR ROWLEY: You just said that the
 17 U.S. has used Section 181 of the Restatement in other
 18 arbitrations. Have you provided us with references?
 19 MR. LEGUM: I didn't mean to say that the
 20 U.S. has relied on Section 181 in particular. There
 21 is a long series of sections in the Restatement Second
 22 that deal with the administration of justice. Some of

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09:31:16 1 those sections deal with a denial of substantive due
 2 process, such as what was at issue in the Loewen case.
 3 Others deal with other aspects of the administration
 4 of justice. The U.S. has relied on other sections in
 5 other arbitrations dealing with the administration of
 6 justice and denial of justice, but it has not, to my
 7 knowledge, relied on Section 181.
 8 ARBITRATOR ROWLEY: And one other question.
 9 Bear with me for a moment.
 10 MR. LEGUM: Please.
 11 ARBITRATOR ROWLEY: In reviewing the
 12 interaction between the FDA and Apotex following the
 13 Etobicoke inspection and leading up to the Signet
 14 inspection, we see in Exhibit C-502--and I'm going to
 15 summarize it. You can look at it--an e-mail from
 16 Valerie Jensen, who has been identified as the
 17 Associate Director of the FDA who has responsibility
 18 for drug shortages, an e-mail and a list of Apotex
 19 products which indicates market shares and so on.
 20 And I wonder if you can identify for us
 21 further references in the record to Apotex drug
 22 shortages, if there are any. And you may not be able

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09:33:25 1 to do it off the top of your head. And we can discuss
2 the timing of that identification.

3 MR. LEGUM: In order to provide a more
4 comprehensive listing, it would take us a little
5 while, but we can certainly have it ready by noon when
6 we resume.

7 PRESIDENT VEEDER: As you recall, we asked
8 you for lists of various materials in relation to
9 Novartis and Teva. You can do it at the same time,
10 when you can do it.

11 MR. LEGUM: Absolutely.

12 PRESIDENT VEEDER: Okay. One question,
13 really, about your treatment of the decision of the
14 Eastern District of New York U.S. District Court in
15 Bellarno, and you distinguished it on the basis that
16 wording was not--the wording of the Import Alert in
17 that case was not the sole reason given by that court.

18 If you had a copy of that judgment, could you
19 just show us the particular passage you might have in
20 mind? If it helps, I'm looking at the paragraph at
21 Page 3 in the second column where the Court lists
22 various factors. It's a paragraph that starts "In

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09:35:45 1 look at the next page, that's where it has listings
2 referring to Apotex Inc. at Signet and Etobicoke. And
3 there it says date published, September 30, 2009.
4 This was the earliest published version of the Import
5 Alert that we could locate at the time that we
6 submitted our Request for Arbitration and Memorial.
7 So this is the earliest version we were able to locate
8 at that time.

9 PRESIDENT VEEDER: The first page has this
10 wording that you've highlighted in yellow?

11 MR. LEGUM: Yes.

12 PRESIDENT VEEDER: I recall seeing the second
13 page, but not the first. Thank you for that.

14 MR. LEGUM: And the U.S. has put in another
15 version of this, but I don't have the exhibit
16 reference, which--I'm told it's R-158, but that was
17 not something that we had access to.

18 PRESIDENT VEEDER: Is that worded the same
19 way?

20 MR. LEGUM: Let's take a look. Yeah. So the
21 second paragraph--the last sentence under "Reason for
22 Alert" reads "When and if FDA confirms that

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09:34:43 1 sum, therefore, although the Courts speak of two
2 criteria, in reality, four interrelated factors must
3 be considered: The binding effect of the
4 pronouncement, the degree of discretion accorded the
5 Agency in applying the pronouncement, deference to the
6 Agency's characterization, and the language of the
7 pronouncement itself."

8 MR. LEGUM: Correct. The language of the
9 pronouncement itself is the last of those factors, and
10 that's what the change in language would go to.

11 PRESIDENT VEEDER: Your submission is that
12 that's only one the four factors that's been changed
13 with the wording of the new Import Alert.

14 MR. LEGUM: It's only one of the four factors
15 that's been slightly changed with the wording of the
16 new Import Alert.

17 PRESIDENT VEEDER: If you come to the exhibit
18 you showed us, C-110, and this is dated the 10th of
19 February 2009. Has this played a part of this hearing
20 before? I don't recall seeing this. But maybe I've
21 overlooked it.

22 MR. LEGUM: Right. So if the Tribunal will

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09:37:31 1 corrections have been made, the respective firm's
2 pharmaceutical products will be removed from automatic
3 detention."

4 PRESIDENT VEEDER: Still getting it up. Is
5 the first sentence there as well? "FDA will detain,"
6 is that sentence there?

7 MR. LEGUM: I'm sorry. Where does it say
8 "FDA will detain"?

9 PRESIDENT VEEDER: Under "Reasons for Alert"
10 at C-110.

11 MR. LEGUM: Yeah. The second sentence.

12 PRESIDENT VEEDER: Yes.

13 MR. LEGUM: Yes. That's there too. "FDA
14 will detain affected products if inspection has
15 revealed that a firm is not operating in conformity
16 with Current Good Manufacturing Practices, cGMPs."

17 PRESIDENT VEEDER: Okay. Thank you. Thank
18 you very much, indeed, for those submissions.

19 MR. LEGUM: Thank you. I would like to, once
20 again, thank the Court Reporter and ICSID and the
21 Tribunal for their patient attention to us during
22 these past weeks--week.

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09:38:38 1 PRESIDENT VEEDER: Thank you for that too.
 2 We haven't finished yet.
 3 We're going to take a break and then we're
 4 going to hear the Respondent's submissions. Forgive
 5 me; it slipped my mind, how long you would like to
 6 take before you come back. Is it an hour or an hour
 7 and a half? Was it even longer?
 8 MS. GROSH: The current schedule would be
 9 noon.
 10 PRESIDENT VEEDER: Noon. That's it. So we
 11 come back at noon.
 12 MS. GROSH: That's correct.
 13 (Whereupon, at 9:39 a.m., the hearing was
 14 adjourned until 12:00 p.m., the same day.)
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1 AFTERNOON SESSION
 2 PRESIDENT VEEDER: Let's resume. We now have
 3 the Reply submissions from the Respondent.
 4 CLOSING REPLY SUBMISSIONS
 5 MS. GROSH: Thank you, Mr. President. I will
 6 begin our rebuttal remarks, and then I will turn the
 7 floor over to my colleague, Mr. Sharpe.
 8 PRESIDENT VEEDER: Give me one moment.
 9 Should this be open session or closed
 10 session? We'd just gone into closed session.
 11 MS. GROSH: It can remain in open session and
 12 there is one place in my remarks where I will indicate
 13 that we'll need to close the feed.
 14 PRESIDENT VEEDER: Forgive me for
 15 interrupting. I believe we need to open the
 16 session--which it is now open. Tell us when you want
 17 it closed.
 18 MS. GROSH: Very good. Thank you,
 19 Mr. President.
 20 Apotex's submissions over the past two days
 21 have been remarkable in how much they rely on the
 22 assumption that the United States bears the burden to

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1 disprove Apotex's claims that they were treated less
 2 favorably under Article 1102 and 1103. Apotex asks
 3 this Tribunal to presume that the United States has
 4 violated the NAFTA based on conjecture and improper
 5 inferences, and then attempts to put the burden on the
 6 United States to rebut that presumption. As we've
 7 made clear several times, the United States bears no
 8 such burden.
 9 Apotex also conveniently ignores much of the
 10 evidence that is in the record. We have submitted
 11 numerous Witness Statements, and the Tribunal has
 12 heard hours of Witness testimony on FDA's careful
 13 consideration of enforcement against Apotex and its
 14 alleged competitors.
 15 On this point, we direct the Tribunal to the
 16 testimony of Dr. Rosa, who was subject to hours of
 17 cross-examination and who testified that these
 18 determinations are often made at meetings rather than
 19 in e-mails or other written documents which help to
 20 fill gaps, but many times only tell part of the story.
 21 This is on Pages 870-872, 886, and 899-900 of the
 22 transcript.

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1 Dr. Rosa has now sworn three times as to the
 2 veracity of his Statements. Once for each Witness
 3 Statement and once again during this hearing. Members
 4 of the Tribunal, you can assess his credibility on
 5 this point and others for yourselves.
 6 Specifically for the suggestion that no drug
 7 shortage analysis was performed for Teva or Sandoz
 8 because there isn't a comprehensive e-mail on this
 9 point, I would refer the Tribunal to Dr. Rosa's direct
 10 testimony that drug shortage analyses are always
 11 performed for any case where there are serious
 12 compliance issues and the Agency is contemplating
 13 enforcement action. This can be found at Pages 846
 14 and 886-887 of the transcript.
 15 Dr. Rosa also discussed the drug shortage
 16 analyses specifically for Teva and Sandoz, which you
 17 can find at pages 989-990, 971-973, and 1032-1033.
 18 As for the argument that the Corrective
 19 Actions proposed by Teva were equivalent to those
 20 proposed by Apotex, I would invite the Tribunal to
 21 recall Dr. Rosa's explanation on this point where he
 22 noted that in the realm of corrective action, one must

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1 also look to how serious the underlying problems are.
2 And that is on Page 970 of the transcript.

3 The key point for the Tribunal is Dr. Rosa's
4 conclusion that Teva Jerusalem's facility was not
5 operating outside a state of control. Whereas,
6 Apotex's facilities were out of control. Nor can
7 Apotex ignore the documents showing that Teva limited
8 distribution as recorded in C-569 and that its
9 products were medically necessary and in short supply
10 of drugs. Those documents are at R-131, R-192, and
11 C-569.

12 In this regard, I would like to call
13 Tribunal's attention again to the text of the e-mail
14 at R-131, where the FDA stated that it was working
15 with Teva to keep manufacturing medically necessary
16 drugs at the supply levels needed to meet patient
17 needs while fixing their problems as long as benefit
18 outweighs any potential risks.

19 Counsel for Apotex also suggested that there
20 was no evidence of corrective action by Sandoz. I
21 would refer the Tribunal to Dr. Rosa's testimony at
22 Pages 1037-1038 and 1042-1043 of the transcript where

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1 this point is addressed, as was the point that Sandoz
2 was operating within a state of control at its Québec
3 facility, whereas Apotex was not.

4 Nor can Apotex ignore the documents showing
5 that Sandoz Canada voluntarily limited production, and
6 those documents are at R-91, R-92, and R-208. And
7 that Sandoz only exported to the United States
8 life-sustaining single-source sterile injectable drugs
9 such as the one Apotex highlighted this morning and
10 covered at C-448.

11 The United States also encourages the
12 Tribunal to read in full Apotex's letter to the FDA of
13 August 28, 2009, and that's at Exhibit C-66. Apotex
14 cited this as its Corrective Action Plan response.
15 And just as Apotex had during the August 17, 2009,
16 teleconference, Apotex declined in Exhibit C-66 to
17 limit production or distribution in any meaningful
18 way. That is, Apotex was only willing to limit
19 distribution of one or two drugs, and it was entirely
20 unwilling to cease or limit production to allow for
21 remediation despite deficiencies in all six of its
22 quality systems.

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1 FDA, moreover, determined that adoption of
2 the Import Alert with respect to Etobicoke and Signet
3 would not create any sustained shortages other than
4 for the medically necessary drug deferiprone.

5 I would also remind the Tribunal of
6 Dr. Rosa's broader point, that when one is looking to
7 Corrective Actions, it is not just the promises on
8 paper but also the follow-through.

9 ARBITRATOR ROWLEY: Could I just interrupt
10 you for a moment? You just said the FDA determined
11 that the adoption of Import Alert with respect to
12 Etobicoke and Signet would not create any sustained
13 drug shortages.

14 Have you got a reference for that?

15 MS. GROSH: Let me check, Mr. Rowley. If it
16 would be okay, I will continue and my colleagues will
17 provide that reference.

18 PRESIDENT VEEDER: Of course.

19 MS. GROSH: So, as Dr. Rosa testified, when
20 they're looking at Corrective Actions, it is not just
21 the promises on paper but also the follow-through, and
22 that in his view, Apotex was falling short in this

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1 regard and continues to do so to this day. And that
2 is on Page 958 of the transcript.

3 Mr. President, I think it is now at this time
4 that I would ask that the feed be cut so that I can
5 respond to another of Apotex's arguments that was
6 raised this morning.

7 PRESIDENT VEEDER: Let's cut the feed. Thank
8 you. The feed is cut.

CONFIDENTIAL PORTION

1 MS. GROSH: It was also claimed this morning
 2 that the Signet facility made injectable products,
 3 referring to Exhibit C-127. In fact, the Signet
 4 facility did not manufacture any sterile injectable
 5 products at the relevant time. Exhibit C-127 refers
 6 to a drug called [REDACTED]. It was not approved by
 7 manufacture by Apotex in 2009. At the time of the
 8 2011 re-inspection, the New Drug Application for
 9 [REDACTED] was still not approved, and the pre-approval
 10 test of [REDACTED] failed during the 2011 inspection.
 11 And this is discussed at Paragraph 25 of Mr. Goga's
 12 Witness Statement and on Page 19 of the 2011 Signet
 13 EIR, which is at Exhibit R-71.

14 At the conclusion of the test, Apotex's Vice
 15 President for Quality, Ed Carey, apparently described
 16 the [REDACTED] test as a "disaster."

17 Most importantly, Apotex did not mention this
 18 this morning, that this application was ultimately
 19 withdrawn by Apotex. Indeed, review of Apotex Corp.'s
 20 list of products sold in the United States at C-317
 21 makes clear that Apotex Corp. does not sell any
 22

1 sterile injectable products from Etobicoke or Signet.
 2 But, instead, sells sterile injectable products from
 3 third parties such as Hospira.

4 It is thus incorrect that Apotex was in the
 5 same situation as manufacturers of sterile
 6 injectables. It was not making any such drugs for the
 7 U.S. market at either Signet or Etobicoke.

8 And, Mr. President, I think we can now open
 9 the feed again.

10 PRESIDENT VEEDER: Let's open the feed.

11 MS. GROSH: Thank you.

12 PRESIDENT VEEDER: It is now open.
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NONCONFIDENTIAL PORTION

1 MS. GROSH: In addition to this string of
 2 inaccurate statements, counsel curiously asserted this
 3 morning that issues regarding the United States's
 4 legal constraints in providing documents and
 5 information concerning its competitors have not been
 6 raised before in this arbitration. He says in the
 7 rough transcript from this morning at Page 10, "Had
 8 such a critical issue been raised earlier in the
 9 proceedings, the Parties and the Tribunal would have
 10 been in a position to do something to address it."

11 Now, in fact, these precise issues were
 12 raised with and addressed by the Tribunal last March.
 13 On February 18, 2013, Apotex served a massive document
 14 request on the United States. Requests 31, 32, 33,
 15 35, and 36 related to Teva and Sandoz/Novartis. In
 16 response, the United States offered to provide Apotex
 17 the 483s and the EIRs of its comparators, with the
 18 exception of the EIR for Sandoz's Boucherville
 19 facility, which was still under investigation. We did
 20 provide the 483 for that facility.
 21

22 In a March 1, 2013, letter to Apotex, the

1 United States explained why it could not provide
 2 Apotex other documents regarding its marketplace
 3 competitors. And here I quote from that letter.
 4 "Many of the documents Apotex seeks contain highly
 5 sensitive, business confidential, and trade secret
 6 information from its competitors. These requests are,
 7 one, overbroad as they seek far more information than
 8 is reasonably necessary for Apotex to assert its
 9 claims; and, two, not consistent with the IBA Rules,
 10 which contemplate protection of such information from
 11 disclosure; three, not consistent with U.S. law which
 12 obligates FDA to protect such information; and, four,
 13 not in keeping with Apotex's own expectations of the
 14 FDA, given the concerns Apotex has expressed about
 15 protecting such information from disclosure."

16 Members of the Tribunal, that is what we said
 17 to Apotex in our March 2013 letter. We also cited to
 18 the statutes and regulations that Ms. Thornton cited
 19 yesterday in response to a question from the Tribunal
 20 and that Mr. Legum discussed this morning. Mr. Legum
 21 dismisses these laws as irrelevant, but they are
 22 anything but. These laws are necessary to facilitate

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1 full disclosure from regulated companies to FDA. They
2 relate to all manufacturing processes, including end
3 products.

4 Under some of these statutes, it is a crime
5 to disclose such information, and FDA personnel who
6 release the information can be personally subject to
7 criminal punishment. As we mentioned, this statute
8 prohibits the dissemination of trade secret
9 information even from FDA to the State Department.
10 Companies have also sought significant damages in
11 court from federal agencies for disclosing trade
12 secrets.

13 There is no exception in these statutes for
14 arbitral proceedings. They are the very definition of
15 a legal impediment as recognized by the IBA Rules on
16 Evidence. And that's under Article 9.

17 Unsatisfied with this response, Apotex
18 brought its Sandoz and Teva document request to the
19 Tribunal on March 15, 2013. Apotex submitted a
20 heavily annotated Redfern with multiple Legal
21 Authorities attempting to justify its requests. With
22 the United States's submission that same day, we

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1 provided Tribunal with copies of our March 1 letter,
2 which I just quoted from, and Apotex's response to
3 that letter. Thus, this matter was fully presented to
4 the Tribunal for decision.

5 The Tribunal, in a March 29, 2013, Order,
6 denied all of Apotex's requests related to
7 Sandoz/Novartis and Teva. The Tribunal acknowledged
8 the United States's offer to produce the 483s and the
9 EIRs, ordered the United States to produce those
10 particular documents. The Tribunal also acknowledged
11 the Parties' agreement on narrowing the request at 36.
12 Otherwise, Apotex's request, denied the request in
13 full.

14 The Tribunal's reasons for denying these
15 requests, including that the documents were--and I
16 quote from the Tribunal's order--"currently subject to
17 legal impediment, insufficiently identified and also
18 insufficiently described as a narrow and significant
19 category of documentation, insufficiently shown to be
20 relevant and material, insufficiently shown to be
21 reasonably necessary, and its production reasonably
22 proportionate." The Tribunal also expressly cited

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1 FDA's new policy on redacting information concerning
2 third-party drug products as a basis for denying the
3 requests.

4 Thus, this issue has already been fully
5 decided by the Tribunal, Apotex's statements this
6 morning notwithstanding. The United States was
7 entitled to rely on the Tribunal's decision and should
8 not now be held responsible for Apotex's inability to
9 craft careful, considered document requests that
10 stayed within the bounds of the United States's legal
11 limitations.

12 The Tribunal's decision did not somehow shift
13 the burden to the United States to disprove Apotex's
14 like-circumstances analysis. Indeed, we are likely
15 hearing these arguments from Apotex at this late date
16 because Apotex realizes that as it crafted its claims
17 and developed them through the course of the written
18 submissions, it has fallen short of substantiating its
19 claims as it is required to do as Claimant.

20 Now, before I conclude, I'd like to make a
21 brief comment about counsel's statements regarding
22 Article 1105. Apotex this morning argued that the

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1 United States did not explain why it has cited other
2 provisions of the Restatement but does not accept
3 Section 181. And this was prompted by a question from
4 Mr. Rowley.

5 First, the United States does not accept the
6 entirety of the Restatement as reflecting customary
7 international law. Where it agrees with it, the
8 United States so indicates; and where it does not, the
9 United States also so indicates, both in litigation
10 before U.S. courts and Tribunals such as this one.

11 With regard to the portions of the
12 Restatement invoked by counsel to support its claims,
13 we made our position clear. And I would refer the
14 Tribunal to Paragraphs 318-320 of our Rejoinder. In
15 particular, I would refer the Tribunal to
16 Paragraph 320, and its accompanying footnotes where
17 this very point is discussed.

18 With that, Members of the Tribunal, I would
19 like to direct the presentation to my colleague,
20 Mr. Sharpe.

21 PRESIDENT VEEDER: Just before you do that,
22 can you just confirm the date of the letter that you

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1 cited in regard to document production? I had you as
2 saying 1st of March; the letter I'm looking at the
3 20th of March, but maybe there were two letters.

4 MS. GROSH: There were two letters. Let me
5 just grab my documents.

6 PRESIDENT VEEDER: You can do that later. Do
7 later. Just come back to it later.

8 Thank you very much.

9 QUESTIONS FROM THE TRIBUNAL

10 ARBITRATOR CROOK: I have two questions, and
11 I apologize for the first one. This is something I
12 should have asked both Parties earlier on, but at some
13 point can somebody tell me what R-236 is? It's
14 unlabeled. It's a long document listing a lot of
15 Apotex products. I'm just not clear what it is.

16 The second question--and counsel, this goes
17 to the question whether 21 USC 331 and the other
18 Authorities are relevant here. Now, Claimant
19 maintained this morning that the relevant information
20 would not be trade secrets for purposes of the CFR
21 definition, and can you walk us through that a little
22 bit? You represent to us that these statutes apply;

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1 they say they don't.

2 Can you clarify that for us?

3 MS. GROSH: I can. Just one moment,
4 Mr. Crook.

5 (Pause.)

6 MS. GROSH: Mr. Crook, as I understand from
7 our colleagues at FDA, many of the documents will
8 contain a variety of types of information, but it is
9 common that there will be aspects of information, of
10 facts, of references to elements that go to
11 manufacturing. And that the FDA, in the first
12 instance, is very careful about looking to that
13 information to ensure that they do not address
14 elements of manufacturing processes. This can even
15 relate to computer systems and things that they have
16 in place to generate processes that perhaps their
17 comparators do not.

18 So it is not just a question of ingredients,
19 formulas for specific products.

20 MR. SHARPE: Thank you, Mr. President, and
21 Members of the Tribunal. I am pleased to conclude the
22 U.S. rebuttal. Like Apotex, we will not be able to

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1 cover every point previously raised, and we would ask
2 that no inference be drawn from issues not discussed.

3 I would like to make four points. Let me
4 first begin with a word about Article 1139(h). Apotex
5 suggested this morning that the United States does not
6 contest that Apotex Holdings has made an investment
7 under Article 1139(h). That is not correct. The
8 United States accepts that Apotex Holdings is an
9 investor with an investment under Article 1139(a),
10 because Apotex Holdings indirectly established an
11 enterprise, Apotex Corp., in the United States.

12 Apotex Holdings does not have an investment
13 under Article 1139(h) simply because it commits
14 resources to the United States. Article 1139(h)
15 protects as investments interests arising from the
16 commitment of capital or other resources in the
17 territory of a Party to economic activity in such
18 territory. Apotex Holdings has not established any
19 such interests, including any ANDAs that it may
20 indirectly own through Apotex Inc. To the contrary,
21 the resources Apotex Holdings contributes to the
22 United States concerns the U.S. enterprise,

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1 Apotex Corp.

2 Second, following up on the question posed by
3 Mr. Rowley concerning the nature of the ANDA and the
4 Apotex I and II Award, I would draw the Tribunal's
5 attention, again, to the Federal Food, Drug, and
6 Cosmetic Act, which provides that no manufacturer can
7 market a drug in the United States unless the
8 manufacturer files an ANDA, that the ANDA is approved,
9 and that it is effective. I refer the Tribunal to
10 CLA-234. This requirement applies regardless if
11 the--of whether the drugs are manufactured inside the
12 United States or whether they're imported into the
13 United States.

14 ANDAs must contain information demonstrating
15 that the facilities used for the manufacture of the
16 drug are cGMP compliant. This information is required
17 for approval of any ANDA. If FDA determines that the
18 facility producing the drug is not cGMP compliant, it
19 may take steps to revoke the approved ANDA.

20 Now turning to Mr. Rowley's specific question
21 of an ANDA in the hands of a U.S.-based manufacturing
22 facility. Under that scenario, an ANDA may not work

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1 like an export permit, but we would submit that the
 2 Tribunal need not decide that issue because it's not
 3 at issue here. All of Apotex's ANDAs are applications
 4 for its foreign drug manufacturing facilities to
 5 market drugs for export and sale by others in the
 6 United States.

7 As you know, all of Apotex's manufacturing
 8 facilities are located outside of the United States.
 9 And as we previously stated, Apotex Inc.'s ANDAs are
 10 prepared in Canada. Apotex pays no taxes on
 11 ANDA-related activities in the United States. And
 12 with that in mind, I would ask that we return to
 13 Paragraph 224 of the Apotex I and II Award. That
 14 states, "The jurisdictional issue here turns upon the
 15 inherent nature of the relevant ANDAs, not the nature
 16 of Apotex's rights over them. As set out above, even
 17 assuming that the ANDAs were Apotex's exclusive
 18 property, they remain no more than applications for
 19 permission to (in this case) export, and as such,
 20 neither fell within NAFTA Article 1139(g) nor
 21 constituted investments as contemplated more generally
 22 by NAFTA Chapter 11."

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1 PRESIDENT VEEDER: Give me a second. You are
 2 doubtless reading Paragraph 24, but it can't be
 3 Paragraph 24.

4 MR. SHARPE: 224, I apologize.

5 THE PRESIDENT: 224.

6 PRESIDENT VEEDER: Yes. Thank you.

7 MR. SHARPE: Yes. Apologies.

8 I would ask you to consider first the phrase
 9 "relevant ANDAs." As we explained, all of Apotex
 10 Inc.'s ANDAs are applications for its foreign
 11 manufacturing facilities to market drugs for export
 12 and sale in the United States. The same was true with
 13 respect to the two ANDAs at issue in the previous
 14 arbitration.

15 Second, I would ask you to consider the
 16 phrase "in this case." In this case, just as in the
 17 previous case, the inherent nature of Apotex's ANDAs
 18 is precisely the same because the relevant ANDAs all
 19 are no more than applications for permission to export
 20 drugs to the United States for sale by others. So
 21 there is no need--there is no basis to find the
 22 decision and the reasoning of the Apotex I and II

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1 Award, which is final and binding, we would submit, is
 2 not res judicata, concerning Apotex's alleged
 3 investment in its ANDAs.

4 Finally, I'll just note that there is only a
 5 limited and narrow exception to the application of
 6 res judicata under international law for "manifest
 7 error." Merely disagreeing with the decision of a
 8 previous Tribunal is insufficient to deny the final
 9 and binding effect of the Award. This was explained
 10 in the Trail Smelter arbitration, CLA-623. That's on
 11 Page 1957.

12 Third, I would just like to say a quick word
 13 about Cargill versus Mexico. Apotex suggested this
 14 morning that this case and the Cargill case are
 15 similar because Mexico had adopted Measures that
 16 prevented an investment in Mexico from obtaining
 17 supplies from its U.S. affiliate, which constituted a
 18 legal impediment to operations by the Mexican
 19 investment.

20 But Cargill and Cargill de Mexico are not
 21 mere affiliates. Cargill owned and controlled
 22 Cargill de Mexico. Further, Cargill had established

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1 Cargill de Mexico precisely to sell its products in
 2 Mexico. And the Measures adopted by Mexico against
 3 Cargill de Mexico legally prevented Cargill de Mexico
 4 from conducting business operations in Mexico.

5 Here, by contrast, Apotex Inc. does not own
 6 or control Apotex Corp. Apotex Inc. did not establish
 7 that it set up Apotex Corp. specifically to sell
 8 Apotex products in the United States, or at least
 9 that's what Apotex has represented to U.S. courts. I
 10 would direct you to Paragraph 309 of the U.S.
 11 Counter-Memorial for relevant citations.

12 And, finally, the challenged Measure here,
 13 the Import Alert, in no way prevented Apotex Corp.
 14 from continuing business operations in the United
 15 States during this period. Its operations continued
 16 unabated. This case, we submit, is in no way
 17 comparable to Cargill.

18 Finally, I would like to discuss Apotex's
 19 treatment of Bellarno versus FDA, which is in the
 20 record at RLA-212. In Bellarno, the District Court
 21 addressed a new FDA Import Alert, 66-14, which
 22 concerned goods exported and then reimported. This

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1 case is very different from Bellarno. That case
 2 concerned how Bellarno could get a product that had
 3 already been detained released into U.S. commerce.
 4 The Court pointed to many factors to show why it
 5 believed FDA was imposing these as things that a firm
 6 must show to gain admission of the products. First,
 7 FDA had told Bellarno that the Agency could not
 8 release the product "until all the requirements of the
 9 Import Alert are met."

10 Second, FDA had publicly stated that the
 11 Import Alert "required chain of custody information,
 12 requirements that were tightened over time."

13 Third, the memo the FDA official issued along
 14 with the Import Alert said it should be "enforced" on
 15 Monday and there should be "no exceptions to the
 16 strict enforcement."

17 Fourth, the language of the Import Alert
 18 showed that it was meant to be a directive by such
 19 terms as "automatically" and "shall."

20 The Court thus determined that the Import
 21 Alert had binding effect on FDA and importers and had
 22 been impermissibly adopted without notice and comment

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1 rulemaking, as required by the Administrative
 2 Procedure Act. That's at Page 416 of the Award. The
 3 Court did not purport to rule on Import Alerts more
 4 generally, including those lacking such mandatory
 5 language.

6 Last Wednesday, Apotex described this holding
 7 similarly at Pages 571-572 of the transcript. But
 8 yesterday and today, we heard a different
 9 interpretation. This morning, Apotex stated that the
 10 Court had found Import Alerts to be binding. That's
 11 at Page 15 of the rough transcript. That is not a
 12 proper reading of Bellarno. As I previously informed
 13 the Tribunal, Import Alert 66-40 had been amended to
 14 remove any reference to automatic detention, to make
 15 clear that the field itself determines whether a good
 16 meets the legal standard for adulteration and may be
 17 detained without physical examination on that basis.

18 I would ask that you look at a copy of Import
 19 Alert that was circulated. It is also Tab 33 in the
 20 Joint Core Bundle.

21 As you can see, it states at the top: "The
 22 revision of this Import Alert, dated 8/17/2007,

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1 changes the name of the Import Alert and removes
 2 references to 'automatic detention.' changes are
 3 bracketed with an ellipsis."

4 Also, as can you see with the instructions to
 5 the field in 66-40, it says below: "Districts may
 6 detain the specified pharmaceutical products from the
 7 firms identified in the attachment to this alert."

8 We find it regrettable that Apotex would
 9 point to a stray reference to automatic detention for
 10 the first time in its rebuttal and not refer the
 11 Tribunal to the statement above that the terms
 12 "automatic detention" were to have been eliminated
 13 entirely from the Import Alert.

14 Further distinguishing Import Alert 66-40
 15 from the Import Alert at issue in Bellarno, the
 16 version of the Import Alert from September 27, 2009,
 17 which Apotex submitted, has this additional language
 18 in bold text: "This Import Alert represents the
 19 Agency's current guidance to FDA field personnel
 20 regarding the manufacturers and/or products at issue.
 21 It does not create or confer any rights for or on any
 22 person, and it does not operate to bind FDA or the

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1 public."

2 Thus, Apotex's reliance on Bellarno is
 3 misplaced. To the contrary, if Apotex had thought
 4 that the Import Alert required the automatic detention
 5 of its products, in violation of the APA, presumably
 6 it would have sued FDA, just as Bellarno had done.
 7 But the Import Alert did not require automatic
 8 detention, and Apotex did not sue the Agency.

9 Members of the Tribunal, contrary to Apotex's
 10 assertions, the Import Alert did not lead to automatic
 11 detention of its drugs. They were detained because
 12 the field office had determined that those drugs were
 13 deemed to be adulterated for cGMP violations. The
 14 Import Alert, to reiterate, was not the Measure that,
 15 as a legal matter, prevented Apotex or any other
 16 company from selling drugs from Etobicoke and Signet
 17 in the United States. The Measure did not relate to
 18 any investor or investment in this arbitration.

19 Mr. President, Members of the Tribunal, that
 20 concludes the United States's rebuttal.

21 As stated by Ms. McLeod yesterday, we
 22 respectfully request that the Tribunal dismiss all

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1 claims with prejudice and Award all costs to the
2 United States.

3 We also reiterate our deep appreciation to
4 the Tribunal and all involved in these proceedings,
5 including Claimants' counsel for their professionalism
6 and courtesy throughout these proceedings. Thank you
7 very much.

8 If you could call on Ms. Grosh to answer your
9 last question.

10 PRESIDENT VEEDER: Please.

11 MS. GROSH: Thank you, Mr. President. I
12 think we can be very brief.

13 First of all, I believe that Mr. Rowley asked
14 for information. I had made a statement concerning
15 the shortages that were analyzed by FDA in connection
16 with Signet and Etobicoke, and I believe you asked
17 where the cite--where we had cites in the record. So
18 let me just give those to you.

19 We would refer you to C-357, C-376, C-499,
20 C-502, C-520, C-521, R-154; and then Paragraphs 20 and
21 Paragraph 29 of the Second Statement of Dr. Rosa; and
22 then also Dr. Rosa's testimony, which can be found at

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1 Pages 949-955 of the transcript.

2 Then, with respect to President Veeder's
3 question about the letters concerning--the letters in
4 discovery, the letter I was referring to was March 1.
5 That was a letter that the United States sent to
6 Apotex regarding its request for production. Apotex
7 responded to the United States in a letter of March 5.
8 And then, on March 15, the United States sent a letter
9 to the Tribunal indicating disagreements between the
10 Parties regarding the various requests.

11 Now, there was another letter that the United
12 States submitted to the Tribunal on March 20. That's
13 reflected in the introduction of the Tribunal's Order
14 deciding the production issues, and that order is
15 dated March 29.

16 Then finally--

17 PRESIDENT VEEDER: I definitely have a letter
18 20th of March which has a very similar passage. Is
19 that part of the sequence?

20 MS. GROSH: Yes, it is. That letter is a
21 letter that the United States sent to the Tribunal.

22 The letter that I'm referring to of March 1

1781

1 is a letter that the United States did not send to the
2 Tribunal; it was a letter that was sent to Apotex, and
3 then we appended that as an Annex to our March 15
4 letter to the Tribunal.

5 PRESIDENT VEEDER: Thank you.

6 MS. GROSH: And then, finally, Mr. Crook
7 asked a question about the chart that was submitted at
8 R-236 and specifically what was represented in that
9 chart. It is a chart of Apotex's ANDAs, site
10 transfers, and potential licensees. And this was put
11 into the record to show that Apotex could have
12 referred its approved ANDAs to facilities other than
13 Etobicoke and Signet, including other Apotex
14 facilities and third-party facilities.

15 PROCEDURAL MATTERS

16 PRESIDENT VEEDER: Thank you very much.

17 We've come to the end of the Reply
18 submissions from the Respondent.

19 We have a certain amount of housekeeping that
20 we need to consider. We asked you on Saturday to
21 provide us with lists of various documentary and
22 evidential references. I know there's a storm coming

1782

1 tonight. If it can't be done this afternoon, take
2 extra time, but we'd like a complete documentary
3 evidential list of the matters referred to. That's
4 the first thing.

5 Secondly, we raised something about costs
6 yesterday, about an exchange for the first round of
7 submissions and then a brief reply in response to the
8 other side's first cost submissions. Have you agreed
9 a date for that?

10 MR. LEGUM: Mr. President, with your
11 permission, can I address both of those issues?

12 PRESIDENT VEEDER: Yes.

13 MR. LEGUM: So in terms of the lists, we have
14 prepared our list and we are prepared to hand it out
15 to the Tribunal and opposing counsel at this point.
16 The list is in two parts. In the first part, there's
17 the main exhibits that really go into the substance of
18 the issues concerning Teva and Sandoz. And then
19 there's another list which is much longer, which is
20 essentially every document that has either of those
21 words in them. So it's a much larger selection, but
22 it will be a selection that will contain a number of

1783

1 documents that do not have direct relevance to the
2 issues.

3 And then there's a list to the pleadings--of
4 references in the pleadings.

5 We also have a list of references to FDA drug
6 shortage analyses for Apotex products which differs a
7 little bit from what the United States put forward.
8 So we'll be passing that out as well with the
9 Tribunal's permission.

10 PRESIDENT VEEDER: Given that it's a common
11 exercise, would it make sense for you to hand over the
12 list to the Respondents, and then maybe you can agree
13 on a list? You can add--don't subtract, because all
14 we want is a neutral list. We don't want submissions.
15 But if there's anything remotely relevant, add it to
16 the pile. That might save time and effort.

17 MR. LEGUM: Perhaps we could frame it in
18 terms of the U.S. adding anything that they wish to
19 the list that we prepared. I'm just not sure that
20 we're going to be around to agree anything this
21 afternoon.

22 PRESIDENT VEEDER: Oh, I see what you mean.

1785

1 obviously this week is a problem. Okay. So that's
2 the first matter.

3 Now, the second matter was costs.

4 MR. LEGUM: Just one footnote on the question
5 posed by Arbitrator Crook. We would suggest that the
6 Tribunal also take a look at C-388, which contains an
7 email that provides context for part of the list that
8 was included in the exhibit that was R-236.

9 So finally we cost come to costs. I believe
10 that the Parties have an agreement in principle. We
11 haven't talked about specific dates. The specific
12 dates that I would put forward, which are both
13 Fridays, are the 17th of January for the initial round
14 and then the 7th of February for the second round.

15 I would make one other note, which is that
16 because of the way that invoicing and the accounting
17 system works in France, it is possible that there will
18 be a small amount of additional charges that we'll
19 need to address in the supplement on February 7
20 because of invoices that just didn't get processed
21 through the system fast enough to be covered in
22 mid-January.

1784

1 Yes. It doesn't have to be agreed. It can be a
2 common document and you can add it, subject to finding
3 a color printer in different colors.

4 Would that work? I mean, is that--I ask the
5 Respondent? Would that be useful?

6 MS. GROSH: Yes, that would be good for us.

7 PRESIDENT VEEDER: I mean, you went through a
8 lot of references yourself.

9 MS. GROSH: We did. And we think that that
10 would be a good way to proceed.

11 PRESIDENT VEEDER: Okay. Let's do that.
12 Because we don't need it today, but it would be nice
13 to have it quite soon. So if you can get it to
14 us--obviously this week is awkward--by the end of next
15 week.

16 MS. GROSH: That is certainly doable, I
17 think.

18 PRESIDENT VEEDER: You look troubled.

19 MR. LEGUM: Well, we're done, so far as we're
20 concerned. And so if it's the end of next week. That
21 is certainly fine from our perspective.

22 CHAIRMAN: Okay. As soon as you can. But

1786

1 PRESIDENT VEEDER: Would it make sense to
2 have the first round after the 7th of February?

3 MR. LEGUM: I understand that date is not
4 convenient for the Respondent.

5 PRESIDENT VEEDER: Okay. Let's hear the
6 Respondent about that.

7 MS. GROSH: Mr. President, we thought that
8 your suggestion of a mid-January date was a good one.
9 That's just a little over a month away, and we
10 certainly would be in a position to provide that
11 information then. We have a hearing scheduled for the
12 spring that is rather onerous, so we would like to put
13 an end to this matter and move on to the next thing.

14 PRESIDENT VEEDER: Get rid of it. It sounds
15 as though there will be a little dribble after the 7th
16 of February. Does that cause you concern? You may
17 have...

18 MS. GROSH: As long as it's a little dribble.

19 PRESIDENT VEEDER: We'll see if it's a
20 sizzle.

21 (Laughter.)

22 PRESIDENT VEEDER: That's okay. Well, let's

1787

1 go along with that, then. The first round, Friday the
2 17th. I'm all for Fridays. And then the second round
3 on the 7th of February, understanding that there may
4 be an additional item for from the Claimants on the
5 7th of February.

6 We don't want hundreds of pages. I mean,
7 there's a rule of reason about this. If we need to
8 ask questions, we'll ask you for more.

9 MR. LEGUM: Just the so record is perfectly
10 clear, these are simultaneous exchanges that we're
11 contemplating.

12 PRESIDENT VEEDER: Yes. Yes.

13 The next item is just one final look at the
14 transcript. Not for corrections, because it is
15 perfect, but if there were missing negatives, we ought
16 to know about that. Again, can we give you a deadline
17 for that? Again, it is not "urgent-urgent," but have
18 you got a date in mind?

19 MR. LEGUM: I believe that this is addressed
20 in the first Procedural Order, and it is something
21 like 14 days or 15 days or something like that.

22 PRESIDENT VEEDER: We'll look that up.

1789

1 obviously ICSID, our Secretary, our stenographer, for
2 all the work they've done, but also very much also to
3 thank both legal teams. It's been a very useful and
4 pleasant hearing for the Tribunal, and we recognize
5 very much not only the professionalism of those who
6 have been speaking to us, but also all those behind
7 them who have been responsible for making this such an
8 efficient hearing. We don't discount the enormous
9 amount of work that goes on in preparing a hearing
10 like this. So thank you to all of you from the
11 Tribunal. We very much appreciated it, and we'll
12 continue to appreciate it.

13 Unless there is something more, we shall now
14 close the hearing. We ask the Claimants first.

15 MR. LEGUM: No, Mr. President.

16 PRESIDENT VEEDER: And the Respondent.

17 MS. GROSH: No, Mr. President.

18 PRESIDENT VEEDER: Well, we close the
19 hearing, and we wish you all, with the storm coming,
20 bon voyage.

21 (Whereupon, at 12:49 p.m., the hearing was
22 concluded.)

1788

1 14 days would be fine. Whatever it says.

2 MR. LEGUM: 15 days is what my colleague
3 says.

4 PRESIDENT VEEDER: Are you happy with that?
5 Respondents?

6 MS. GROSH: Yes. That's fine. We also
7 recall that that's what the Procedural Order provided
8 for.

9 PRESIDENT VEEDER: Thank you.

10 As far as the Tribunal is concerned, we start
11 our deliberations this afternoon, and you should know
12 that we have fixed to return to Washington on the 24th
13 and 25th of February, when we shall be looking at a
14 draft document. I'm not going to say what it is. And
15 depending on what happens there, we shall report to
16 you thereafter. We can't give you, obviously, a fixed
17 date as to what happens thereafter because it depends
18 on our work between now and February and our
19 deliberations on the 24th and 25th of February. But
20 after that, we shall keep you informed as to our
21 progress.

22 I think from our part, we'd like to thank

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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